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ood Drug Cosmetic Law JOURNAL

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

The New Age of FDA Rule-Making

. . . . . STEPHEN HULL McNAMARA

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

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As Associate Chief Counsel for Enforcement in the Food and Drug Administration, *Eugene M. Pfeifer* discusses the Agency's views and procedures concerning Section 305 hearings. He explains the evaluative process of the Food and Drug Administration and the seven criteria used in determining whether a Section 305 hearing is warranted. "Section 305 Hearings and Criminal Prosecutions" begins on page 376.

"Product Recall" is *Robert W. Harkins'* review of changes in recall procedures made by the Food and Drug Administration in the recent revision of its Regulatory Procedures Manual. Beginning on page 383, the article contains a brief summary of the new provisions as well as discussion of publicity generated by a recall and its effect on corporate policy. Dr. Harkins is Vice-President of Scientific Affairs of the Grocery Manufacturers of America, Inc.

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Symposium on Food Regulations. *Stephen Hull McNamara's* paper was presented at the Symposium on "Food Regulations—Present and Future," which was held at the University of Wisconsin in Madison, Wisconsin on May 6, 1976. Mr. McNamara, Associate Chief Counsel for Food in the Food and Drug Administration, speaks about current trends in FDA regulation making, citing the statutory authority and case history used by the Agency as its regulatory basis. The article, "The New Age of FDA Rule-Making," begins on page 393.

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Dr. Howard R. Roberts details the efforts of the Food and Drug Administration to ensure the safety of the food supply and, at the same time, respond to scientific advances. His article, "Food Additives—A Study in the Evolution of Safety," which begins on page 404, concentrates on flavors, colors, quality assurance and direct and indirect food additives. Dr. Roberts is Acting Director of the Bureau of Foods in the Food and Drug Administration.

In "Management of Scientific Resources," beginning on page 413, *Dr. Robert O. Nesheim* presents an overview of scientific research, with emphasis on corporate strategy for optimum use of the scientific team. The article, written by the Vice-President of research and development of The Quaker Oats Company, touches on many areas of the topic, including the changing role of research and development and the need for government, university and industry scientific interaction.

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Journal

Section 305 Hearings and Criminal Prosecutions

By EUGENE M. PFEIFER

Mr. Pfeifer Is Associate Chief Counsel for Enforcement in the Food and Drug Administration.

OBVIOUSLY, THE MOST SEVERE ENFORCEMENT PROBLEM a company and its managers can face is a criminal prosecution under the Federal Food, Drug and Cosmetic Act or other statutes enforced by the Food and Drug Administration (FDA) which authorize prosecution. For simplicity's sake, my remarks will be directed only to the Food, Drug and Cosmetic Act.

From a reading of the Act, it is apparent that:

(1) any violation carries the potential for prosecution of both artificial business entities, such as corporations, and individuals who own or manage businesses;

(2) because wrongful intent is not an element of the offense, responsible persons with no specific intent to break the law nevertheless may be prosecuted for violations;

(3) potential penalties upon conviction are significant, particularly for individuals who run the risk, albeit a remote risk, of confinement as well as a fine: and

(4) the range of businesses to which the law applies encompasses not only primary businesses in which food, drugs, devices and cosmetics are manufactured, processed, packed or held for sale, but also ancillary businesses such as consulting labora-

tories and exterminators which service primary components of the industries.

Additionally, history teaches us that most criminal prosecutions result in conviction, either because the defendants plead guilty or "no contest" before the trial commences or because the evidence presented convinces the trier-of-facts that a conviction is warranted. Having stated these facts, one might wonder why he or she is in this business. Ostensibly, it could be made to appear that any official in a regulated industry is in constant jeopardy. But, as the student of history also knows, only a small percentage of violations result in prosecution.

Evaluative Process

Since the Supreme Court's decision in *United States v. Park,* much attention has been focused on the process through which and the criteria under which a criminal prosecution is initiated. Within the limits of my remarks, I propose to tell you generally what the evaluative process is, how we judge whether a violation should be the cause of a criminal proceeding and, finally, a little about a Section 305 hearing.

There are certain things I cannot tell you. For instance, it is not possible to set a limit for filth or a percentage for drug super- or sub-potency which, if exceeded, will result in the institution of criminal proceedings. Such specificity is not possible given the tens of thousands of articles and the variety of businesses and different practices falling within the purview of the FDA. In addition, other factors of at least equal importance must be considered. However, before dealing with the factors which are considered when weighing a potential prosecution, it would be helpful to summarize briefly the system through which a potential case is evaluated. With this background, I am confident that you will begin to appreciate that decisions to prosecute are not impulsive, *ad hoc* gestures but, rather, are the products of a deliberate scheme which employs the talents of many persons with different disciplines, and which is designed to safeguard against improvident action.

Each decision to prosecute a case is reviewed at several administrative levels within the FDA and in the Office of the Chief Counsel of the FDA. This review process ordinarily involves a minimum of from 12 to 15 persons. In some instances, many more persons participate in the review. Each successive stage of review represents a more critical examination of the action under consideration.

Generally, cases arise as a consequence of an inspection conducted by a district office where at least one investigator, two analysts, a supervisory investigator and a supervisory chemist participate in establishing the facts involved and in making an initial recommendation that regulatory action be pursued. Thereafter, a compliance officer, the chief of the compliance unit and the director of the involved district review the matter. If they agree that a prosecution should be considered, they will request that the bureau with responsibility for the product classification (for example, Bureau of Drugs, Bureau of Foods, etc.) authorize the requesting district to give the proposed defendants an opportunity to explain in a Section 305 hearing why prosecution should not be pursued. The district's request is then reviewed by a bureau consumer safety officer and one or more of the officer's superiors.

Section 305 Hearing

If the decision is to conduct a Section 305 hearing, the district assigns a hearing officer who presides over the hearing. All of the evidence and the report of the hearing officer are again reviewed by the district compliance unit, the district director and, in some cases, the regional food and drug director. The district's recommendation to proceed with prosecution is reviewed again in the appropriate bureau by a consumer safety officer and one or more of the officer's supervisors. The matter is then referred to the Office of the Associate Commissioner for Compliance for review by at least two more officials before it is finally reviewed by the attorney assigned to the case and the Chief Counsel of the FDA. Thereafter, if a decision to initiate a prosecution is reached, the matter is referred to the United States Department of Justice where it is again reviewed before filing.

Contrary to views occasionally expressed by FDA critics, these officials use neither a dart board nor a lottery drum in exercising their responsibilities. There are certain criteria against which the conduct of the potential defendants is measured at every stage of the evaluation process.

Of necessity, these criteria will be stated in general terms since they apply across the board to all businesses regulated under the Federal Food, Drug and Cosmetic Act. Thus, whether a business is large or small, whether it is engaged in manufacturing, warehousing, or packaging, or whether its products are foods, medical devices, cosmetics or drugs, these criteria constitute the standards referred to by the FDA.

There are generally seven criteria, one or more of which must be met, before a Section 305 hearing is authorized and, ultimately, before a prosecution is initiated against a business. There is an eighth consideration which must be satisfied before prosecution of an individual is considered to be warranted.

First, any deliberate or intentional violation of any provision of the law will be considered for criminal prosecution. Purely economic violations will be viewed no differently than violations which pose a threat of injury to the public health.

Gross Negligence

Second, any violation caused by gross negligence or reckless disregard of the requirements of any provision of law will be considered for prosecution in the same light as a deliberate violation.

Third, any violation which exposes the public to the risk of potentially dangerous conditions will be considered for prosecution.

Fourth, any violation which is obvious or easily detectable to a person knowledgeable about the involved industry will be considered for prosecution. "Obvious" does not always mean detectable through the unaided senses. General insanitary conditions in a warehouse or manufacturing facility may be detected without using special investigative techniques. Other violations, such as unacceptable bacterial contamination, are no less obvious notwithstanding the use of special laboratory techniques to detect them. Certain other systems defects, such as failure to analyze finished drug products for potency may be no less obvious, depending on the circumstances presented. The keystone here is the standard which should be met by the person engaged in the particular activity, not what the eye can see.

Fifth, any uncorrected or recurrent violation will be considered for prosecution. A violative condition which persists or occurs after information concerning the same or similar violative conditions has been provided to, or is detected by, some responsible employee or officer of the business, may result in criminal prosecution. Businesses and individuals cannot wait until the FDA discovers violative conditions before making correction. We are all aware that some businesses and individuals seek to walk a fine line between compliance with the law and violative conduct and, thereby, to achieve a savings of money and effort that more publicly responsible individuals and businesses deliberately invest to assure compliance. Such conduct is unacceptable, for

the simple reason that marginal efforts usually result in intermittent violative conduct. We consider marginal effort to be clearly irresponsible and will consider prosecution in all instances.

Quality Control System

The sixth factor is in many respects the most important. We will consider for prosecution any violation which results from any act of commission or omission and which could have been prevented, detected or corrected, for we believe it is the duty of all regulated firms and individuals to take affirmative systematized action to assure compliance with the law. The adoption of an adequate quality control system, rigidly enforced and sufficiently funded, will prevent violations which otherwise would be difficult to detect. The absence of such a system will weigh heavily when prosecution is considered.

Seventh, any violation which may have resulted in significant economic damage to the segment of the public affected will be considered for prosecution. The FDA is not concerned only with protection of public health. It has an equal obligation to protect the public from economic violations of law. Violations which result either in significant monetary damage to a relatively small portion of the public or in relatively small damage to a large segment of the public cause significant monetary damage to the public in the aggregate and are considered as serious infractions of the law.

Eighth is the criteria we use to determine which individuals to prosecute. I say "which individuals" because it is the policy of the FDA to include individuals in almost all prosecutions. Corporations do not commit violations alone. They are artificial entities designed, operated and maintained by real people who, for profit, have taken on the responsibility of providing food, medical devices and pharmaceutical products for over two hundred million people.

Prosecution of a business without including an individual or individuals would rarely serve to impart the deterrent effect that a case should have upon the persons involved and those similarly situated. Prosecution of a business entity can result only in monetary fines, which may be absorbed as the cost of doing business. To be effective, prosecution should include those individuals responsible for the conduct of their businesses and with the power to correct violations. Thus, any individual who knew or should have known of the circumstances, conditions or actions surrounding a violation, and who occupied a position with the power and/or authority to prevent, detect

or correct the violation, whether directly or indirectly, may be included in a criminal prosecution.

Responsibility

Commissioner Schmidt, at the nineteenth annual conference of the Food and Drug Law Institute, quoted with approval the remarks of Admiral Rickover on responsibility. Since I am unaware of any better explanation of our approach to prosecution of individuals, I will let the Admiral's words speak for us. He said:

"Responsibility is a unique concept; it can only reside and inhere in a single individual. You may share it with others, but your portion is not diminished. You may delegate it, but it is still with you. You may disclaim it but you cannot divest yourself of it. Even if you do not recognize it or admit its presence, you cannot escape it. If responsibility is rightfully yours, no evasion, or ignorance, or passing the blame can shift the burden to someone else."

We are aware that many in the regulated industries do not agree with our approach to individual responsibility. That is, however, the fair reading of the statute and the position to which we strongly adhere. And this is why I said our sixth criterion is so important. The public is best protected against violative articles and responsible officials are best protected against a possible prosecution when a well-designed and comprehensive quality control system is maintained. It costs money—lots of money, as you know—but it must be regarded as crucial.

Finally, a few words about the Section 305 hearing. Prospective defendants ordinarily will receive notice providing them with an opportunity to appear before a hearing officer and to present their views regarding the contemplated prosecution. While Section 305 of the Act provides for such a presentation of views, the notice and hearing are not a prerequisite to the institution of proceedings.

Response is voluntary and may be made in writing, in person or through a representative. A *Miranda*-type warning concerning the right to remain silent and the use of incriminating statements is not required in our view and will not be given. Because the hearings are informal, formal rules of evidence do not apply. Ordinarily, the hearing will not be transcribed but, rather, summarized in writing by the official conducting the hearing.

The only advice I can provide with respect to the hearing consists of one "do" and several "don't's." There is a natural inclination in the past of someone appearing at a Section 305 hearing to present facts selectively, choosing only those which are exculpatory and fail-

ing to deal forthrightly with the facts which led to the violation and precipitated the Section 305 hearing. If a person chooses to respond to a hearing notice, he does so openly, candidly and fully. He cannot hurt himself, for the Agency already has enough information to justify prosecution.

All Factors

Now the "don't." While the Agency takes all factors into account, there are several approaches which, though frequently proferred as reasons to forgo prosecution, carry little, if any, weight. A case will not be deterred by these arguments:

(1) the persons involved already have suffered loss of money and reputation as a result of publicity and other enforcement activities preceding the institution of criminal prosecution and that prosecution is not needed;

(2) correction has been accomplished now that violative conditions have been discovered;

(3) that resources did not permit a better effort to correct or to prevent the violation, or that age, illness or infirmity of an individual defendant militates against prosecution.

We do not view these arguments as persuasive. If seizures or recalls necessary for the alleviation of the violation cause monetary loss or adverse publicity, we view these only as the natural independent consequences of violative conduct, not as a substitute for prosecution. Nor is voluntary correction of a violation, once discovered, a meritorious argument. The corrections would not be necessary if the business or individual had been observing the law in the first instance and, in any event, correction would be required by judicial decree in the absence of voluntary action. As for those who claim a lack of adequate resources, our view is that the venture should not have been undertaken in the first instance. We believe, finally, an individual not too aged, ill or infirm to occupy a position of responsibility affecting the public health is not too aged, ill or infirm to make a public accounting. An individual too aged, too ill, too infirm, too lacking in training, experience and resources to comply with the law menaces the public and has no place in the industries regulated by the FDA. **[The End]**

Product Recall

By ROBERT W. HARKINS, Ph.D.

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

IT MAY BE HELPFUL to this audience to take a few minutes to review the Food and Drug Administration's (FDA's) recent republication of its Recall Procedures in the Regulatory Procedures Manual. This publication is an internal document which spells out how Agency personnel shall conduct themselves. It is a worthwhile document to review if you have recall responsibilities for your corporation.

While the FDA has no statutory authority to require a recall of a violative product, clearly such authority is exerted by the Agency. The FDA recognizes that recalls are the most effective method of removing violative products from the marketplace. The FDA believes an Agency-initiated recall is the action of choice where there is a definitive threat or potential threat to life, or where a significant number of injuries are known, or where gross consumer fraud requires extensive removal of a faulty product from the market.

Recognizing the power of the recall, the FDA has balanced this authority with a rather complex set of internal procedures to ensure full participation of a number of individuals before a recall would be initiated by the Agency. Requests for FDA-initiated recalls must be approved by, or made with, the knowledge of the Associate Commissioner for Compliance. "As a matter of general policy . . . FDA will have evidence capable of supporting a legal action, if necessary, prior to requesting FDA-initiated recalls. It is recognized that there may be exceptions when a serious danger to life is involved, or other emergency circumstances exist." While there may be specific and heated disputes on the facts in a specific case, the Agency has set for itself internal guidelines which, in the abstract, are noncontroversial.

Touching on several sections which are of particular interest, the Agency has divided recalls into three parts: (1) Class I, where there are products which cause serious, adverse health consequences

or death; (2) Class II, where there are temporary or medically reversible adverse health consequences; and (3) Class III, where use of a violative product is not likely to cause adverse health consequences. In contrast with the earlier versions of the Regulatory Procedures Manual, a Class I or Class II recall no longer invokes an automatic response from the Agency. The Agency will continue to conduct effectiveness checks, but the degree of the effectiveness checks will be tailored to the facts of a specific recall. The Agency has matured and recognizes that "each circumstance which necessitates a recall is unique and requires its own recall strategy."

A Reputation to Protect

When a corporation is presented with circumstances which appear to justify a recall, the agony of the decision centers as much on the adverse publicity which accrues to the corporation as on financial circumstances. Each corporation selling brand name goods has a reputation to protect. Protection of your brand name is *not* the business of the FDA. You should be aware that not every recall necessarily will be accompanied by the sound of trumpets and the roll of drums from the Parklawn castle. The Procedures Manual spells out three options on publicity:

(1) press release (nationwide or affected areas only);

(2) communication with specific segments of the population (physicians, veterinarians, hospitals, etc.); or

(3) none.

There is, however, a "hooker" in this situation. Whether or not there is publicity generated by the Agency through its active efforts, *all* recalls nevertheless will appear on the weekly recall list. Let me try to distinguish between these Agency actions. By publicity, it is meant that the trumpets will be sounded to announce the violation. While you may be able to avoid the trumpets in a particular circumstance, your company name will still appear on the castle door along with the names of other sinners who have fallen from grace. Hence, there may still be press inquiries and searching questions arising from the weekly recall list, although the Agency will not go out of its way to stimulate press inquiries.

The FDA can also be expected to conduct an in-depth inspection of the firm to determine the basic cause for each Class I and Class II recall. You need to be prepared. The Procedures Manual states that:

"If the District Office encounters delays by the recalling firm (such as diverting the inspector through the hierarchy of firm attorneys, managers, vice presidents, etc., or requiring clearances from the firm's legal staff, etc.) this information, with the District recommendations for correction, should be referred to EDRO/Field Compliance Branch, with a copy to the appropriate Bureau Recall Unit."

Rigorous Standard of Cooperation

Quite obviously, the Agency will impose a more rigorous standard of cooperation during the time of a recall than on other, happier occasions. Since there is the possibility of legal action against the corporation, you and your colleagues will be subjected to an intense period of high emotion. While you are tossed and turned, and expected to do the impossible, keep your eye on the consumer as your first priority. While we are not suggesting that you abnegate your legal responsibilities, certainly *not* at a meeting of the Food and Drug Law Institute, keep your eye on the consumer and undertake those efforts, individually or with the FDA, which will relieve the problem as quickly as possible. As for your legal protection, depend upon the establishment of a clear log of activities undertaken by the corporation. A good-faith effort on your part is what is expected by the courts, and establishing a record of those efforts is clearly your responsibility.

PRODUCT RECALL REFERENCES

(1) *Guidelines for Product Recall.* A 120-page manual prepared by the Grocery Manufacturers of America, Inc., as a practical aid to help perfect corporate recall mechanisms to ensure consumer protection.

(2) "Recall Procedures," Chapter 5-00, of the Regulatory Procedures Manual of the Food and Drug Administration, February 18, 1976. The chapter defines recalls and recall policy and specifies the duties and responsibilities of the FDA and the procedures to be followed relative to recalls. Available under the Freedom of Information Act from the Supervisor, Public Records and Documents Center, FDA, Rockville, Maryland 20852. Also reprinted in the March 1976 issue of "The Gold Sheet."

(3) Khan, Paul and Healton, Donald C., "Recall of Food Products: Emergency Standby Procedures at the Home Office," 27 FOOD DRUG COSMETIC LAW JOURNAL 709 (Nov. 1972).

(4) Fisk, George and Chandran, Rajan, "How to Trace and Recall Products," *Harvard Business Review* 90 (Nov.-Dec. 1975).

[The End]

Section 305 Hearings—Defense Considerations

By RAYMOND D. McMURRAY

Mr. McMurray Is a Partner in the Law Firm of McMurray and Pendergast.

Introduction

ONE NEVER KNOWS what will appear in the morning's mail, and if you are a manufacturer of foods, drugs, cosmetics, devices or diagnostic products, your morning mail can be exciting indeed if it contains Form FD-466 with its accompanying materials.

Form FD-466 bears in its upper right hand corner in a black box the phrase "NOTICE OF HEARING." This is the official beginning of a procedure "mandated" by Section 305 of the Federal Food, Drug and Cosmetic Act. I will explain later why there are quotes around the word "mandated." Section 305 reads as follows:

"Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."

The Notice of Hearing

As a general rule, a Notice of Hearing will arrive by certified mail, return receipt requested. It is sent from the district office of the Food and Drug Administration (FDA) having jurisdiction over the facility in which violations are alleged to have occurred. It is directed to the company and (uniformly, these days) to one or more individuals. It invites those addressed to an informal hearing to be held at the district office before a compliance officer (usually the official who has signed the Notice) at a specific date and time. Attached to the Notice of Hearing is a Charge Sheet which details

the alleged violations of the Federal Food, Drug and Cosmetic Act and relates these alleged violations to particular sample numbers which have been assigned by the FDA.

Charges are generally either misbranding or adulteration. The samples have traveled in interstate commerce and, for the most part, there is very little question of jurisdiction. At this point, you will probably remember the request of an FDA inspector that the company give him records concerning the shipment of particular products to consignees in states other than the state in which the facility is located. As a matter of fact, such requests can act as an early warning device signaling that at least the inspector considers the violation serious enough to begin to lay the jurisdictional groundwork in case court action is necessary. It is true that these requests concerning shipments are made rather routinely and, for the most part, either nothing comes from them or there is a seizure rather than criminal action. Nevertheless, when interstate shipment information is sought and received, an important step has been taken by the FDA.

The Notice of Hearing tracks the language of the statute in that it says that the informal hearing is to give the respondent an opportunity to give his views in the matter. To explain the nature of the hearing, there is an Information Sheet Form FD-466a also attached. Finally, the recipient is warned that if no response is received on or before the date set for the informal hearing, the decision of the FDA on whether to refer the matter to the Department of Justice for prosecution will be based on the evidence at hand.

It has always been a curiosity to me that, although the Notice of Hearing and its attendant documents are clearly based on Section 305 of the Act, nowhere in them is the respondent referred to the statute. Is this merely oversight?

Preparation for Hearing

Make no mistake about it, a Section 305 hearing is a most important contact with the FDA. The Agency uses it to screen flagrant violations from others which, although prohibited by the Act, appear not to require severe punishment. However, prior to the issuance of a Notice of Hearing, a case already will have been made within the Agency for prosecution and the matter will have been considered important enough to have been discussed with compliance officers in Rockville.

It is important that the company and the individuals put together a response which is well thought out, carefully prepared and documented wherever possible. The time set for the hearing in the Notice is generally not less than two nor more than three weeks from the date thereof. However, it usually is possible to secure a reasonable extension of time for the hearing, especially if a good deal of investigation and marshalling of facts and exhibits is necessary. As in any proceeding, adversary or otherwise, one should never seek delay for its own sake but should seek it in order to be as well prepared as possible. Depending upon the violation alleged, the time necessary to prepare can vary widely.

It is not a good idea to hold back any information on the consideration that, if the matter does proceed to trial, you will not have opened your whole hand to the regulatory agency. This attitude is short-sighted. Although it is true that you are exposing your defenses to the Agency, you are also giving it an opportunity to judge the nature of the violation. I will have more to say about this later.

The informal nature of the hearing also allows you to put in background information by way of mitigation and make certain assertions which might not be admissible in a trial. There is only one tactic in preparing for a Section 305 hearing and that is to put together sufficient information to convince the District Director either that a violation did not occur or that, if it did, the circumstances are such that prosecution would accomplish no real purpose. Hopefully, whatever violation is alleged can be stated to have been corrected and that future operation of the facility will continue to adhere strictly to the requirements of the law and pertinent regulations. It is in order to have visual aids, including photographs where appropriate, charts, graphs and the like. By indicating, by a thorough response, that you have given the matter your best effort, you go a long way toward convincing the FDA that you are sincere in whatever your response contains.

The Hearing

One of the decisions which must be made is whether or not to appear in person or be represented by an attorney. The corporation can appear by one of its officers, and individuals may appear *pro se*. It is considered, however, that appearance by an attorney who has been instrumental in preparing the response is preferred.

A very real consideration where the corporation and several of its employees are named is whether or not the employees should be

represented by counsel other than counsel representing the corporation. It is not inconceivable that individuals could have defenses unavailable to the corporation. By the same token, certain individuals could have defenses unavailable to the other individuals. An example of such a situation is an employee named in the Notice who notified his supervisor—also named in the Notice—of the existence of the violation but no steps were taken to correct it. This again raises the possibility of multiple groups of lawyers appearing in an early stage of action which is not an appetizing thought in terms of time expended and cost. Some respondents prefer to await the outcome of the hearing before engaging counsel for those individuals listed in the Notice, should the matter proceed to trial. Others consider it useful to have at least one other counsel helping in the preparation of the response, whose job it is to protect as much as possible the interests of the individuals. This is totally a judgmental matter but, in general, the more severe the alleged violation and its sanction, the more weight must be given to the possibility of an early role for counsel for the individuals.

It is elementary that no admissions of guilt should be made and that, consistent with full cooperation with the Agency, events should never be characterized by the respondents as violations. There is nothing to prevent the reference at trial to admissions against interest made by or on behalf of respondents at a Section 305 hearing. So-called violations are always "alleged" and references are always to "events" or "situations," the circumstances surrounding which did not result in a violation described in the Charge Sheet.

Perhaps the seed of greatest misunderstanding of the lawyer's role in a Section 305 hearing arises under these circumstances. There are those who consider the refusal to admit a violation as evincing an attitude of lack of cooperation. One might even have some anxious moments with clients in this regard. However, since the proceeding is clearly a precursor to criminal action and since there is no guarantee of immunity, counsel is well-advised to be aware of the pitfalls both of admitting liability on the one hand and in holding back relevant information on the other. Fortunately most compliance officers are aware of the delicate nature of advocacy in this situation and are tolerant of the necessary disclaimers and sometimes cumbersome sentence structure.

The hearing generally is held somewhere in the district office in a room suitable to the accommodation of those present. It can

be anywhere from the Compliance Officer's own office to a large conference room. The Compliance Officer may or may not be accompanied by another FDA employee. If he is, it is usually because the other employee is training for future duty as a Compliance Officer. If a violation is considered to be extreme, the FDA might insist upon the appearance of a particular individual respondent. If this is the case, the Compliance Officer reads a *Miranda*-type warning to the individual. Since this primarily involves a notice that the respondent has a right to counsel and since counsel is present, the warning serves only to meet a requirement that it be given, while at the same time indicating the seriousness with which the FDA regards the alleged violation. It also indicates that the Agency has already "zeroed in" on the individual as the responsible criminal actor. Thus, as a general rule, individuals should appear through an attorney unless there is something really valuable to be gained by their appearance.

The Compliance Officer opens the hearing by reading the charges on the Charge Sheet and asks if these are generally understood. After that he turns the meeting over to the respondents and hears oral arguments, sees exhibits and receives written documents that are profferred by them. There are no rules of evidence and, therefore, all things are received whether stated orally or presented in writing and made a part of the record. Respondents and the FDA are at liberty to ask whatever questions occur. It generally is helpful to make certain that the Compliance Officer understands and has a good grasp of the matters presented. At the conclusion of the hearing, which can take from a few minutes to several hours depending upon the subject matter and the type of presentation made, the Compliance Officer requests a stenographer to come into the room and, in the presence of the respondents, dictates his understanding of the views presented. At the conclusion of this report, the respondents are given an opportunity to state their views and either disagree with some of the conclusions of the Compliance Officer or offer further information bearing on those views. Here again, no statement is refused and, depending upon whether or not it is perceived that the Compliance Officer understands the response, any statement by a respondent may or need not be made.

Post-Section 305 Hearing

After the Section 305 hearing, the Compliance Officer makes his report and recommendation for prosecution or no prosecution. The

recommendation is forwarded through channels to the appropriate Compliance Office branch at FDA headquarters where it is reviewed and another prosecute or no prosecute decision is made. The unfortunate thing about the post-Section 305 hearing situation, which I hope could be corrected when the FDA issues its promised regulations dealing with these hearings, is that one never hears what the result is. One more or less waits for the Agency to drop the other shoe and, the longer the wait, generally the better the news. There is a provision in the regulations[1] providing a system under certain safeguards whereby a Freedom of Information request may be made. If the consideration of criminal prosecution based upon a Section 305 hearing has been closed with a recommendation not to prosecute, such information may be made available. This is one way of getting to know the result but the FDA must recognize the understandable reluctance of a respondent to make such a request. It seems to me that it would not be asking too much to have the respondents notified of the decision. I have been told by FDA compliance officers that such a decision might remove certain options from the Agency in case of further violations either of the same nature or of a different nature (presumably within the time of the statute of limitations). I believe that sufficient caveats can be built into a notification arrangement whereby respondents may be told that, at least for the present, there will be no prosecution and that the Section 305 hearing is closed, thus ending the agonizing suspense otherwise built into a system calculated—by the FDA's characterization—to help the respondent.

The Requirement for a Hearing

You will recall that the clear language of Section 305 seems to mandate an informal hearing before any recommendation is made to the Department of Justice for prosecution. This is so. But the implication that a criminal prosecution cannot be commenced without it is invalid.

It has been held that Notice under Section 305 is administrative and the lack of it does not deprive a court of jurisdiction.[2] This principle, which was reiterated in the now famous *Dotterweich* case,[3] is overshadowed by the fact that the *Park* case[4] relied on other principles expounded in *Dotterweich*, relating to the criminal responsibility of

[1] 21 CFR 1.6(c).

[2] *U. S. v. Commercial Creamery Company*, 43 F. Supp. 714 (DC Wash. 1942).

[3] *U. S. v. Dotterweich*, 320 U. S. 277 (1943).

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

corporate executives. Defendant Dotterweich was not afforded a Section 305 hearing and moved that the charges against him be dismissed because of this. The Court held that the opportunity for a Section 305 hearing is not a prerequisite to prosecution, relying on *U. S. v. Morgan*,[5] which had so held under a similar 1906 Act provision, and the legislative history of Section 305, indicating that Congress did not intend to overturn this proposition because of a change in phraseology from the 1906 to the 1936 Act.

The rationale is that the clear mandate to all United States attorneys to prosecute based on criminal acts of which they have knowledge cannot be frustrated by an administrative requirement within a particular agency. The law in this regard is settled.

Conclusion

A Section 305 hearing is important and should be given the most intense consideration by those charged with responding. It is an opportunity to make a full disclosure with the benefits and drawbacks attendant thereto. Consistent with the protection of the client as far as admissions against interest are concerned, every effort should be made to cooperate fully and to show the good faith and continuing compliance efforts of the respondent. For its part, I urge the FDA to hasten the day when more adequate guidelines are written[6] governing the procedure with an especial consideration given to notifying the respondents that the case has been closed administratively so that all involved might get back to the business of producing foods, drugs, cosmetics, devices and the like without the uncomfortable spectre of the possibility of criminal prosecution looking indefinitely over the shoulder. **[The End]**

[5] *U. S. v. Morgan*, 222 U. S. 274 (1911).

[6] Subsequent to the presentation of this paper the FDA published, in the *Federal Register* of April 7, 1976, proposed rules for its internal practices and procedures governing Informal Hearing Before Report on Criminal Violation under Section 305 of the Act. See 41 *F. R.* 14769 (Apr. 7, 1976).

The New Age of FDA Rule-Making

By STEPHEN HULL McNAMARA

Mr. McNamara Is Associate Chief Counsel for Food in the Food and Drug Administration.

IT IS A PLEASURE to have this opportunity to be with you and to participate in this symposium on food regulation held in honor of Professor Kenneth G. Weckel.

As an attorney for the Food and Drug Administration (FDA), I have been asked to offer some personal views on the subject of current trends in FDA regulation making, or "rule-making" as lawyers would put it. In recent years the state of the law concerning the legal status and permissible scope of FDA rule-making has changed dramatically. I am pleased to have this opportunity to share with you some FDA perspectives about "what it all means" and "where we are going."

I. The Rule-Making Authority in the Federal Food, Drug and Cosmetic Act

(1) *Sections 701(e) and 409.*—The Federal Food, Drug and Cosmetic Act[1] provides that five types of food regulations are to be promulgated by the FDA pursuant to formal rule-making procedures incorporated in Section 701(e).[2] These are:

(1) regulations establishing a *definition and standard of identity for a food;*[3]

(2) regulations establishing *labeling requirements for a special dietary food;*[4]

(3) regulations establishing *emergency permit controls* for a class of food;[5]

[1] 21 U. S. C. 301 *et seq.*
[2] 21 U. S. C. 371(e).
[3] 31 U. S. C. 341.
[4] 21 U. S. C. 343(j).
[5] 21 U. S. C. 344(a).

(4) regulations establishing *tolerances for poisonous or deleterious substances* in food;[6] and

(5) regulations listing a *color additive* for use in food.[7]

In addition, the Act provides that *food additive regulations* are to be promulgated by the FDA pursuant to formal rule-making procedures incorporated in Section 409.[8] The rule-making procedures of Sections 701(e) and 409 include an opportunity for an adversely affected person to request a formal administrative hearing before an Administrative Law Judge.[9] The Act provides that anyone who will be adversely affected by the final regulations may file a petition for review in a United States Court of Appeals.[10] These regulations have long been recognized as having the force and effect of law, and they are not subject to collateral attack on their merits when the FDA seeks to enforce them in court.[11]

(2) *Section 701(a) Regulations.*—In addition to the specific rule-making provisions mentioned in Subsection (1) above, Section 701(a) of the Act[12] provides: "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 [FDA]." The Act does not specify the procedures that the FDA must follow in promulgating Section 701(a) regulations and it makes no provision for judicial review of such regulations. It is this general, open-ended authority "to promulgate regulations for the efficient enforcement of this Act," long neglected by the FDA, which is the source of the recent developments in FDA rule-making that are the subject of this paper.

II. The "Historical View" of the Status of Section 701(a) Regulations

For thirty years after passage of the Federal Food, Drug and Cosmetic Act in 1938, it was accepted among many food and drug

[6] 21 U. S. C. 346.

[7] 21 U. S. C. 376.

[8] 21 U. S. C. 348. The Act also provides that a regulation establishing a pesticide residue tolerance for a food shall be promulgated pursuant to formal rule-making procedures. Such regulations are promulgated by the Environmental Protection Agency. 21 U. S. C. 346a.

[9] 21 U. S. C. 371(e)(2), 348(f)(1).

[10] 21 U. S. C. 371(f)(1), 348(g)(1).

[11] *United States v. Bodine Produce Company,* 206 F. Supp. 201 (DC Ariz. 1962); *United States v. 20 Cases . . . "Buitoni 20% Protein Spaghetti,"* 130 F. Supp. 715, 717 (DC Del. 1954), affirmed *per curiam* 228 F. 2d 912 (CA-3 1956); *cf. United States v. Lord-Mott Co.,* 57 F. Supp. 128 (DC Md. 1944). The latter was decided prior to the Administrative Procedure Act (APA), rejected in *Bodine* and, to my knowledge, is not seriously pressed as valid statement of the law by the private food and drug bar at this time.

[12] 21 U. S. C. 371(a).

lawyers that Section 701(a) regulations, insofar as they purported to establish requirements for the labeling or composition of foods, were "merely interpretative" or "advisory" of the FDA's opinion concerning the requirements of the Act. One well-known food and drug lawyer put it this way:

"Interpretive regulations . . . issued pursuant to section 701(a) consist of FDA opinions of the meanings of various sections of the Act, and opinions as to the impact of those sections on particular fact situations. They have advisory effect only. That is, they tell private parties what the FDA position will be in an enforcement proceeding. But in that proceeding, the court must consider, on a full evidentiary showing, whether the particular conduct challenged by the FDA pursuant to its announced enforcement policy is a violation of the Act."[13]

III. The Abbott Laboratories Decision

Conventional wisdom concerning the "merely interpretative" status of the FDA's Section 701(a) regulations began to crumble in 1967 when the United States Supreme Court decided *Abbott Laboratories v. Gardner*.[14] *Abbott* involved two Section 701(a) regulations which required certain labeling and advertising for prescription drugs. Without waiting for the FDA to recommend an action for condemnation of a drug product pursuant to the labeling requirements of the Act, the industry sued the Agency seeking a declaratory judgment that the regulations' interpretation of the Act was improper and exceeded the FDA's authority. The FDA responded that judicial review of the issue was premature and would have to wait until it acted to enforce its interpretation of the law, that is, until an allegedly violative product was seized in a civil seizure action. The Supreme Court rejected the FDA's position, ruling that the regulations constituted "final agency action" and that judicial review of the regulations could be had immediately in a United States District Court.

This decision, at first viewed by the industry as a great victory authorizing pre-enforcement judicial review of Section 701(a) rule-making, proved to be a two-edged sword. William Goodrich, the FDA's Chief Counsel, thereafter maintained that if FDA regulations issued pursuant to Section 701(a) had such legal status that they were subject to pre-enforcement judicial review, then they were not

[13] Munsey, Rodney, "Survey of Current Legal Problems in the Drug Area," 23 FOOD DRUG COSMETIC LAW JOURNAL 449, 454 (Sept. 1968), as quoted in *National Nutritional Foods Assn. v. Weinberger*, 512 F. 2d 688, 696 (CA-2 1975), *cert. denied* — U. S. —, 96 S. Ct. 44 (1975).

[14] 387 U. S. 136 (1967).

merely insubstantial expressions of Agency opinion but instead legal requirements with the status of law.[15]

IV. The Constitution Theory

In December of 1972, FDA Chief Counsel Peter Barton Hutt, speaking to the annual Educational Conference of the Food and Drug Law Institute, added an additional perspective which made the *Abbott* decision of even greater import. He analogized the Act to a "constitution" which authorized the FDA to specify any requirement that is reasonably related to the Act's purpose and that is not specifically prohibited by the Act, and he asserted that the FDA possessed wide-ranging authority to promulgate regulations to further the general public health purposes of the Act.[16]

Thus, the FDA had come to assert a twofold claim of rule-making authority under Section 701(a): (1) the FDA cited *Abbott* for the proposition that Section 701(a) regulations had the binding status of law; and (2) the FDA asserted that it possessed authority under Section 701(a) to impose wide-ranging innovative requirements not specifically mentioned in the Federal Food, Drug and Cosmetic Act, for example, the authority to require detailed nutrition labeling when a nutrition claim is made for a food[17] and the authority to establish a common or

[15] "Thus, if within the Commissioner's authority, they [the Section 701(a) regulations] have the status of law and violations of them carry heavy criminal and civil sanctions." *Abbott Laboratories v. Gardner, supra* 387 U. S. at 151—152.

[16] ". . . 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.

". . . the fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the Food and Drug Administration exerting initiative and leadership in the public interest. Except where expressly prohibited, I believe the Food and Drug Administration is obligated to develop whatever innovative and creative regulatory programs are reasonable and are most appropriate to achieve the fundamental objectives laid down by Congress. And in spite of the diversity of the Agency's new programs, I am not at all certain that the Food and Drug Administration has yet begun to explore the full reaches of existing statutory authority." Hutt, Peter Barton, "Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act," 28 FOOD DRUG COSMETIC LAW JOURNAL 177, 178—179 (March 1973). For an immediate response by Mr. Hutt's former mentor, opening with reference to an apocryphal story that it was a former pupil who handled Socrates the hemlock, see Austern, H. Thomas, "Philosophy of Regulation—A Reply to Mr. Hutt," 28 FOOD DRUG COSMETIC LAW JOURNAL 189 (March 1973). This same issue of the FOOD DRUG COSMETIC LAW JOURNAL includes several interesting papers on the philosophy of regulation at the FDA.

[17] 21 CFR 1.17.

usual name for a food requiring declaration of the percentage of a characterizing ingredient present in the food.[18]

V. The Recent Case Law

The recent case law has clearly sustained the FDA's assertions concerning the binding legal status and broad permissible scope of Section 701(a) regulations.

(1) In *Ciba-Geigy Co. v. Richardson*,[19] the FDA had withdrawn approval of a new drug on the ground that there was lack of "substantial evidence" to support claims of effectiveness. The Agency had relied upon Section 701(a) of the Act to promulgate regulations detailing requirements for the granting of a hearing on the issue of efficacy. In affirming the FDA's action, the Court stated that "the Commissioner has the power to issue binding interpretative regulations. . . . Indeed the particularization of a statute by rule-making is not only acceptable in lieu of protracted piecemeal litigation . . . but it is the preferred procedure."[20]

Such language—"binding interpretative regulations"—would have been a *non sequitur* under the old interpretation of the FDA's Section 701(a) rule-making authority. Manufacturers generally had contended that such regulations were "merely interpretative." In *Ciba-Geigy*, the Second Circuit recognized that the regulations at issue were "interpretative" of the Act, but went on to rule that they were nevertheless "binding."

(2) *The 1973 Supreme Court cases.*—In four significant decisions involving the FDA's authority over drugs, decided in 1973, the Supreme Court broadly sustained the Agency's power to promulgate substantive regulations that have the binding force of law pursuant to Section 701(a) of the Act.[21] The Supreme Court upheld the power of the FDA under Section 701(a) to promulgate binding regulations which defined the standards of evidence to be met by drug manufacturers to demonstrate the efficacy of their products in new drug applications and permitted the withdrawal without a hearing of an application failing to meet these standards. Any doubt that the FDA might not have the power to issue binding regulations under Section 701(a) of

[18] 21 CFR 102.

[19] 446 F. 2d 466 (CA-2 1971).

[20] 446 F. 2d at 468.

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

the Act disappeared with the decisions in these cases, as subsequent case law has recognized.

(3) In *National Nutritional Foods Association v. Weinberger*,[22] involving review of Section 701(a) regulations which specified that vitamin A and D preparations in excess of certain specified levels would be deemed to be prescription drugs rather than foods, the United States Court of Appeals for the Second Circuit stated that Section 701(a) of the Act gives the FDA "the power to promulgate substantive regulations having the binding force of law."

(4) In *National Health Federation v. Weinberger*,[23] the FDA successfully argued for the first time a new proposition—that review of a Section 701(a) regulation should be confined to a single consolidated case in one court and that a second attack on a Section 701(a) regulation in a second court should be dismissed. The Court of Appeals for the Seventh Circuit agreed and ordered the United States District Court for the Northern District of Illinois to dismiss a second attack on Section 701(a) regulations which were already under review in another Circuit.

(5) Finally, three very recent decisions in the United States District Court for the District of Columbia have amplified the judicial recognition of the FDA's authority to issue binding regulations under Section 701(a) of the Federal Food, Drug and Cosmetic Act.

In *Cosmetic, Toiletry and Fragrance Association, Inc. v. Schmidt*,[24] Judge Richey upheld Section 701(a) regulations requiring specific warnings on aerosol food, drug and cosmetic products. The Court specifically ruled that the FDA's "broad statutory powers to promulgate regulations for the efficient enforcement of the Act, 21 U. S. C. 371(a)," include authority to require that warning statements appear on the immediate label of a product.

In *American Frozen Food Institute v. Mathews*,[25] Judge Robinson sustained FDA regulations promulgated pursuant to Section 701(a) of the Act which establish common or usual names for "seafood cocktails" (requiring the percentage of seafood present in the food to be declared as a part of the name) and "frozen heat-and-serve dinners" (requiring that the "dinner" contain at least three of certain specified types of characterizing components, one of which must be a significant

[22] 512 F. 2d 688. 697 (CA-2 1975), cert. denied — U. S. —, 96 S. Ct. 44 (1975).

[23] 518 F. 2d 711 (CA-7 1975).

[24] — F. Supp. —, Civil No. 75-1715 (DC DofC 1976).

[25] — F. Supp. —, Civil No. 74-354 (DC DofC 1976).

source of protein, and that the name of the "dinner" include a list of the characterizing components in descending order of predominance, followed by any other servings of food present in descending order of predominance). Judge Robinson ruled that the FDA could employ Section 701(a) not only to recognize an existing name but also, as in this case, to require the industry to employ a more informative name than is currently in use.

And in *National Confectioners Association v. Mathews,*[26] Judge Green ruled that the FDA may rely on Section 701(a) of the Act to promulgate good manufacturing practice (GMP) regulations for the manufacture of confectionery products. These regulations require, among other things, coding of the shipping containers or retail packages in order to facilitate recalls.

There is a single dissenting case—*United States v. Everett Fisheries, Inc.*[27] This was a criminal prosecution in which the District Court for the Western District of Wisconsin found the defendants not guilty, ruling that violation of the FDA's GMP regulations governing the manufacture of smoked fish did not automatically establish a criminal violation of the Act. This decision has not been appealed. (The double jeopardy clause of the Constitution ordinarily forbids the government from appealing a criminal case.) However, the case is not much of a precedent for any proposition other than that "inconsistent pleadings lead to confused decisions." Examination of the briefs filed with the Court shows that the government made inconsistent legal arguments before the Court and did *not* consistently argue that the regulations had the force of law. Furthermore, the Court waited more than two years after trial before entering a verdict, and the "Opinion and Order" made no mention of the 1973 Supreme Court decisions or the *National Nutritional Foods Association* decision. Such circumstances tend to undermine the credibility of *Everett.*

VI. The New Age

Richard A. Merrill, who became the FDA's Chief Counsel in 1975, has continued to press the trends developed under Counsels Goodrich and Hutt—there will be no voluntary withdrawal by the FDA from the new ground won in battles over the extent of the Agency's Section 701(a) rule-making authority.

[26] — F. Supp. —, Civil Action No. 75-1272 (DC DofC 1976).

[27] — F. Supp —, No. 72-CR-109 (DC WD Wisc. 1975).

Indeed, it would seem clear to us at the FDA that the new era of rule-making is in everyone's interest. Developing new legal requirements by rule-making under Section 701(a) is fairer and more efficient than developing new law case-by-case in civil seizure actions, injunctions and criminal cases in the federal courts. Even the United States Congress has recognized the validity of this proposition. The conference report which determined the final details of recent legislation concerning the FDA's authority to regulate dietary supplements included the following statement:

"The Secretary [Food and Drug Administration] in recent years has relied increasingly on administrative rulemaking to enforce the requirements of the law [Federal Food, Drug, and Cosmetic Act]. Rulemaking affords opportunity for broader participation in the formulation of agency policy, promotes clarity of legal requirements, and assures equitable application of the law, while at the same time it reduces the cost to the taxpayer of case-by-case enforcement. The Secretary's legal authority, under section 701(a) of the Act, to adopt binding regulations has been recognized by the Supreme Court. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U. S. 609 (1973); *Abbott Laboratories v. Gardner*, 387 U. S. 136 (1967). This authority has recently been upheld by the United States Court of Appeals for the Second Circuit. *National Nutritional Foods Assn. v. Weinberger*, 512 F. 2d 688 (C. A. 2, 1975)."[28]

Furthermore, the FDA is *not* free to require "anything it wants" and ride roughshod over the regulated industry. Rule-making by the Agency under Section 701(a) is subject to direct review in a United States District Court,[29] and it will be invalidated by the courts if, *inter alia,* it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[30]

In addition, the FDA must follow scrupulously the procedural requirements for rule-making mandated by the Administrative Procedure Act (APA).[31] The Agency must publish in the *Federal Register* a notice of the proposed rule-making, which is required to include *inter alia* "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[32] In practice, the FDA has endeavored to provide *more* than the APA requires. Agency

[28] Conference Report to accompany H. R. 7988, 94th Congress, 2nd Session, H. R. Rep. No. 94-1005, Health Research and Health Services Amendments of 1976, pp. 27—28 (April 2, 1976).

[29] The Federal Food, Drug and Cosmetic Act includes no provision concerning judicial review of Section 701(a) rule-making. However, it is undisputed that such rule-making is subject to direct review in a United States District Court pursuant to the APA and/or the Declaratory Judgment Act. *Abbott Laboratories v. Gardner*, 387 U. S. 136 (1967). See Administrative Procedure Act, 5 U. S. C. 702, 703; Declaratory Judgment Act, 28 U. S. C. 2201—2202.

[30] 5 U. S. C. 706.

[31] 5 U. S. C. 553.

[32] 5 U. S. C. 553(b).

proposals now routinely include not only the terms of the proposed regulation but an extensive preamble explaining the intended purpose and effect of the proposal as well as the facts which support it.

Public Comment

The APA also requires that the Agency provide an opportunity for public comment on a proposed regulation. Standard FDA procedure now is to allow 60 days for comment and, when good cause is shown, the Agency will extend the comment period. All comments are placed in a public file in the Office of the Food and Drug Administration Hearing Clerk, where they are subject to scrutiny and cross-comment by all interested persons. Comments filed in response to proposals frequently are reported in the trade press, such as the *Food Chemical News*. The FDA encourages that comments include factual data and expert opinion relevant to the proposed rule-making.

Furthermore, the APA requires that, after consideration of the relevant matter presented during the comment period, the Agency "shall incorporate in the rules adopted a concise general statement of their basis and purpose."[33] Again, the FDA has endeavored to provide more than the APA requires. Typically, final FDA regulations include a detailed preamble which discusses each type of comment which has been received and provides the Commissioner's response to the comment.

The FDA recognizes that, whatever the minimum legal requirements for support of rule-making are, successful defense of a regulation on judicial review ultimately depends upon showing the court that the Agency has evaluated conscientiously all views and data offered by interested persons and that its final regulation is supported by data and sound reasoning.

The upshot of all this is that the FDA now assembles an extensive official record in the development of a Section 701(a) regulation. This record is available for public scrutiny in the Office of the Hearing Clerk and, except in unusual circumstances, in future cases involving judicial review of FDA rule-making under Section 701(a), judicial review may properly be restricted to the record compiled by the Agency in the rule-making proceeding. A court, in reviewing such a Section 701(a) regulation, may properly refuse to receive additional evidence, and restrict its inquiry to determining whether the regulation is valid

[33] 5 U. S. C. 553(c).

in light of the FDA's proposal, the documents filed with the Hearing Clerk, and the explanation offered in the final order.[34]

Summary

In summary, I would suggest that the following general principles have properly come to apply in this new age of Section 701(a) rule-making.

(1) The FDA may promulgate regulations pursuant to Section 701(a) of the Federal Food, Drug and Cosmetic Act to impose requirements reasonably designed to further the general purposes of the Act to assure a safe, wholesome and informatively labeled product. These regulations, if adequately supported, have the status of law.

(2) Anyone who wishes to make his or her views known concerning a regulation proposed by the Agency should file with the FDA Hearing Clerk a comment in response to the proposal. In this regard, brief conclusory views are not particularly helpful and are not likely to be accorded much weight by the FDA or the courts. It is the detailed comment, offering data from an informed source, which is most persuasive. Such comments require conscientious consideration by the FDA, with an explanation of its conclusions in the preamble to its final regulation.

(3) Anyone opposed to a proposed Section 701(a) regulation should make his or her complete case against the regulation in comments filed with the FDA in response to the proposal. A court may refuse to consider arguments and data that were not presented to the Agency.[35]

(4) If a person is adversely affected by a final Section 701(a) regulation and contemplates seeking judicial review, we suggest that

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[34] See *Rodway v. USDA*, 514 F. 2d 809, 817 (CA DofC 1975); *Automotive Parts & Accessories Association v. Boyd*, 407 F. 2d 330, 336 (CA DofC 1968); *National Petroleum Refiners Association v. FTC*, 392 F. Supp. 1052 (DC DofC 1974). More generally, the Supreme Court, in *Camp v. Pitts*, 411 U. S. 138, 142—143 (1973), has stated that judicial review should be based upon the record created by the Agency when the Agency has made a record. And see Wright, "The Courts and the Rulemaking Process: The Limits of Judicial Review," 59 *Cornell Law Review* 375, 395 (1974); Pedersen, Jr., "Formal Records and Informal Rulemaking," 85 *Yale Law Journal* 38, 79 (1975); and Verkuil, "Judicial Review of Informal Rulemaking," 60 *Virginia Law Review* 185, 203—204, 248 (1974).

[35] The FDA is likely to argue that a challenge to a regulation, to be raised by direct judicial review, must have been raised in the course of the rule-making proceeding before the Agency. See *Portland Cement Association v. Ruckelshaus*, 486 F. 2d 375, 394 (CA DofC 1973), cert. denied 417 U. S. 921 (1974) and

(Continued on the following page.)

he or she first file a petition for reconsideration with the FDA, offering the arguments and data which are believed to show that the Agency has acted improperly or inadvisedly. This may cause the FDA to institute changes and, if not, it will assure that the relevant issues and data may properly be raised in an action for judicial review and that the court will have in the record an exchange of views between the plaintiffs and the FDA which is focused upon the issues to be considered by the court. This will foster informed judicial review.

(5) If an adversely affected person determines to seek judicial review of a Section 701(a) regulation (hopefully, after a petition for reconsideration has been ruled upon by the FDA), he or she should do so quickly. Waiting too long may result in unfairness, in that other members of the industry have begun to comply. The Supreme Court has recognized that the FDA may raise the defense of "laches," that is, at some point a court will dismiss an attack upon a Section 701(a) regulation because the plaintiffs have waited too long to bring their case.[36]

(6) After an action for judicial review of a Section 701(a) regulation has been instituted by an adversely affected person, other persons who may wish to obtain judicial review should seek to intervene in this action rather than pursue separate actions. The FDA has recently won a case *dismissing* a second attack on an Agency regulation because another suit had already been lodged by other persons in another Circuit.[37] **[The End]**

(Footnote 35 continued.)
citations in footnote 34 *supra*. It can also be argued that persons who fail to participate in the administrative proceeding by the filing of comments forfeit their rights to seek direct review of the resulting regulation in court. See *Nader v. Nuclear Regulatory Commission*, 513 F. 2d 1045, 1055 (CA DofC 1975) ("... those who refrain from participation in rulemaking proceedings may not obtain direct judicial review of the regulations resulting"); *Gage v. AEC*, 479 F. 2d 1214, 1218—1219 (CA DofC 1973) (formal rule-making).

[36] *Abbott Laboratories v. Gardner*, 387 U. S. at 155.

[37] *National Health Federation v. Weinberger*, 518 F. 2d 711 (CA-7 1975).

Food Additives—A Study in the Evolution of Safety

By HOWARD R. ROBERTS, Ph.D.

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PROBABLY EVERY ONE AT THIS MEETING would agree that the subject of "food additives" is a complicated one. It is a subject which generates considerable industry, government and public concern. This concern is not new. It grows to some extent from the fact that the unfolding story of the use of chemicals in foods obviously has not been an endless process of dazzling achievements unmarred by occasional setbacks. Despite the complexities, I hope I can provide some indication of how the Food and Drug Administration's (FDA's) activities in the food additives area may impact on your business.

Let me begin by trying to put our mutual concern about the additive problem in perspective. Many consumers are firmly convinced that "additives" are bad. These fears and beliefs are being reinforced, and the ranks of anti-additive consumers are being increased every day by constant pressure from activists and a barrage of information and misinformation from the media. This is bad enough by itself but, in addition, consumers are being told by the government that their chocolate pudding and decaffeinated coffee may not be safe. The biggest impact, however, comes from the food industry telling the consumer to "buy this natural product—contains no artificial ingredients" and obviously implying that products which do should be avoided. At the same time, industry cries foul when other products containing artificial ingredients are held up to public scorn.

It is not remarkable that consumer confidence in food safety has decreased markedly in the past few years. This change in consumer confidence cannot be ignored. In our democratic society, the American consumer is a bit like the end result of crossing a tiger with a parrot—you may not like what the creature says but, when it talks, you had better listen.

During the past few years, there have been increasing demands for greater assurance of safety for FDA-regulated food ingredients. This is, in large measure, an evolutionary process and quite naturally flows not only from consumer expectations but also from the ability of our scientific technology to define problems in new ways.

This being the case, education of consumers as to the safety of, and need for, additives is not the answer—even if it could be done. Instead, we need to stop our self-flagellation and try a new approach.

Technological Change

If a manufacturer fails to respond to the evolution of technological change, its plant becomes obsolete. If it fails to measure and respond to consumer expectation, it faces a loss of its share of the market because of "old fashioned" products. By the same token, if a regulatory agency fails to adopt scientific refinements and respond to consumer demands, the result is the same: antiquated safety standards and reduced consumer protection and confidence. In my view, the recent criticisms of the design and implementation of certain animal studies conducted by industry to demonstrate the safety of additives derives from the failure of laboratories to appreciate and institute changing concepts of laboratory practice. Similarly, accusations of negligence on the part of the FDA in monitoring these studies can be traced to a failure to establish the proper priorities at many levels, both in and outside government. I feel that the response of the FDA to these criticisms and pressure, to scientific advances and to a redefinition of scientific discipline must be evolutionary. We, therefore, have initiated a new integrated program, the implementation of which will assure a greater level of safety for all food additives. Conversely, it will eliminate those additives which cannot live up to present day standards. In so doing, consumer concern about the safety of food additives should be measurably allayed.

Our program basically involves updating the toxicology profile of all food additives in order to provide specific assurance that food additives do not induce cancer, other chronic diseases, reproductive effects or mutagenic changes in future generations. This does not imply that currently regulated additives are known to produce harmful effects in our population, but rather that there is a need to produce additional information to assure safe continued use of these ingredients by applying modern safety standards.

I feel that this approach is our only real choice. Rather than continuing to react on an *ad hoc* basis as additives come into question one by one, we should, as the Scottish say, "beard the lion in his den."

This new program consists of five major parts, some of which are new initiatives and some of which are refinements of existing programs. These parts are:

(1) the continuing safety review of the uses of the non-flavor ingredients which were classified as generally recognized as safe (GRAS);

(2) a safety review of direct food additives, other than flavors, which have been regulated by the FDA since 1958;

(3) a safety review of flavors and spices;

(4) a fresh evaluation of the procedures used to assess the safety of indirect additives as well as a safety review of the substances involved; and

(5) a laboratory quality assurance program.

In addition, we currently have underway a comprehensive review of all provisionally listed color additives.

Definitions

Most of you are familiar with our law and how it operates, but on the chance that some may not have their copy of the Federal Food, Drug and Cosmetic Act handy, let me supply a few definitions before discussing our new additives program. Food is defined by the Act as: ". . . (1) Articles used for food or drink for man or other animals (2) chewing gum and (3) articles used for components of any such article."

That is a pretty broad definition. For example, one is struck by the fact that this definition does not differentiate between alcoholic

and nonalcoholic drink. Thus, alcoholic beverages are clearly subject to labeling and other provisions of the Act. Another definition with which most of you are familiar is that of a food additive. The Act defines a food additive in part as:

". . . any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food and including any source of radiation intended for any such use). . . ."

The law then makes some exceptions:

(1) those substances which are GRAS;

(2) a properly used pesticide chemical in or on a raw agricultural commodity;

(3) color additives;

(4) items given "prior safety" sanctions by the FDA or the Department of Agriculture (USDA) prior to 1958; and

(5) new animal drugs.

There is not sufficient time to discuss pesticides, animal drugs or chemical contaminants at this session. The only point of citing these definitions is to remind ourselves of the scope of the legislation. Everything used in or on food, and, in the case of packaging, even around food, must be regulated by the FDA or be judged recognized as GRAS.

GRAS Review

The concept of GRAS was born during the hearings on food additives which resulted in the passage of the amendment. Certain ingredient uses were exempted from regulation if the substance was

". . . generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. . . ."

Quite logically, early FDA activity in this area was restricted to publishing examples of GRAS ingredients and advisory opinions in response to questions about GRAS status. Then the sky fell.

In 1969 when cyclamate, then listed as GRAS, was prohibited by Secretary of Health, Education and Welfare Finch, public confidence in other GRAS listed substances deteriorated. As a result,

President Nixon in October of that year directed the FDA to initiate a safety review of the food additives, including the GRAS list. Since literally thousands of substances were GRAS and no one knew exactly what they were, a priority selection had to be made. Based on a variety of sources, usage and, to some extent, safety information, a list of 675 substances was finally selected for safety review.

The FDA's approach to the safety review entailed four sequential phases:

(1) the *collection phase*—a literature search of 50 years of scientific literature to collect all of the safety information relative to each substance and an industrial user survey by the National Academy of Sciences-National Research Council (NAS-NRC) to establish consumer exposure to each substance;

(2) the *collation phase*—the organization of the literature and consumption data into a "scientific literature review";

(3) the *evaluation phase*—an evaluation of the "scientific literature review" to determine whether expert food safety scientists can agree that the substance is generally recognized as safe for its intended use or that some limitation is required in the interest of safety; and

(4) the *implementation phase*—the issuance of proposals and final regulations necessary to implement the evaluations.

The first two phases of the review have been virtually completed and the evaluation phase is drawing to a close. For example, 356 of the 439 nonflavors will have been evaluated by the next fiscal year.

We have not fared so well on the implementation phase. Through this fiscal year, only 47 GRAS substances will be covered by final orders.

In our initial enthusiasms for this project, we had hoped to arrive quickly at a rather comprehensive GRAS list, either by the mechanism of contract evaluations by the Federation of American Societies for Experimental Biology (FASEB) or by a procedural mechanism of GRAS affirmation by petition. We have fallen behind on both counts. I have recently freed some of the Bureau's very scarce manpower resources to this project, and results in terms of *Federal Register* proposals and final orders should be forthcoming.

Our task here is to catch up with regulations and then remain abreast of results as FASEB evaluations are finalized. Efforts beyond the formal GRAS Review program essentially will be restricted to GRAS affirmation, at least in the foreseeable future.

Review of Direct Food Additives

The second program initiative involves the major undertaking of updating our safety profile of direct food additives. Since 1958, we have regulated some 400 food ingredients which are listed in 21 CFR Subpart D, "Food Additives Permitted in Food for Human Consumption." They range from amino acids, the building blocks of nature, to something as apparently strange as yellow prussiate of soda (sodium ferrocyanide decahydrate).

The list is, of course, always growing, with some 41 petitions in our backlog and an additional 10 expected each year. There is also a program of inspections and sample analyses for conformance to Food Chemicals Codex specifications. This relates to whether the food ingredients meet the appropriate specifications to be called food grade.

Our direct additive review program will involve the same four phases as the GRAS review. The FDA has contracted with the NAS to conduct a nationwide industry survey to obtain usage levels. This survey will be initiated by a series of question and answer sessions between industry and the National Academy prior to the issuance of the survey itself in late fall of this year.

In fiscal year '77, the literature search and some collation of safety data will begin, using contractor support. In this phase, petition information will be combined with literature updates to provide a current safety data profile.

The FDA will then evaluate the results of the literature search and collation, as well as the adequacy of the testing supporting the regulation in terms of present day safety requirements. This evaluation may well indicate that additional testing is needed to demonstrate the validity of continued FDA approval of the ingredient for its intended uses. I would hope that industry-government agreement on such needs could be reached without the benefit of court intervention.

Flavors

There are currently more than 1600 natural and synthetic flavors used in foods. Of these, 236 are included in our GRAS Review program. Another 943 flavors were regulated by the FDA in 1967. Some 300 are included in the Flavoring Extracts Manufacturers Association's GRAS list, and the remainder have not been officially addressed.

Our safety review of flavors is already underway. The literature search has been completed and scientific literature reviews will be completed for about 650 flavors before the end of the fiscal year.

It is worth noting that much of the safety information about the flavors is strictly inferential. Such information is useful when judged in conjunction with test data, but it may be insufficient by itself to meet today's scientific standards. It is becoming more apparent that thorough evaluation of flavors may require some testing component. It is no longer a question of whether to test, but rather how and in what order of priority.

The FASEB currently is developing criteria and recommended priorites for evaluating flavor safety.

Indirect Additives

Indirect food additives (those resulting from a food package or other food contact surfaces) are receiving increased attention, in part because of public concern about polyvinyl chloride. Actually, the FDA has been regulating packaging since its days as the Bureau of Chemistry, in USDA. The current concept of regulating contaminants of food resulting from packaging was born with the 1958 amendments. This concept covers an inventory of some 10,000 components of packaging, including such adjuvants as stabilizers and plasticizers. Whether a packaging item is safe for its intended use depends on a combination of migration studies and toxicity testing. In most cases, migration is not directly measured but instead is estimated based on extraction studies using simulated solvents.

Our plans in this area call first for an evaluation of our migration concepts and the derivation of new analytical methodology as required. The indirect additives will then be approached by functional categories. Based on limit specifications for the basic resins and adjuvants used in specific containers in each category, articles will be fabricated and migration measured. If further safety testing is indicated, our safety review will follow the same procedure as that used for flavor evaluation.

Quality Assurance

Recent events relative to animal safety tests have brought indictments by the media of general government bungling and industry

fraud. Such indictments have the usual lack of veracity which all too frequently is the current approach of the media. Nonetheless, it is clear that we must all put our houses in better order. Assuring the public that we are doing the job they expect of us will require the development and implementation of testing guidelines and what we have called "good laboratory practices." Once this is accomplished, cyclical inspections of some 100 independent and 125 industrial laboratories engaged in safety testing will become a way of life.

Color Additives

I need not dwell on the obvious public emotion and media attention focused on colors. A major effort will be made in this area this year to make final evaluations of the petitions to permanently list some 83 colors still provisionally listed. I have committed the Bureau to ruling up or down on the safety of these colors by September 30, 1976. Further extension of provisional status will be granted only where it can be clearly justified. Fortunately, of the 83 colors, only six are food colors: FD&C Green No. 3, Yellow No. 6, Red No. 3, Red No. 4, Blue No. 2 and Carbon Black.

All of these programs are safety assessment programs. So, in summarizing, I should try one more definition. Safety assessment in the FDA boils down to a rather fundamental catechistical process of asking the right questions and getting the right answers. Naturally, our views as to what are proper questions and answers can vary. We must agree, however, that these questions have to be asked, and proper answers have to be obtained.

Our plan for the safety evaluations that I have outlined today is a first step in being sure that we are asking the right questions, questions which in fact are representative of the latest and best scientific principles.

Such programs and initiatives will cost you the time of many top staff people, resources to finance and carry out tests, and frustrating delays in placing new products on the market. Any other picture I could paint for you would be less than truthful. You can, however, help us in obtaining the necessary resources to carry out these programs in a business-like fashion. We cannot be responsive to legitimate requests from consumers, industry, Congress or even our executive branch managers without resources and adequate funding. We like a lean organization but do not want to be an emaciated one, too debilitated by fatigue to act decisively in the consumer's interest.

Implementation of these programs also would have a definite beneficial effect for everyone. It will clarify the situation so that everyone will be playing the same game by the same rules. It will make priorities known in advance so that surprises about product ingredients will be minimized, thus minimizing dramatic impacts on industry plans and consumer emotions.

This all sounds so simple and obvious when I say it but what are the catches? One catch I have already mentioned is FDA resources. If we are forced to continue with a static level of resources eroded daily by inflation, all bets are off. Another catch is that it will take several years to implement these plans even with increased resources. In the meantime, it will be difficult at best to convince the public that our priorities and courses of action are the best. I'm sure, for example, that the activists have a different set of priorities.

The final catch is that the job never ends. We will not be able to stop after one pass through. Safety review of food additives must be a cyclical process, with re-evaluations occurring as science, products and consumption patterns change. Nonetheless, I think this is the only way to go. I invite your reactions. **[The End]**

FINAL ORDER PROHIBITS CHLOROFORM AS AN INGREDIENT

As of July 29, 1976, any human drug product containing chloroform as an ingredient will be considered to be a new drug, which will be deemed to be misbranded, and any cosmetic product containing chloroform as an ingredient will be deemed adulterated. The new regulations prohibiting the use of chloroform were promulgated by the Food and Drug Administration (FDA) on the basis of tests resulting in cancer in rats. The prohibition refers only to chloroform as an ingredient, active or inactive, but excludes chloroform which is present in residual amounts due to its use as a processing solvent during manufacture. However, the FDA considers the presence of residual chloroform a problem and is studying it intensively to resolve the issue. Any decision will be the subject of future notice, the Agency said. *In vitro* diagnostic products do not come under the requirements of the regulations because the Medical Device Amendments of 1976, which became effective May 28, place all *in vitro* diagnostic products in the device category.

The FDA advised in the preamble to the order that reformulation of a human drug product to remove chloroform as an active or inactive ingredient constitutes a material change, requiring the assignment of a new National Drug Code number.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,662

Management of Scientific Resources

By ROBERT O. NESHEIM, Ph.D.

Dr. Nesheim Is Vice-President of Research and Development of The Quaker Oats Company.

THE ORGANIZING COMMITTEE for this session suggested that I discuss such areas as an overview of the scientific team with particular emphasis on the establishment of priorities and the changing direction of research teams as required by perceived priorities. In addition, it was suggested that consideration be given to how the scientific manpower in industry might be coordinated with scientists in academia and government.

I plan to discuss this topic from four principal aspects:

(1) the changing role of research and development in a consumer products company;

(2) making more effective use of the scientific resources of a company;

(3) some key attributes of the scientific team; and

(4) some aspects of industrial, academic and government scientific interactions.

Before discussing the areas outlined, I think it is important to note that the scientific resources of an organization are primarily its people. The end product of the use of these scientific resources depends upon the quality and the productivity of the people. While laboratory facilities, equipment and budgetary support are important, it is really the quality of the people on the team that makes it produce.

The Changing Role of Research and Development

First, let's consider the changing role of research and development in a consumer products company. A little less than ten years ago, the

primary role for research and development was new products. We are not dealing with just a new products game any more, however. While it is still a significant part of the research and development activity, it occupies a much lesser part of the total effort today than in years past.

There is an increasing amount of research and development support for current businesses. In part, this has been brought about by the rapidly changing cost picture that has occurred in the last few years. In an effort to maintain the price/value relationships of its products in accordance with consumer-perceived needs, it has been necessary to devote more of industry's scientific resources to efforts to maintain costs or to reduce the rate of cost increases.

Likewise, considerable effort has had to go into the maintenance of quality and, in many instances, to improving the quality of products to meet the changing consumer interests. Much effort has been expended in responding to the influence of consumer concerns and government regulations as it relates to existing businesses. There have been examinations of product and process safety, with the identification of potential areas of vulnerability and work generated on these to solidify our knowledge base and avoid surprises.

Also, nutritional labeling has been introduced, which has required considerable extra expenditure for nutritional analyses. Prior to labeling, many food products were analyzed for their nutrient content but not in sufficient quantity to determine the statistical reliability of the analysis. Once the numbers were put on the label, however, this became part of the label claim, and it was necessary to have sufficient analyses to assure compliance with label claims.

With the growing support for existing businesses, there has been an attempt to broaden the base of technology that supports those cornerstone businesses. This has been necessary in order to maintain the quality and profitability of these businesses during these periods of changes in material costs and consumer values.

Making More Effective Use of Scientific Resources

Now, I will relate some of my observations on how to make more effective use of scientific resources in a company. I think the key issue to remember is that a company never has enough scientific resources to fully meet its needs or interests. Therefore, it is essential to establish priorities for the use of these resources.

In order to effectively establish priorities, it is important to have a clearly articulated corporate long-range strategy which spells out the strategic objectives of the company as it relates to current and new businesses. For example, it may be a part of the corporate strategy to manage certain businesses for strong, positive cash flow. Others may be managed for growth. These strategic objectives will have an effect on the allocation of scientific resources and the kind of resources that will be placed behind the product lines in relation to the strategy.

Research and development essentially works on a cycle of at least three to five years. Marketing, on the other hand, tends to work on shorter range cycles of a year or so. In the absence of a clearly articulated corporate strategy, there may be frequent changes in direction growing out of the difference in the length of these cycles. Changes in direction cause much wasted effort in research and development and are very expensive. They are expensive in terms of the expenditures for the effort which is lost, the reduced productivity of the research organization, and its adverse impact on morale of the research team.

Technical Input

I feel it is very important to have strong technical input into strategic planning. One aspect of this is a technical evaluation of the vulnerability of current businesses. We are in a period of increasing energy costs, environmental concerns, changing consumer interests, etc. It is important to analyze the impact of these factors on the vulnerability of current businesses. Also, it is important in the strategic planning process to recognize opportunities for growth or new business development which may be based upon developing technology. Likewise, the potential influence of questions of product or process safety needs to enter into the planning process, and the tactical approach that should be used to resolve these issues and avoid surprises must be considered.

Another method of making more effective use of scientific resources is through increasing the technical input into the ongoing operations area of the company. It is important that we continue to develop more effective systems of quality assurance, of product and process safety, and uniform product quality. There is a great need for expanded interaction between operations and research and development. I feel many opportunities exist for interchange of personnel between research and development and operations. In some instances this may

take the form of only temporary assignments of one to two years in order that research and development personnel actually get operations experience. In other instances people with a year or two of experience in research and development may move into operations where their technology can be important in implementing more effective product and process quality and safety procedures and assure compliance with government regulations.

Certainly an important aspect of improving the utilization of scientific resources is to make sure there is continued interaction with marketing and operations areas of the company to ensure appropriate program reviews. Progress on projects, meeting of schedules, reviewing of priorities and developing problem areas need to be discussed and issues resolved. Priorities need periodic re-examination. The progress on projects needs to be measured and, if it appears that efforts are being nonproductive, consideration should be given to alternative approaches or project termination. Nonproductive projects, or projects for which there is no longer management interest due to a changing set of conditions, should be discontinued early. The continuation of nonproductive efforts is expensive but, most important, it is also very hard on the morale of technical personnel.

It is important that there be research and development involvement in the review of labeling and advertising for technical accuracy. Our labeling copy and other consumer communications must convey technically accurate information to consumers.

Another important area for involvement of the scientific team is in communicating with management on the scientific basis of key issues of current or pending regulation and/or legislation. Key scientific people must be aware of what is going on and make recommendations to management on the basis of the state of technical knowledge. With this input, the company's management can make better informed decisions on these issues.

Some Key Attributes of the Scientific Team

The leading attribute of the scientific team must be, in my opinion, its integrity. The research and development organization must be frank in its discussions with management. It must dig to determine what are the facts, how solid is the information, what are the potential risks in the data base, what is research and development's position. Research and development must make a critical evaluation of its own work. Communications with management must be frank and open, as

management must make sure that it is dealing with the best scientific advice it can have in its decision making.

The scientific team must aggressively seek information and assistance in the solution of technical problems from whatever sources the information may be available. It is important to avoid the NIH (not invented here) syndrome. Management has the right to expect that the research and development organization is aggressively seeking to obtain solid information and making sound technical recommendations.

Another important attribute for the scientific team is diversity in the strengths in its scientific disciplines. It is essential to have a scientific team that is composed of highly qualified people from many scientific disciplines so that their expertise can be brought to bear on the complex problems we are facing today. People should be highly qualified in their disciplines and yet their work should be adequately integrated so that the resources of experts in the various disciplines can be directed to the solution of key problems. It is important for the research and development management not to be bound by organizational constraints in the use of these resources. There is a need for flexibility in the management of these resources so that the necessary talent from whatever available source can be involved in the solution of key problems. This may be accomplished through the use of task forces, project teams or other innovative organizational approaches which permit bringing the necessary talent to bear on an issue. Frequently, the use of these organizational approaches which cut across traditional organizational lines provides challenges for scientists within the organization and provides them an opportunity to show their capability of managing resources in the solution of problems.

Ability to Integrate Information

What I consider to be a very key trait possessed by the most productive research personnel is the ability to integrate information from a wide variety of sources in the solution of problems. Scientists must be trained well in the discipline which is basic to their areas of specialization. However, at the same time, their thinking must be sufficiently broad so they are able to gather information from a wide variety of sources and appropriately integrate it into the solution of problems. I think this is an important aspect of training scientists for the industrial environment.

In the academic area, people may engage in much more narrow research interests and deal with significantly narrow areas of a prob-

lem. In the advanced graduate training of scientists, it frequently is necessary that there be specialization in a narrow part of a particular field in the development of the thesis research problem. This can result in a highly trained scientist but one of narrow interests, which may make it difficult for him to be most productive later in the industrial environment. This does not mean that we should train scientists with a very broad base of knowledge and no depth in a particular discipline, as I feel it is important that a scientist have a very strong grounding in a basic discipline. On the other hand, he must be challenged to think about integrating the fundamental information he may be developing into the functioning of the whole system. I have found that the ability to integrate is one of the key attributes of productive members of our scientific teams.

Scientific Interactions

Finally, I would like to turn to what I consider to be some of the important aspects of industry, university and governmental scientific interaction. It is important that there be strong dialogue among scientists in universities, industry and government. We look to the university scientists to put much emphasis in their research on the development of basic technology in the training of graduate students. We expect governmental scientists to be concerned with issues of safety, broad public health questions and those questions of general interest to the population which require large expenditures of money and major interdisciplinary approaches in their solution. Most university research operations and industrial operations are not equipped to be able to handle problems of this scope. It is extremely important that each area have an understanding of the needs and problems of the other.

One of the ways of accomplishing this is increasing the dialogue among the scientists of these organizations. Industry must work with legislative and regulatory people while regulatory agencies need input from industrial scientists for the evaluation of the need for—and the development of—effective regulations. While industry and regulatory agency discussions frequently generate criticism from consumerists, these discussions are really in the best interests of the consumer. Ineffective or costly regulation is certainly not in the interests of the consumer or the industry. Frequently, the best source of expertise exists in the industry, and to develop regulations without making use of this resource is equivalent to making regulations in a vacuum.

There is also a great need for dialogue between industry and the university scientists. While this often involves specific research discussions, there also needs to be discussion as it relates to other issues, such as food safety, regulatory issues, etc. Regulatory agencies frequently do not get the benefit of the scientific input from academic sources simply because scientists in the university are unaware of some of the proposed regulatory or legislative activities. University scientists are not regular readers of the *Federal Register* or other sources of information which would help to improve their awareness. They have a real challenge in keeping up with the literature in their field of interest. The three-way dialogue among industry, university and governmental scientists can be helpful, however, in assuring that the best scientific resources are brought to bear on key issues. This interchange also can be useful in helping to ensure an adequate funding base to meet the needs of universities and regulatory agencies as a better understanding is achieved concerning the areas needing research support. Industry can be helpful in supporting requests for research in key priority areas.

The entire scientific community faces many challenges today, and these will continue in the future. We face the challenge of meeting the food needs of a growing population, the rising expectations of people in developing areas, and also meeting the rising expectations in our own country as it relates to food safety, food quality, and cost/benefit relationships as perceived by the consumer. These challenges and many more that could be listed demand the best performance from all scientific resources, whether they are in industry, academia or government. It is essential that we all work together if we are to meet the common goal of assuring an adequate and safe food supply which meets the nutritional and social needs of an increasingly demanding public. **[The End]**

DETAILED PRODUCT RECALL PROCEDURES PROPOSED BY FDA

Proposed regulations defining the policy and procedures to be followed by the Food and Drug Administration (FDA) for product recalls have been issued by the Agency. The regulations describe, for the first time, the specific responsibilities of manufacturers and distributors in the conduct of recalls. As defined by the proposal, the term "recall" does not include a market withdrawal or a stock recovery. The policy makes it clear that manufacturers and distributors are expected to assume the responsibility and expense for all product recalls, including follow-up checks on their success in removing defective products from the market. The adequacy of the recalls will be monitored and assessed by the FDA.

The proposed regulations call on the companies to develop detailed contingency plans for recalls. The regulations also state that the FDA should be notified promptly when a firm removes a product from the market, that recalls should be initiated when requested by the FDA, and that reports on a recall's progress should be sent to the Agency on a regular basis. Manufacturers are asked to keep records which will enable them to trace a product's distribution, to use product coding so that a specific batch or item can be easily identified, and to follow up on recalls by finding out why a product was defective.

The proposed regulations apply to most products regulated by the FDA. However, the Medical Device Amendments of 1976 require the Agency to follow a somewhat different policy in connection with certain remedial actions involving medical devices. The regulations do not apply to electronic products subject to the Radiation Control for Health and Safety Act.

Comments on the proposal may be filed until August 30, 1976.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 45,384

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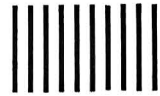

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Complying with ERISA requirements, particularly its reporting and disclos rules, is driving employee benefit plan administrators up the wall. It's imp tant. You and your plan have a lot at stake.

Compliance Guide for Plan Administrators, a new CCH Reporter, provi all-explanatory treatment focused on ERISA reporting and disclosure requirem to help plan administrators comply.

See Inside for More Details . . .