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Food Drug Cosmetic Law JOURNAL

Additional Papers Presented at the Food Drug Law Institute's Pharmaceutical Update IV

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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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Use of FDA Advisory Committees: Present and Future

By PHILIP G. WALTERS

Dr. Walters Is the Special Assistant to the Director, Office of Scientific Evaluation, Bureau of Drugs, Food and Drug Administration.

OVER THE PAST SEVERAL YEARS the responsibilities of the Food and Drug Administration (FDA) have markedly increased. Along with this increase of responsibility has come an expansion of scientific data with which the FDA must deal. Also, the FDA is even more frequently asked to increase the involvement of the sciences, the professions, and the public in our fact-finding and decision-making processes. Consumer groups, private medical practitioners, professional organizations and scientific societies are examples of those who are requesting such involvement. To enable us to make the best possible judgments, we have and will continue to use advisory committees to provide us with information, interpretation and advice which will supplement such information that is generated internally. The important point here is that we use our advisory committees in addition to, and not in lieu of, our in-house professional and paraprofessional reviewing staffs. We believe that the use of expert advisory committees materially expand and broaden knowledge and decision making in those important areas for which we are responsible. This is not in any way intended to deprecate the capabilities of our in-house personnel. Rather, it is to emphasize that

our mission is exceptionally broad and our informational needs are exceptionally diverse, beyond the total scientific grasp of even an expanded roster of employees.

Advantages of the Use of Advisory Committees

Recently, the Commissioner of Food and Drugs outlined for the House Committee on Government Operations, Subcommittee on Intergovernmental Relations the advantages of the use of advisory committees both to FDA as well as to the public. I would like to share those thoughts with you. I quote:

> "(1) The Agency gains access to highest levels of scholarship in the scientific community and in federal agencies other than the FDA. Professional, trade, and consumer organizations are urged to suggest qualified experts conversant with the distinctive requirements, usages, problems, and sensitivities recognized by these dissimilar groups. State-of-the-art knowledge is contributed by individuals engaged in research or clinical practice.
>
> "(2) Regulatory decisions are recognized by affected parties as having the backing of leaders in the medical, academic, and scientific communities, all of whom are visible and accountable.
>
> "(3) Participation by the scientific community improves the credibility and acceptability of Agency decisions because the public recognizes that professional competence and balanced considerations are paramount in the formulation of public policy.
>
> "(4) In areas where the Agency lacks intramural competence to deal with a matter in a definitive fashion, participation of selected technical committees or panels permits a prompt and responsive effort.
>
> "(5) The rotational nature of committee memberships promotes the availability of individuals who are in the forefront of their fields.
>
> "(6) Exposure of consultants and committee members to the Agency's deliberation and problems promotes a desirable dissemination of information which might otherwise be confined to official circles. Moreover, there is ample evidence that broadened awareness of Agency approaches and areas of interest promote understanding in the general scientific community and the de-

velopments of research proposals directed toward Agency requirements.

"(7) The incorporation of advisory committees into the review process aids decision making by providing a formal setting for comprehensive review of data, scientific discussion, and resolution of problems."

In appointing members to advisory committees every effort is made to obtain a balanced membership. We try to have representatives from various scientific and medical disciplines comprising a broad range of interests. As safeguards against conflict of interest, committee members are required to disclose any connections with the regulated industry including involvements with Investigational New Drugs (INDs) and New Drug Applications (NDAs).

Review Process of INDs and NDAs

The Bureau of Drugs is currently in the process of updating, revising, and streamlining its review process of INDs and NDAs. Part of this process has involved a very recent realignment of some of the professional and support personnel within the Bureau's Office of Scientific Evaluation (OSE) in order to establish, within each of the six reviewing divisions, drug-class review groups. All INDs and NDAs are being reclassified into these same drug-class groups (cardiac drugs, gastrointestinal drugs, anti-infectives, dermatology, anti-inflammatory drugs and so on). This rearrangement will establish some seventeen such drug-class groups, each with its own INDs and NDAs, plus its own advisory committee and consultants. We feel this system of handling INDs and NDAs by the drug-class concept will provide a more effective, as well as a more efficient method of processing these important new drug documents. It will also provide our own staff with a much more comprehensive view of those drugs for which they have been given review responsibility.

Closely tied in with this internal rejuvenating of IND/NDA reviewing is an expansion of the use of advisory committees in the actual review process. Specifically, these committees are to be engaged in the review of study protocols during a drug's investigational phases, as well as during the collection of ensuing data. They will then advise FDA as to whether these protocols are well designed and whether the resultant data collected are adequate to demonstrate safety and efficacy for the drugs under consideration.

Currently there are 15 active advisory committees plus three additional committees which are in the process of being established. This is not a new function for FDA advisory committees but rather represents an expansion of this review role. To accomplish this expanded role it is proposed that when an IND or NDA is identified as having met one or more of the criteria set forth by the Bureau of Drugs, an advisory committe member will be designated to work closely with the division's own review team (composed of a medical officer, a pharmacologist, a chemist, and often a biostatistician) from that point on until such time that a final recommendation can be made to the Bureau Director as to the ultimate regulatory course of action. Should the designated committee member's term of appointment expire during the review phases, he or she can be appointed as a review expert and thereby continue to be available to the Bureau on an ad hoc basis for an indefinite period of time. This will allow for continuity of this team review approach not only through a new drug's premarketing phases of investigation but also through any additional postmarketing studies which may be conducted.

Criteria for Committee Involvement

The criteria to be used in deciding specifically which INDs will require advisory committee involvement are:

(1) Those chosen for formal conferences during investigational development

(a) Important therapeutic advance (safety or efficacy)

(b) Novel and improved method for drug delivery

(c) Potential or apparent significant safety hazard

(2) Those requiring termination of studies because of safety problems

(3) Any others in which the committee is interested

The criteria to be used in deciding specifically which NDAs will require advisory committee involvement are:

(1) Significant new drugs

(2) Significant new uses for marketed drugs

(3) Narrow benefit/risk ratio

(4) Controversial efficacy

(5) Those needing or under consideration for Phase IV studies

(6) All drugs the subject of "end of Phase II" conferences

(7) Drugs to be withdrawn from the market because of safety or questionable efficacy

(8) Any others in which the committee is interested

Time frames will be involved in coordinating the review activities of the in-house review team and the individual reviewing committee member.

Admittedly, this increased advisory committee involvement in the review process will cause a parallel increase in the workload of the division's reviewing personnel; however, we feel the advice obtained from the medical and scientific community, as represented by our committee members, can only strengthen the weight of FDA's regulatory decisions. In addition, this expanded role will not only provide FDA reviewing personnel with a much broader basis for decision making but will also provide committee members with increased insights into the scope of new drug development in their particular interest areas. This will tend to assure continuing improvement of the quality of investigational work being conducted in the United States and will encourage the increased openness of the FDA's decision-making process. **[The End]**

ONE UNSAFE INGREDIENT SUFFICIENT FOR SEIZURE OF COMBINATION DRUG

Even if the statement in the District Court's opinion that "the safety and efficacy of combination drugs such as Afrodex cannot be equated with the safety of the components separately or in combination with different ingredients" was erroneous, the error was not grounds for reversal of the finding that Afrodex was not grandfathered and was, therefore, a new drug subject to seizure for lack of an approved new drug application, according to the U. S. Court of Appeals for the Fifth Circuit. The finding that at least one of the individual ingredients of the drug was not and never had been recognized as safe for use in circumstances indicated by its labeling was sufficient to uphold the lower court's decision.

U. S. v. 1,048,000 Capsules, More or Less, Labeled in Part: "Afrodex," etc., CA-5, CCH FOOD DRUG COSMETIC LAW REPORTER

Advisory Committees: An Expanding Concept in the Field of Drug Regulation

The Perspective of a Liaison Representative

By JOSEPH L. KANIG

Dr. Kanig Is Scientific Consultant for The Proprietary Association in Washington, D. C.

I AM SOMEWHAT PLEASED to have been designated to be the last speaker this afternoon. The previous speakers have already presented the major aspects of the advent of advisory committees to the Food and Drug Administration (FDA). Each, in presenting his perspective, has touched on the problems associated with the selection, orientation, and utilization of advisory committees.

With these presentations as a background, I have been asked to comment on the same areas, but from the vantage point of a participant in the deliberations conducted by a specific group of advisory panels to the FDA. Until quite recently, such a vantage point was a near impossibility and I am pleased to offer some of my own insights concerning the advisory process that may serve to augment the excellent presentations by my colleagues in this forum.

As you know, I am currently serving as a Scientific Consultant to The Proprietary Association (PA), and in this capacity I have been nominated by the PA to the Commissioner of the FDA to serve as the Industry Liaison on four of the ongoing Over-the-Counter

(OTC) Drug Review Panels. It is necessary, at this point, for me to explicitly inform you that in presenting my views on such Panels I do so as an individual and not as a representative of The Proprietary Association, the pharmaceutical industry, or any individual company. I am deeply aware of the sensitive nature of my work with these Panels and in no way do I wish to jeopardize the good relationships I have established with them over the past year and a half. I am equally cognizant of the delicate balance I must maintain in serving as the interface between industry and the Panels. It is for these reasons that I must underscore the fact that my remarks here this afternoon are based on my personal evaluation of my experiences in this capacity and represent my very own points of view.

The OTC Drug Review

You have heard that some of the problems inherent in the present system of convening advisory committees stem from the restrictions contained in the Federal Advisory Committee Act of 1972 and from the statutory interpretations. The fine legal points and the delicate questions of interpretation arising from the Act were most ably elucidated by Mr. Hickman earlier in this program. These, and other problems, were brought into focus by the other speakers from different points of view. I believe that I can offer some additional insights into these problems by first presenting an overview of the advisory system I am most familiar with, and then by giving you my personal views on the pros and cons of the real world of advisory panel operations.

The current OTC review process has been in progress for over two years. It was created to establish, in FDA's view, those drugs that are generally considered to be safe and effective and thus resolve one area of difference between industry and the FDA as to what is and what is not a new drug.

Classification of OTC Drugs & Panels

To accomplish this task, the FDA has divided all OTC products into twenty-four categories and has convened seventeen Panels of experts for the express purpose of evaluating the safety, effectiveness and labeling of all nonprescription drugs. The Panels have been asked to make judgments concerning ingredients, formulations, dosages, and

all aspects of labeling for OTC drugs. In addition, as part of their report to the Commissioner, each Panel will prepare a monograph on each class of drugs which will be used as standards for future regulatory purposes. The innovative genius of this type of review is that the category-by-category approach makes an entire field manageable at one time.

Composition of Panels

Each Panel consists of seven voting members and three, or more, nonvoting members. The nonvoting members are: an FDA representative who bears the title of Executive Secretary; one Consumer Liaison nominated by one of the consumer organizations; and, generally, one Industry Liaison. In certain instances, there may be more than one Industry Liaison appointed to a Panel when different segments of the industry (e.g., proprietary, cosmetic, dietary supplements, vitamins, etc.) express a need for specific representation on a Panel. Nonvoting members may participate in all deliberations of the Panel except executive sessions, and receive all materials distributed to the Panel with the exception of confidential industry submissions.

The voting members include a pharmacist (who is usually a pharmacologist, hospital or clinical pharmacist), and medical academicians, clinical pharmacologists, general practitioners, or experts in some area of research associated with the class of drugs under review by that Panel. Voting members are selected from lists of nominations received by FDA from a wide spectrum of organizations and individuals and from the FDA's own lists of experts.

In addition to the voting and nonvoting members of each Panel, the FDA staff members who are present at meetings include the Panel Administrator, a Drug Information Analyst, and on a part-time basis, FDA personnel such as the Director of the OTC Drug Review Staff, and those who may sit in as observers on a "need-to-know" basis.

Orientation of Panels

The first meeting of each Panel is an orientation session in which the Commissioner (or his representative), the General Counsel, the Director of the OTC Review Staff and/or other FDA officials brief the Panelists on their mandate, responsibilities, objectives, regulations, restric-

tions, and other pertinent operational parameters under which they will conduct the review.

Quite understandably, the first few subsequent meetings of the Panel must serve as an extension of the orientation meeting. The Chairman strives to grasp the dimensions of the total effort involved and, with Panel concurrence, attempts to design the mechanics of the assignments, reviews, reports, discussions, and the decision-making apparatus that must be evolved before the Panel may function effectively. In some instances this may be a rapid process, but in others it may take as many as three or four meetings before the Panel settles down to the business of the review with a better understanding of the total operation and the mechanics required in applying a uniform philosophy of evaluation to the drugs involved.

Within the overall framework of the FDA regulations for the OTC review there is room for appropriate flexibility. It is interesting to observe how various Panels develop and utilize that flexibility in identifying and formulating applicable criteria for their work. It is equally interesting to observe how each Panel develops its own personality as a group; one which often plays a large role in how the Panel conducts its business.

One of the criticisms leveled against the advisory panel system is that such groups of experts are often ill-informed concerning the regulatory objectives. They are accused of being too immersed in the academic pursuits underlying their field of expertise and thus unable to grasp the total dimensions of the real world that is being evaluated for regulatory purposes.

In many instances a Panel may begin to wander away from its mandate due to individual bias, inadequate expertise, or preconceived personal philosophies that are outside the required scientific parameters. The FDA is apparently aware of this problem because it has made efforts to direct the Panelists' attention to the nature of the problems and objectives, and to provide guidance to help keep the Panel on course during its deliberations.

Role of the Liaison Members

The Industry and Consumer Liaison members are expected to report to their constituencies in any manner they choose to keep

them informed as to the nature and content of discussions in both open and closed sessions of each Panel. Releasable decisions of the Panels are reported to interested parties as soon as possible after each meeting for the express purpose of eliciting responses, additional data, queries as to interpretations of Panel conclusions, and any legitimate reaction that anyone may wish to give concerning the activities of the Panel.

Panels generally label their decisions as "tentative" until they have had the opportunity to consider feedback from industry or consumer groups. The tentative decisions usually remain so designated until the Panel writes its final report to the Commissioner. This, in effect, provides a sufficient period within which interested parties may generate a suitable response, or to submit additional data for Panel review. In this respect, the liaison members serve one of their most useful functions which, it seems to me, is unparalleled in the history of advisory committees to federal agencies.

Obviously, the role of the Industry Liaison on these Panels does not provide for him to represent any particular company or product. Instead, his participation in Panel discussions is geared to remain on a level that is industry wide. This, however, does not preclude him from providing detailed information to companies as to the Panel's thinking, nor does it preclude him from giving advice on how an individual company might best respond to a situation as it evolves. It also does not prevent him from indicating the different mechanisms for such a response that are available to industry in assisting the Panel.

Without revealing "who said what" at any meeting, the Industry Liaison can nevertheless make available all through the course of the review the trends of the evaluatory process and thus serve to initiate feedback data from industry that has often been helpful to the panelists as they pursue their responsibilities. By the same token, the liaison members are often used as sounding boards by the Panels who solicit their opinions, invite them to contribute of their expertise, or request that they employ their contacts with their respective constituents to provide the Panel with additional data or reactions to tentative proposals. I know of no other advisory system where the regulated industry has such ongoing access to the deliberations and decision-making apparatus of the advisory group.

Pros and Cons of the Advisory Panel System

Without attempting to editorialize, I should now like to present a summary of some of the major criticisms that have been expressed concerning the advisory panels. These include:

(1) Incomplete or inadequate guidance from FDA regarding regulations, agency philosophies, or the practicalities of the situation under review.

(2) Inadequate explanations of the language employed in existing regulations that underlie the advisory process.

(3) Failure to urge the Panels to consider the "track record" of consumer experiences with a drug in addition to controlled scientific evidence, or in lieu of it in cases of very old drugs.

(4) Failure to stress the necessity of establishing standards of proof for old drugs as contrasted to more modern OTC drugs.

(5) Loss of specialized expertise due to FDA efforts to avoid conflict of interest situations.

(6) Tendency on the part of experts to demand more and more detailed clinical studies to assist them in making decisions on the effectiveness of drugs.

(7) Insistence by experts on objective evidence of effectiveness when it is most difficult to apply modern scientific methods in seeking such evidence of relief of largely subjective symptoms.

Not all the criticism may be laid at the doorstep of the FDA. Industry can be faulted as well. For example:

(1) Sometimes, the quality and contents of the submissions are not up to the quality one would expect.

(2) Industry tends to become a little apprehensive of what it considers to be hardline tentative conclusions and thus, companies are often too slow or not sufficiently alert to respond to the various opportunities for input into this flexible review. These opportunities include submission of supplemental data, appearances of industry scientists and medical personnel before open sessions of the Panels, or presentations to the Panel by outside consultants.

(3) Failure on the part of industry to urge Panels to review prescription drugs for possible OTC use when the FDA has

informed all Panels that the Panels have the right to make such recommendations.

I see no great cause for alarm in any of these criticisms mainly because the advisory panel system has already demonstrated that, despite some shortcomings, it is basically sound and flexible, and is designed to provide for the widest possible review of information and views.

It has been said that the OTC Drug Review is the most open advisory process in the history of the Food and Drug Administration. I quite agree. In my view, OTC Review Panels are hardworking and conscientious and have repeatedly demonstrated that they keep an open mind and welcome valid input. Never before has the composition of the Panels, the format of their operation, and the decisions they reach, been so widely disseminated to all interested parties. By virtue of the presence of the liaison members and their reports to their constituents, the consumer and the industry that is being regulated have had the opportunity of almost continuous input into the deliberative process. Despite the problems associated with attempts to obtain the best possible expertise under the restrictions that operate against this goal, the openness of the review, together with the effect of group dynamics and peer pressures within each Panel, make this review one of the best ever undertaken by the Food and Drug Administration.

Conclusion

It is fairly obvious that my remarks stem only from my experiences with the OTC Drug Review. While this is true, it should be noted that Commissioner Schmidt has recently expressed his intention to pattern future advisory committees after those in the OTC Drug Review, and to continue to maintain a format for such committees that provides for input from consumer and industry representation on the Panels.

My personal views applaud these intentions of the Commissioner and I must conclude that if the OTC Drug Review, despite its admitted shortcomings, becomes the pattern for improved future advisory groups, then industry, government and consumers will all benefit from a system that will provide the most open and effective evaluatory forum we have ever experienced. **[The End]**

Medical Device Legislation

By DAVID E. COLLINS

Mr. Collins Is Secretary and Associate General Counsel for Johnson and Johnson.

THE CURRENTLY PROPOSED medical device legislation and its impact on the testing, manufacture and sale of medical device and diagnostic products is our subject matter today. A detailed outline of the current important legislative proposals, and a description of the activities and projects that are presently under way in anticipation of the enactment will be presented. This latter subject—the ongoing programs preparing for the new legislation—is particularly interesting and important. For, in a unique way, much of the pattern of regulatory implementation of this legislation is being woven in advance of enactment, and these current projects are having an important effect on them. Each of our speakers this morning is deeply involved in these activities. They will cover the four major new areas of control envisioned by the legislation—mandatory performance standards; scientific review or premarket clearance; defect notification and its consequences; and the so-called general control category. In addition, we have added a topic of special but quite current interest—the impact on in vitro diagnostic products—already the subject of a comprehensive Food and Drug Administration (FDA) regulatory scheme centering around performance standards and labeling. In our discussions, we will be referring to S. 2368, in the form passed by the Senate in January, 1974.

In so doing, we will attempt to point up the most difficult and controversial aspects of S. 2368 in order to show you the areas of this legislation receiving the most attention by the house. During the question and answer period, Rod Munsey will update all of us on the current status of the House's deliberations and the prognosis for passage this term.

Evolution

The legislation we are considering—S. 2368, and its companion measure H. R. 9984—were introduced in the late summer of 1973 by Senator Ted Kennedy and Representative Paul Rogers. Their origin however lies in the 1970 report of the so-called "Cooper" Committee, a select government committee, headed by the National Institute of Health's (NIH) Doctor Theodore Cooper, assigned the task of studying the need for new medical device legislation. This committee recognized the essential differences between drugs and devices and recommended new legislation carefully molded to the unique characteristics of these products. The principal thrust of the Cooper Committee Report was that governmental premarket clearance a la the new drug provisions of the Food, Drug and Cosmetic (FD & C) Act should not be the predominant regulatory instrument for medical devices as it is for drugs. Rather primary emphasis should be placed on mandatory standards as a means of insuring safety, reliability and effectiveness without undue interference with product development and innovation. Premarket clearance should only be used in those high risk situations where standards would not be effective in reducing the risk. These recommendations have been the guidelines that all subsequent legislative efforts have followed until the Kennedy Bill was reported out of committee and passed by the Senate. At that time, due to the efforts of Senator Gaylord Nelson, the preclearance authority of the Secretary was greatly expanded, as Rod Munsey will point out later.

At about the time of the Cooper Committee deliberations, a group of trade and professional associations interested in the device and diagnostic field gathered together to form the Interassociation Ad Hoc Committee on Devices. Twelve to fifteen associations belong to this ad hoc group and they have been meeting and working on device legislation and related matters ever since.

It took a while for the Cooper Committee Report to be acted on, but in December of 1971, the Nixon Administration introduced H. R. 12316, patterned after the Cooper Committee recommendations. To my knowledge, this represented the first considered attempt to propose a regulatory scheme for devices which recognized and was adapted to the unique characteristics of these products and this

industry and not merely patterned after drug regulation. This Bill, reintroduced in the 93rd Congress as H. R. 6073, was the foundation used by Kennedy/Rogers in constructing their proposals. The Senate has passed Mr. Kennedy's revised version of his Bill, and hearings have been held by Congressman Rogers' subcommittee in the House. However, no subcommittee markup has been made as yet.

General Structure of Legislation

That's where we are today. Let us turn now to S. 2368 and examine its general structure. It is, in form, an amendment to the current FD & C Act, but don't let that deceive you. It is without question a brand new and comprehensive regulatory scheme governing the development, testing, manufacture, promotion and sale, and post sale aspects, of medical devices and diagnostics. It is in many important aspects quite different in form and in philosophy from the provisions governing drugs, and, testifying to the fact that regulators learn from experience, it is more comprehensive in its approach than were the drug amendments of 1962.

As new legislation, the appropriate starting point for understanding is its new definition of "device." This is found in Section 706 very near to the end of the bill and is designed to resolve the seemingly endless question whether a product is a device or a drug. Despite the fact that the definition reads superficially like the drug definition, the intent has been to make the two mutually exclusive. The heart of the new device definition is the requirement that in order to be a device a product must not achieve any of its "principal intended purposes through chemical action within or on the body" and further must not be "dependent upon being metabolized for the achievement of any of its principal intended purposes." It is the hope that these companion phenomena, both measurable objectively, will resolve the drug v. device question.

Premarket and Postmarket Controls

A further aid to understanding lies in the contrast between this proposal and existing law. As you all know, the current FD & C Act limits FDA's regulatory authority in the device and nondrug diagnostic field to actions after the initial marketing of a new product.

The major requirements are directed to adulteration and misbranding. In contrast, the new legislation imposes extensive and varied forms of pre-new-product-marketing controls coupled with a broadening of the Agency's post-new-product-marketing authority. Premarketing controls are found principally in the premarket clearance or scientific review section, in the mandatory performance standard section and in the substantive Good Manufacturing Practice (GMP) authority. Major additional postmarketing controls are found in the defect notification and related provisions, records and reports requirements, the authority to ban unreasonably risky or deceptive products, and the controls over prescription device advertising. Our panel will touch on each of these in greater detail later. For now, it suffices to focus on the void-filling characteristic of this bill.

Another focus which is important for understanding also represents the major difference between this regulatory scheme and that currently applicable to drugs. Under this legislation, the final decision on whether a product is to be regulated by standards or premarket clearance lies specifically and clearly with the Secretary. There is no issue here, as in the drug field, whether the manufacturer has a co-equal right of determination, with the final decision lying with the courts. The final decision under this legislation lies with the Secretary, and the court's function is one of review to determine if he has decided in accordance with the statutorily established criteria. The other side of this coin is also important. Almost without exception, this legislation is not self executing. The applicability of its major provisions will await the Secretary's implementing activity. More on that later.

Product Classification

The legislation, once passed, will apply its preclearance and performance standard requirements to existing products as well as new ones. Therefore, following the recommendation of the Cooper Committee, S. 2368 provides that expert panels will review all products now on the market and will recommend or classify them as requiring scientific review, performance standards, or merely the so-called general controls. These panels are to be appointed by the Secretary and are given one year to complete their assignments. The panels are to be organized according to the various medical specialities. Each

panel is to have a nonvoting representative of consumer and of industry interests. The panels are to report their recommendations to the Secretary who will make the final decision.

As far as new products being developed after the panels have concluded their initial task, S. 2368 requires the manufacturer of such a product, if it has not already been classified as a part of a broader class of products, to obtain such a classification from the Secretary. The expert panels will remain in existence to assist in this task.

For manufacturers, the crucial question in this classification process is what criteria will be used by the panels in recommending scientific review or mandatory standards. Don Stone and Rod Munsey will touch on this later, but I should like to note that it is on this specific point that S. 2368 departed from the Cooper Committee concept. For it provides in new Section 511(c)(1)(B) that the panels must classify a product in the preclearance category if it is life sustaining or life supporting regardless of whether mandatory performance standards could be effective in regulating the product. This requirement greatly expands the number and kinds of products to be subjected to preclearance.

Effective Dates

Before turning this over to Don Stone, let me touch briefly on one implication of the effectivity provisions of this legislation. As I mentioned, virtually none of it is self executing. The Secretary is required to act before its major new provisions come into force. Each of our panelists will detail for you the time elements involved. The point I wish to make here is that FDA, realizing the tremendous amount of work that has to be done to get this machine started, has already begun without awaiting passage. Thus, they already have expert panels considering the classification of devices; they have already let contracts for the development of product performance standards; they already are working on good manufacturing practice proposals for devices and diagnostics; they already are hiring people and drafting regulations. In short, the engine has started and in my view it is incumbent on industry and the medical and dental professions to hop aboard. For only in that way can we participate in steering the project.

[The End]

Regulation Through Product Standards

By DONALD R. STONE

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WHEN THE MEDICAL DEVICE AMENDMENTS to the Food, Drug and Cosmetic Act become law, it is generally expected that most medical devices will be regulated by product performance standards. Several legislative proposals have been introduced to the 93rd Congress. The bills receiving principal attention were S. 2368, authored by Senator Edward Kennedy (Mass.) and H. R. 9984, authored by Representative Paul Rogers (Fla.). Hearings have been held in both the House and Senate in which views were presented by members of industry, the professions, consumer organizations, and the Administration. As a result of those hearings, substantial amendments were made in the originally proposed language of S. 2368. The amended bill was reported out of the committee and passed the Senate on February 1, 1974. At present, the House has not yet held a markup session.

Performance Standards

Senate Bill 2368, as it passed the Senate, contains strong emphasis on performance standards. That emphasis was added during the markup session as were other changes described below, apparently in response to many comments made during the hearings. The criteria for the initiation of the standard-making process were changed to indicate that standards would be preferred as the method of regulation when other means might not be appropriate to reduce or eliminate the product risks. A "conflict of interest" provision was also added,

requiring any person or organization proposing to write standards for the Food and Drug Administration (FDA) to disclose any proprietary interest in the device subject to the standard. The provision also requires that, in most cases, persons or organizations with no proprietary interest be granted preference in the awarding of contracts for establishment of standards.

"Banned Device" Provision

A "banned device" provision was also inserted. That provision was intended to provide a simple means of eliminating quack devices without requiring many legitimate devices to be regulated through scientific review. A final major change in the standards section of the bill, as it passed the Senate, was to provide a provision for expedited amendment of existing standards. That provision would allow product improvements to be implemented on an interim basis while the normal process for amending standards runs its course.

I believe that an effective way to understand the mandatory standard-making provisions of the Medical Device Amendments is to proceed step by step through the process required to establish, then amend or revoke, a mandatory standard. In the description of that process, the text referred to will be that of S. 2368 as it passed the Senate on February 1, 1974.

Classification of a Device

While the standard-setting section becomes effective immediately upon passage of the bill, no mandatory standard-setting activity can be undertaken by the Food and Drug Administration until the appropriate classification panel has completed its work and preliminarily classified a device as appropriate for regulation through product standards. To so classify a device, the panel must decide that performance standards will assure effectiveness, or reduce or eliminate unreasonable risk of illness or injury and that other means may not be appropriate to reduce or eliminate that risk.[1] The preliminary classification will be published in the *Federal Register*.[2] After the panel has decided that a particular device can be regulated by product performance

[1] S. 2368, 93d Congress, 2d Session, Sec. 101, § 511(c)(2)(1974).

[2] S. 2368, 93d Congress, 2d Session, Sec. 201, § 511(d)(1974).

standards, the Food and Drug Administration is required to consult with federal standard-setting agencies and with voluntary standard-setting agencies before initiating a formal standard-making procedure. The FDA is encouraged, when contemplating initiation of standard-setting activities, to invite participation of informed persons in the scientific, professional, industry, and consumer organizations through workshops, conferences, and other similar means.

Findings Published

After FDA has consulted with the appropriate agencies and organizations, it can initiate a standards proceeding by publishing a notice in the *Federal Register*. That notice must contain a description of the device, the nature of the risks to be controlled, a summary of the data supporting the need for a standard, an identification of any existing standards known to FDA, and an invitation to either submit existing standards or an offer to develop a standard within 180 days after the publication of the notice.[3] The 180-day time period may be changed if FDA finds that a different period is appropriate. FDA must provide a comment period after publication of the notice initiating the standards proceeding. During the comment period, all interested parties may file comments on the need to initiate a standard-making proceeding. The bill does not specify any particular time period within which such comments must be received.

After receiving comments, together with proposed standards and/or proposals to develop standards, FDA is required to make and publish findings on the need for a performance standard before it can proceed with development or adoption of such a standard.[4] The findings must take into consideration the degree of risk of illness or injury, the approximate number of devices to be covered by the standard, the benefit to the public to be achieved, and the probable effect of the standard upon the utility, cost, or availability of the devices. The findings must also explore ways in which FDA's objectives may be achieved with minimal disruption of competition and of manufacturing practices and must take into account any data and comments submitted pursuant to the notice of the initiation of the proceeding. The findings on the need for the establishment of a standard

[3] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(c)(1)(1974).

[4] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(c)(2)(1974).

are appealable to the courts within 30 days after publication.[5] The appeal process is the same as that followed upon issuance of a final order promulgating, amending, or revoking a standard. Once the Food and Drug Administration has published its findings that a standard is needed, it can proceed with the establishment of mandatory performance standards. Such performance standards must relate to safety and effectiveness, including effectiveness over time. They can include, when necessary, standards relating to composition, construction, compatibility with power systems and connections, properties, and uniform identification of the device. A standard will include test methods for determining compliance with the standard. It can also require standardized labeling instructions and warnings for proper installation, maintenance, operation, and use. A standard may include a requirement for individual lot testing, either by FDA or under its direction, when it is determined that no other more practical means are available.[6] If the product will be used by a physician or other specially trained person, such use will be taken into account when determining device safety and effectiveness and the degree of standardization necessary.[7]

Development of a Standard

The Food and Drug Administration has three options in establishing mandatory performance standards. First, it may adopt existing standards;[8] second, it may accept an offer of a third party to develop a standard;[9] or third, FDA itself may develop the standard.[10] If FDA decides that an existing standard may be an acceptable performance standard, it can immediately publish that standard in the *Federal Register* as the proposed standard. FDA is not, however, required to accept an existing standard even if it determines that the standard would be acceptable. Instead, it may decide to accept the offer to develop a proposed standard. Before an offer can be accepted, FDA must find that the offeror is competent to undertake and complete development of the standard within the time period specified in the

[5] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(c)(3)(1974).
[6] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(a)(1)(1974).
[7] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(a)(4)(1974).
[8] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(b)(1974).
[9] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(e)(1974).
[10] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(f)(1974).

original notice initiating the standard-making proceeding.[11] Anyone offering to develop a standard for FDA must disclose certain specified information concerning potential conflicts of interest. FDA must take into account the offeror's proprietary interest in the device for which the standard is to be developed and, whenever practical, it must give priority to offerors who have no such interest. The name and address of the person whose offer is accepted together with a summary of the terms of the offer must be published in the *Federal Register*.[12] FDA can fund the development of the standard when accepting such an offer.[13] FDA may itself develop standards if no one accepts its offer to develop a standard, or if it refuses to accept any offers to develop the standard (for whatever reason), or if FDA has accepted an offer but later determines that the contractor is either unwilling or unable to continue the development of the standard.[14]

Advisory Committee Established

Once a proposed standard is developed, it must be published by FDA before it can become mandatory. However, either before or after publication of the proposed standard, it may be referred to an advisory committee of experts for a report and recommendation on any matter which requires the exercise of scientific judgment.[15] The advisory committee of experts will be appointed by FDA and can be the panel of experts which originally classified the device, or which is acting as the standing advisory panel to review applications for scientific review. If a request is made by any interested person within the comment time after publication of the proposed standard, referral to the advisory committee is mandatory. Once a proposal has been referred to the advisory committee, any interested person has the right to consult with the committee, and the committee is authorized to consult with any person concerning the matter referred to it.

FDA Issues Final Order

FDA is required, within one year after the time set for the submission of existing standards or for the development of a new stan-

[11] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(e)(1)(1974).
[12] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(e)(2)(1974).
[13] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(e) (3) (1974).
[14] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(f)(1974).
[15] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(h)(1)(1974).

card, to either promulgate a proposed standard or terminate the proceeding.[16] If FDA chooses to promulgate a proposed standard, it must allow a comment period of 60-90 days after publication of the proposal. As stated above, any time during that comment period, any interested person can request referral of the proposal to the advisory committee for review of scientific matters. After close of the comment period, FDA has up to 90 days to review the comments and must then issue a final order.[17] The final order may either promulgate the proposed standard as a final performance standard, propose an amended standard, or terminate the proceedings. If the proposed standard is promulgated as a final standard, either unchanged or with minor modifications, the order must contain the reasons for adoption and must define an effective date which is not less than 30 days after the promulgation date. The promulgation order must also include findings that the performance standard is appropriate to ensure effectiveness or to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of the device and that other means may not be appropriate to reduce or eliminate that risk. If FDA decides to substantially amend the proposed standard, it must allow 30 days for comment after publication of the amended proposal.[18]

When FDA issues a final order promulgating a performance standard, it may, by regulation, prohibit stockpiling of devices between the promulgation date and the effective date of the standard. The anti-stockpiling provision[19] prohibits an importer or manufacturer from producing or importing the device at a significantly greater rate during the time between promulgation and the effective date of the standard than it did during a defined base period prior to the promulgation date.

FDA has the power to either amend or revoke any mandatory standard it has promulgated. Amendment of the standard may be accomplished by the FDA on its own initiative or upon the petition of any interested party.[20] Proposed amendments must be published in the *Federal Register*. The bill also contains an expedited amendment

[16] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(g)(1)(A)(1974).
[17] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(g)(1)(B)(1974).
[18] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(g)(1)(B)(1974).
[19] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(g)(6)(1974).
[20] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(g)(3)(1974).

procedure[21] under which FDA may declare an amendment effective on an interim basis after giving interested parties an opportunity for an informal hearing. The expedited amendment procedure may be used to rapidly implement desirable changes or to expeditiously reduce or eliminate hazards to the public health or safety. The expedited procedure cannot be used to prohibit the sale or interstate shipment of devices which would be permitted under the existing performance standard. FDA also must find that use of the expedited amendment procedure is in the public interest.

Senate Bill 2368 also includes a provision[22] for the granting of temporary permits to deviate from an existing performance standard. Such permits can be granted by FDA to permit the interstate shipment of devices for purposes of investigation or testing to gain data bearing on the desirability of amending the standard.

Right to Revoke a Standard

FDA has the right to revoke any performance standard, or any part of a performance standard when it finds there is no longer a need for the standard or that the standard is no longer in the public interest.[23] The proposed revocation must be published as a proposal with a summary of the reasons for FDA's determination. The proposal must also set forth the manner in which interested persons may examine data and other information relevant to that determination and the time period within which comments may be made with respect to the proposed revocation. The bill sets no specific time limit for the finalization of revocation proceedings. After considering the comments and views of interested persons, FDA must publish a final revocation order including the reasons for its action and the date upon which the revocation becomes effective.

A final order promulgating, amending, or revoking a standard, or terminating proceedings for the establishment of a standard is subject to court appeal within 30 days after its publication.[24] The appeal may be filed by petition to the Court of Appeals in the District of Columbia, or to the Court of Appeals in the district in which the

[21] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(m)(1974).

[22] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(k)(1974).

[23] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(g)(2)(1974).

[24] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(g)(5)(1974).

petitioner either resides or maintains his principal place of business. The petitioner may request the right to present additional evidence but must show good cause why the evidence was not presented to FDA previously. All such evidence (together with any rebuttal evidence) will be considered by the Food and Drug Administration. FDA's determination of the facts is conclusive if it is supported by substantial evidence. The reviewing court can either affirm the FDA's order, or set it aside either in whole or in part, *only* on the basis that the order does not comply with law. The decision of the Court of Appeals is further reviewable by the Supreme Court upon writ of certiorari or by certification.

Exemptions

Senate Bill 2368 contains several exemptions from the requirement of compliance with standards. All veterinary products are specifically exempted as are those products which are subject to scientific review (except when the approved application requires conformance to a standard).[25] Another exemption allows a single manufacturer to request the right to use the scientific review mechanism, rather than the standards mechanism, for a product that would normally be subject to a standard. However, that exemption applies only if FDA specifically approves use of the scientific review process. The final exemption is for custom devices and is severely restricted.[26] It applies only to devices ordered by physicians, or other specially qualified persons which FDA has authorized by regulation, and which have been specially ordered for individual patients. The custom device exemption may not be used as a course of conduct by a manufacturer to distribute its products; such devices must not be generally available in finished form, and may not be available through commercial channels. Unfortunately, the terms "course of conduct," "generally available in finished form" and "commercial channels" are not defined in the bill.

The standards section of S. 2368 also contains a provision allowing FDA to require testing of devices by the manufacturer to assure that they comply with applicable mandatory standards.[27] Alternatively, the manufacturer must assure FDA that the device has been

[25] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(j)(1974).

[26] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(l)(1974).

[27] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(i)(1)(1974).

manufactured under a program of quality control that is in accordance with the requirements of current Good Manufacturing Practices. Under that provision, FDA is required to review the testing and quality control programs on a continuing basis. These testing provisions, along with the authority of FDA to issue substantive regulations defining current Good Manufacturing Practices, gives FDA enormous flexibility and power in determining how devices subject to performance standards will be built and tested.

Anti-Quack Device Provision

The final important provision within the standards section covers banned devices and is intended to be an anti-quack device provision.[28] It allows FDA to ban a device from interstate commerce after consultation with the appropriate expert advisory panel and after affording an informal hearing to interested persons. FDA must find that the device presents an unreasonable risk of illness, injury, or deception and that no feasible performance standard or approved application for scientific review will protect the public from risk. After the consultation, hearing, and findings, FDA may propose a regulation declaring the device banned. FDA would also have the interim power to ban a device immediately upon publication of the proposed banning order, if it finds that the banning will expeditiously reduce or eliminate a hazard to public health and safety, or help to eradicate a fraud or gross deception of the public.[29] The interested parties must be given an opportunity for an informal hearing before the interim power is exercised. The banned device provision was added to the bill to provide FDA with a means to control fraudulent devices without requiring many legitimate devices, more properly controlled by standards or general controls, to be subjected to the scientific review process. Prior to the inclusion of this provision, FDA often argued that scientific review, or licensing, was required for all, or most, devices so that fraudulent or quack products could be kept off the market.

Amendments

Senate Bill 2368 contains conforming amendments to the misbranding and adulteration provisions of the Food, Drug and Cosmetic

[28] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(m)(1974).

[29] S. 2368, 93d Congress, 2d Session, Sec. 201, § 513(m)(2)(1974).

Act to integrate the standard-setting authority with those provisions. One amendment makes a device adulterated if it is subject to a standard, or represented as subject to a standard, and does not conform to the standard, or if it is a banned device.[30] A second conforming amendment makes a device misbranded unless its labeling bears the instructions and warnings prescribed in an applicable standard, or unless the manufacturer complies with the test standards.[31] The bill also contains a federal preemption clause which generally prohibits the states from setting standards which conflict with federal performance standards except under highly unusual circumstances.[32] However, purchases for state or local government use may specify requirements exceeding the federal standards.[33]

Current Status of Standards Activities

In anticipation of legislation, FDA has become active in several levels of voluntary standards activity. David Link, Acting Director, Bureau of Medical Devices and Diagnostic Products (BuDD), is Chairman of the Medical Device Technical Advisory Board (MDTAB) of the American National Standards Institute (ANSI). The MDTAB has responsibility for guiding the efforts of the American National Standards committees which act as consensus bodies prior to ANSI adoption of standards. One of these committees, C105 on Medical Electronics, has Robert Cangelosi, Acting Director of Medical Device Standards and Research Division, BuDD, as one of its members along with representatives of industry, users (medical) and general interest groups such as standards bodies and professional organizations; e.g., the Institute of Electrical and Electronics Engineers. These functions associated with ANSI are not standard-writing bodies, but exist for direction and review.

An American National standard must have the continual consensus of the interest groups involved. Therefore, the MDTAB and such committees as C105 help provide a consensus body and forum for periodic review. For those familiar with the adversary-type relationships common among those interests, the likelihood of consensus appears impossible. It is slow, that's certain! However, consensus is

[30] S. 2368, 93d Congress, 2d Session, Sec. 202(a)(1974).

[31] S. 2368, 93d Congress, 2d Session, Sec. 202(b)(1974).

[32] S. 2368, 93d Congress, 2d Session, Sec. 704, § 903(a)(1974).

[33] S. 2368, 93d Congress, 2d Session, Sec. 704, § 903(b)(1974).

considered to exist when no substantive objection remains. Of course, ANSI standards are voluntary, so compliance is optional. Dissidents can, in principle, do their own thing. The crunch comes when a municipality or a large institution adopts an ANSI standard as mandatory within its jurisdiction.

Actual voluntary standards writing currently takes place in several groups. The FDA is active in these as well. Representatives of the FDA have attended standards meetings of the Association for the Advancement of Medical Instrumentation (AAMI). Until his recent death, Leon DeMerre, Health Scientist Administrator of the Division of Research and Classification, was Chairman of the American Society for Testing and Materials' (ASTM's) Subcommittee D20-24, Section 03 covering plastics for medical use. This committee is developing standards for specifying such materials as well as for testing them. FDA has expressed a commitment to existing standard-writing mechanisms but is definitely not satisfied with the rate of progress. Applying both stick and carrot has been a recent approach. In late summer of 1973, the Agency awarded a contract to an independent test lab to develop a standard for D. C. defibrillators. Although obviously a trial balloon, this action showed much precedent-setting potential, thereby causing anxiety in consensus standards groups. The tempo of consensus standards writing for medical devices appears to have increased, in part due to this anxiety. The standard developed under that contract is being debated in meetings of AAMI and others and will apparently be subjected to ANSI procedures prior to publication for comment in the *Federal Register*.

Contract Awarding

Contract awarding serves as the carrot, as well. On May 16, 1974, FDA awarded a contract to AAMI to develop standards for implanted cardiac pacemakers. A Request for Proposal has also been issued for the development of electrosurgical equipment standards. Certainly, other such requests are on the way.

Other voluntary standards efforts are either completed or under way. AAMI has produced standards for cardiac valves. A safe leakage current limits standard is also nearing completion in AAMI. Standards for implantable metals have been produced by the F-4

Committee of ASTM. The medical plastic standards effort in ASTM has been noted earlier. The Sterile Disposable Device Committee of the Health Industries Association is considering standards for devices under their purview. These include single use surgical kits, disposable syringes, sterile tubing and other such devices.

These and other organizations have varying degrees of expertise in voluntary standards writing. With the prospect of such standards becoming mandatory by regulation (and violation of them a criminal offense), standards writing must and will become a more exacting field. Most, if not all, standard-writing bodies will be upgrading their ability to get background, resolve conflict and formulate wording.

Radical Changes in Medical Device Industry

In my opinion, the mandatory standard-making authority conferred by Section 513 of S. 2368 will radically change the product development and marketing practices of the medical device industry. It will also change the activities and attitudes of many voluntary consensus standard-setting groups. The Food and Drug Administration will be given a powerful weapon to force the serious and rapid development of meaningful performance standards governing medical devices. The variation in product from one manufacturer to another will almost certainly be reduced by the standards authority. There is no doubt that some economies are to be gained by standardizing the performance and other characteristics of many medical devices. However, unless the custom device exemption is broadened, it may be extremely difficult to satisfy the needs of many patients who do not fit normal patterns or those of medical practitioners with unique needs or ideas. Unreasonable use of the standard-making authority by either the Agency, the regulated industry, or consumer organizations will result in needless expense and unwarranted reduction of free choice in product distinctions or features. **[The End]**

Regulation Through Premarket Clearance

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WITH THE POSSIBLE EXCEPTION of lot-by-lot certification, no regulatory tool causes manufacturers in the food, drug, cosmetic, and devices field as much concern as premarketing clearance or scientific review. As you know, once a product has been deemed subject to such review, no commercial marketing is permitted until the Agency gives the "O.K." Indeed, with regard to drugs (under existing law), and with regard to devices (under the proposed legislation), the Food and Drug Administration (FDA) may arbitrarily enjoin a manufacturer from even conducting the tests required to establish whether its product is effective, and the Agency order invoking such prohibition may not be appealed to the courts. Some figures on the slowdown in drug discovery and development in the U. S. since 1962, the year the FDA was given authority to preclear drugs on the basis of effectiveness, will shed light on the concern over scientific review. First, regarding drug development time, the Chairman of the Industrial Research Institute stated the following last year:

"Average development time during the period 1958-62 was 2 years, from 1968-72, it was 5½ to 8 years. Time for regulatory approval of products requiring premarketing review was 6 months in 1962. In 1969 it was 40 months. Adding together the development time to the regulatory approval time brings the total to 8½ to 11 years from the time a product is discovered until the time it hits the market. How about development *costs?* In 1962, they were 1.2 million per product. In 1972, they were 11.5 million. Let's look at it another way. There were 152 single entity drugs introduced in the U. S. for the years 1958-1960 and only 41 for the period 1968-1970, and *finally* from the point of view of drug introductions in the U. S. compared to other sophisticated countries, the following has been observed:

"From 1961 through 1970, the U. S. ranked *first* in the *discovery* of single chemical entities, but *fourth* in the *introduction* of such entities. If one calculates the ratio of new drug introductions to new drug discoveries during the period 1963 to 1970, one notes that the U. S. ratio is by far the worst of all the sophisticated countries.

"No one claims that the 1962 Drug Amendments were the sole causes of the slowdown in new drug introduction but all agree that they were a contributing cause."

Stages of the Scientific Review Process

In my remarks this morning, I will describe the scientific review provisions which will most likely be contained in device legislation, as finally passed. I will also point out some of their probable effects on manufacturers. Unless otherwise stated, the proposed legislation referred to will be the Kennedy bill, S. 2368.

As indicated by Dave Collins, the first step along the road toward scientific review would be a recommendation by an independent review panel that scientific reexamination be required. The recommendation would be made because of a lack of sufficient information regarding the effectiveness or safety of the device and because of a determination that scientific review is more appropriate than the promulgation of standards. Legislation, as finally passed, may incorporate in its criteria reference to the "life supporting or life sustaining" concept, but it is uncertain just how this criterion would be included. Under Senator Nelson's proposed amendment to S. 2368, FDA would have to impose scientific review on a device which is life supporting or life sustaining if insufficient information exists on its safety and effectiveness.

A recommendation for preliminary classification by a panel (which could be changed by FDA after consultation with the panel) would be followed by the publishing of a proposal in the *Federal Register;* and then by a review of comments received on the proposal. The preliminary classification would then be published in the *Federal Register;* however, this classification would not be self-operating. Before scientific review actually could be required, FDA would have to publish a final classification which is appealable to the courts.

Thus, before scientific review could be required, manufacturers would have opportunity to submit data to the panel making the preliminary recommendations; would be able to comment to FDA on its proposal to preliminarily classify; and would be able to appeal

a final classification order to the courts. Among the findings that must be made to justify scientific review (in addition to those referred to earlier) would be the degree of risk associated with the device, the benefit to be expected from the device compared to the effect on utility, cost, or availability from a requirement of scientific review, and a summary of the data on which FDA had found a need for scientific review.

Once the final determination is made, no manufacturer could commercially market the product until FDA approved an application containing, among other things, *adequate* scientific evidence showing that the device was effective and sufficient information showing that it was safe. Adequate scientific evidence is defined to mean "sufficient well-controlled investigations," unless the Secretary determines that other valid scientific evidence is sufficient.

Investigations of Devices

In order to conduct the extensive investigations required to obtain adequate scientific evidence, manufacturers would be permitted to ship devices for investigations if certain conditions were met. An outline of planned clinical testing would have to be submitted either to FDA or to local institutional review committees. Assurance would have to be given that rigorous patient consent requirements would be met and adequate records would be maintained and reports submitted. The Secretary could delay approval of a planned investigation and could arbitrarily stop a manufacturer's testing program at any time.

Once the testing was completed and the new device application was submitted, the FDA would refer the application to the same panel that originally classified the device for its report and recommendation. No time limit for such report and recommendation is set forth in the bill. However, the overall review process of the application cannot exceed 120 days unless the applicant agrees. To give you an idea of what may be coming, a new drug application was filed recently consisting of 400 volumes which made a 12-foot high stack.

If approval of the application were denied, a manufacturer could request that it be referred to an independent advisory committee for its views. (The proposed legislation is unclear as to whether such a request could be filed prior to the denial of an application, and if it

could be so filed, whether the review by the independent review panel would be in addition to, or in lieu of, review by the panel that originally classified the device.) In any event, the manufacturer would have the right to consult with the independent advisory committee. After FDA took final action refusing to approve a device application, a manufacturer could appeal the action to the courts.

Devices Not Subject to Review

Three categories of devices may not be made subject to scientific review. They are: custom devices, devices intended for animal use, and devices made subject to a mechanism called a product development protocol. Use of such a protocol may be permitted in lieu of new device applications at the discretion of FDA. This mechanism is intended to apply to devices which are subject to frequent modification, rapid obsolescence, or which would not likely be produced in substantial volume. The scientific review mechanism would be inappropriate for *such products* because of cost, time, and/or burden factors, yet the expected benefit to be derived from them is such that they should be allowed on the market. The protocol mechanism would permit FDA and the manufacturer to agree on a protocol pursuant to which clinical trials could commence and could be modified without FDA approval as long as the trial results and changes in the procedures were within limits allowed in the protocol. If the final results of the trials were as anticipated, the manufacturer would notify FDA by the filing of a certification of completion. Under the Rogers bill, after such notification, the manufacturer could commercially market the product without FDA having to take any affirmative approval action, if the Agency had not taken action within 90 days after the filing of the certificate. Thus, FDA would be able to maintain complete surveillance over a product but at the same time not inhibit rapid development for commercial use.

It might be helpful to discuss for a moment the relationship of standards to scientific review under the legislation. First, under the procedure set up in the statute, if a product has been made subject to a standard and a manufacturer wanted to market a slightly different product for competitive reasons, he would petition FDA to be permitted to submit an application for scientific review of the deviating product. FDA may or may not permit the application to be

filed or approved. Secondly, FDA, on its own, could require that a particular manufacturer's device conforming to a standard be also made subject to scientific review. With regard to a device or class of device made subject to approved applications, the proposed legislation is not specific as to whether a standard could be later promulgated. If it could be, all manufacturers could market such a device without submitting any application or other data. In my view, the law would be construed to permit the promulgation of such a standard, at least if the standing panels agreed. In any event, with regard to any application for scientific review of a device having components subject to standards, those characteristics of the device subject to the provisions of the existing standards would have to comply with the standards, unless information justifying deviation was submitted in the application for scientific review.

Time Provisions

A word should be said concerning how soon after passage of the legislation the scientific review provisions of the bill could be made to apply to specific devices. First, the panels are given *one year* to make their recommendations as to preliminary classification. These recommendations would then have to be published for comment and then republished as preliminary classifications by FDA. Still, scientific review requirements could not be made to apply until a later *final* classification was made. Once a final classification was made, court review could further delay the application of requirements for scientific review.

Manufacturers would have to request classification from FDA in the case of devices not included in the preliminary classifications. This classification would be appealable. Thus, no scientific review could be imposed at least until final classification, which could take from 6 months to 2 years. The time required would depend in part on how readily findings of existing classification panels could be used for the findings required under the bill. Further, another provision in the bill guarantees that scientific review requirements cannot be imposed for a year after passage of the law. Finally, as to uses of devices in existence at the time a device is *finally classified* (a year or so after passage), scientific review provisions could not apply until *30 months after such final classification* except as regards a particular manufacturer who earlier files a device application and such appli-

cation is disapproved. FDA may grant 30 months in addition to the original 30 in certain circumstances. Thus, it is conceivable that for some time after passage of the law, manufacturers would be free to market new products and still have ample time after final classification to submit substantiating data. Certainly, for those large-volume devices currently under development which could be made subject to scientific review under legislation, now is the time to be compiling adequate scientific data. The same can be said for those products currently on the market which meet the criteria for scientific review set forth in proposed legislation. Unlike the case with drug legislation in 1938 and 1962, there are no permanent grandfather clauses in the proposed device legislation.

Effects on Public and Industry

What will be the effects on the public and on industry if the scientific review provisions of the Kennedy bill are enacted into law? First, because of the rigorous and ever-developing concepts of well-controlled investigations, it will be far more expensive and time consuming to develop new products. The small manufacturers who have contributed so much to the development of novel and useful devices in the past will be less able to contribute in the future. To offset this disadvantage somewhat, there will be some increase in the safety features of some devices. However, one fact remains—a slowdown in the introduction of new and useful devices is inevitable. This slowdown will be aided by the voices of the consumerists and the Congressmen out for consumer votes who publicly would urge that absolute safety be the rule rather than positive benefit-to-risk ratios. Another result will be the removal of some worthwhile devices from the market because the cost of necessary testing cannot be justified because of limited market demand. It can be anticipated that some important devices will be available overseas before they can be marketed in the U. S.

Responsible officials in FDA realize these problems. Accordingly, they would prefer that new legislation emphasize standards and limit scientific review to those situations where such review is really needed. Hopefully, the criteria in the Kennedy bill and in the Rogers bill will be appropriately modified before legislation so that the public will be assured continued availability of needed medical devices.

[The End]

Medical Device Defect Notification, Product Return, Repair or Replacement

By RICHARD D. MANTHEI

Mr. Manthei Is Corporate Director of Regulatory Affairs and Quality Assurance for American Hospital Supply Corporation.

THE DEFECT NOTIFICATION, repair, replacement or refund provisions which appear in Senator Edward M. Kennedy's (S. 2368) and Representative Paul G. Rogers' (H. 9984) medical device bills would affect the entire medical device industry. These provisions may have been overlooked because of general concern over scientific review and standards requirements. All medical devices would be covered by these provisions, regardless of classification. They are important enough to be given careful consideration. Perhaps the effect of these provisions upon the medical device industry could best be demonstrated by outlining the types of problems a manufacturer of a potentially defective device could encounter.

For purposes of illustration, let us assume that Company X makes an implantable device. As a result of continuing research and development, Company X introduced a new model of an older device approximately one year ago. The new device, which appeared to eliminate or lessen some of the problems associated with previous similar devices, has been implanted in approximately one thousand patients.

Company X has recently been notified of the deaths of several patients in whom the new model had been implanted approximately eleven months ago. Autopsies performed on two of these patients revealed that the same part of both devices had broken, thus causing the devices to fail. Investigations on behalf of the company indicated that several possibilities existed as to the cause of failure:

(1) Improper implantation by the surgeon, which may have caused the devices to crack or weaken and fail after extended use in the patient;

(2) Individual idiosyncrasies of the patients involved, perhaps resulting in an adverse inter-reaction in the patient's body; or

(3) Improper handling by hospital personnel prior to implantation, which may have caused the device to crack or weaken and fail after extended use in the patient.

Unfortunately for Company X, none of the aforementioned possibilities can be clearly demonstrated to have caused the failures. Therefore, the possibility exists that the use of the device in humans over extended periods may bring about stresses or conditions which were not evident during clinical trials.

Let us further assume that, as with many implant procedures, the procedure required to implant Company X's device is difficult. Past history indicates that 19 percent of all patients who have the device implanted will not survive because of complications associated with the required operation. In addition, past history indicates that the reoperation fatality rate is approximately two times the fatality rate of the original operation. (It is my understanding that these figures are not unrealistic for a number of implant operations.)

Since Senator Kennedy's bill is the only one which has passed either House of Congress at this time, let us continue our illustration assuming that the defect notification, repair, replacement or refund provisions of the Kennedy bill are in effect.

Notification

Under the Kennedy bill, a manufacturer, distributor, or importer of a medical device would have to notify the Secretary of the Department of Health, Education and Welfare (HEW) of any information

it acquires which would "reasonably support the conclusion" that the device contained a *defect* which could create a *substantial risk* to the public health or safety. It is safe to assume that the Secretary of HEW will delegate its authority for the regulation of medical devices to the Food and Drug Administration (FDA). Company X would, therefore, have to answer two questions in determining whether it should notify FDA:

(1) Does the device contain a defect?

(2) If the device does contain a defect, does the defect create a substantial risk to the public health or safety?

The Kennedy bill defines "defect" as a deficiency in design, materials or workmanship. Specifically excluded from the definition are deficiencies resulting from the use of improper accessories, from improper installation, maintenance, repair or use of the device or from use of the device after the lifetime represented by the manufacturer has expired.

Since the management of Company X is not certain whether their problem relates to design, materials, workmanship or improper installation, they may have to assume for purposes of the defect notification provisions that their product does contain a "defect." Although "substantial risk" is not defined in the bill, Company X would have to conclude that death is, in fact, a substantial risk to the public health and safety.

Since the failure to notify the FDA could result in a fine for the company or fines and imprisonment for company officials, let us assume that Company X decides to notify the FDA of their potential problem. Under the Kennedy bill, notification to FDA by Company X would have to contain a description of the suspected defect, an evaluation of the hazard and a statement of measures being taken to correct the problem. Although we cannot be certain as to how the FDA would administer these provisions, we do know that the Consumer Product Safety Commission (under similar provisions of the Consumer Product Safety Act) has recently promulgated regulations requiring notification within 24 hours after knowledge of a defect, followed by written confirmation within 48 hours. We also know that the Consumer Product Safety Commission will then require a more detailed written submission from the chief executive

officer of the company or from someone within the corporation to whom the chief executive officer delegates this authority.

Agency Action

The Kennedy bill also places certain requirements on the Food and Drug Administration. If, after notification by Company X, the FDA should determine that the company's device presents a "substantial hazard" to the public health and safety, and that some type of notification is required in order to protect the public from this hazard, the FDA must give adequate notice to all appropriate parties, such as manufacturers, distributors, retailers, health professionals and users.

Let us assume that the FDA decides that notification at this time should go only to the physician level and not to the general public. Their decision is based upon uncertainty as to the cause of the product failure and upon the FDA's judgment not to alarm every patient who has ever had a similar device implanted. Owing to this decision by FDA, the Kennedy bill requires the FDA to provide all health professionals who have been notified of the defect with the opportunity to comment on the advisability of notifying the general public of the hazard. Within thirty days after notification to health professionals, the FDA must notify the general public of the hazard, if the FDA determines that notification would not endanger the public health.

For purposes of this illustration, we do not need to determine whether or not the FDA decides to notify the general public. We wish only to point out that these provisions are available if the FDA determines it is necessary to use them. It is also noteworthy that notification is to be by the means "best suited under the circumstances." Undoubtedly, the FDA could use the news media, if necessary. Obviously, general public notice could cause Company X many additional problems.

Return, Repair or Replacement

Company X's problems are not over with notification. The FDA has at its disposal additional remedies. If, after affording interested

parties, including consumers and consumer organizations, an opportunity for an informal hearing, the FDA determines that Company X's device presents a substantial hazard to the public health and safety, and that additional FDA action is necessary in the interest of public health, they may order Company X or any or all of its distributors or retailers to elect one of the following actions:

(1) Repair the device;

(2) Replace the device with a like or equivalent device which does not contain the defect; or

(3) Refund the purchase price of the device, less a reasonable allowance for use if the device has been in possession of the user for more than one year.

The Kennedy bill further provides that no charge will be made to persons availing themselves of any of the aforementioned remedies and that persons pursuing such remedies should be reimbursed for any expenses they may incur. The bill also would allow the FDA to require reimbursement for expenses incurred by other manufacturers, distributors or retailers in carrying out the elected remedy.

As with the failure to notify FDA of a defect, the failure to comply with an order by FDA to refund, repair or replace a defective device may result in a fine for the company and fines or imprisonment for company officials.

Company X would likely face a very difficult time in the next several months. In addition to the possibility of replacing or repairing the defective device in a possible 1,000 patients, Company X could also be forced to pay for all costs associated with this replacement. Considering the patient's now doubled risk with reoperation, Company X's problems magnify many times.

As sort of a parting shot, the bill provides that remedies set forth in the bill are in addition to, and not in substitution for, any other remedies provided by law. This means that Company X, after acting prudently under the notification, refund, repair or replacement provisions, may now be faced with a number of product liability claims and perhaps several wrongful death actions in addition to the expenses incurred in replacing or repairing the defective product.

Other Manufacturers, Distributors or Retailers of Medical Devices

The illustration presented is an extreme one. Not all manufacturers, distributors, or retailers of medical devices will have to face the problems of Company X. All members of the medical device industry will, however, be affected to some degree.

Although the illustration related to a product which may have failed because of a defect, the failure to conform to an applicable standard could also bring the same provisions into effect. For example, if Company Y manufactures a medical device which is subject to a promulgated standard and it is determined that the device deviates from the standard in any respect, Company Y would have to notify the FDA of that deviation. The FDA then would have to make determinations similar to those which we have discussed relating to Company X's potentially defective device. If the FDA should determine that a substantial hazard is involved because of the deviation from the standard, Company Y could be faced with the election of repair, replacement or refund as well as with the many other problems encountered by Company X.

Summary

It could be argued that Company X should have reacted in a manner similar to that which we have discussed without medical device legislation. Perhaps this is true. No attempt has been made to discuss moral or ethical considerations which may be involved. It must be pointed out, however, that under either the Kennedy or Rogers bills many of the determinations which have formerly been settled in a court of law will be made by FDA.

Hopefully, I have been able to demonstrate the importance of the defect notification, refund, repair or replacement provisions of current medical device legislation. Certainly, these provisions will have an impact on the development and marketing of medical devices.

[The End]

Device Legislation—GMP's, Inspection, Records and Reports and Prescription Device Advertising

By JOSEPH R. RADZIUS

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IT IS NOW COMMON KNOWLEDGE that the enactment of medical device legislation is imminent. If the law is not passed during this session of Congress, it will undoubtedly be reintroduced during the next. The law is forthcoming and were it not for Watergate and the precedence of other health and environmental legislation due to expire soon, it probably would be in effect now.

I have been asked to prepare remarks about the portions of the Kennedy bill dealing with (1) Good Manufacturing Practices (GMP's), (2) Records and Reports, (3) Inspection, and (4) Prescription Device Advertising. The intent of this presentation is to briefly analyze these portions.

GMP's

The original Federal Food, Drug, and Cosmetic Act was enacted in 1906 and has been amended several times, most notably in 1962. I say 1962, because the Kefauver-Harris Amendments of 1962 authorized the Food and Drug Administration (FDA) to establish for drugs, by regulation (Sections 133.1 through 133.15), current Good Manufacturing Practices. Drugs which are not manufactured under

conforming methods and/or in conforming facilities are considered adulterated and in violation of Section 501 of the Act.

Under the Kennedy bill, 501 is now amended to authorize the Secretary of Health, Education and Welfare (HEW) to issue "substantive" current Good Manufacturing Practices regulations applicable to medical device establishments which manufacture, process, or handle medical devices. Authority to issue such regulations is granted by Section 701 (A) of the Act.

"Legislative Leapfrogging"

Under existing drug provisions, the standards for current Good Manufacturing Practices (as reflected in Agency regulations) were not explicitly declared by Congress to be "substantive"—they are "interpretative." In the case of devices, these regulations will be "substantive" and are clearly to be of binding impact, having the force and effect of law. In other words, in the manufacture of drugs, the burden of establishing an alleged violation of current Good Manufacturing Practices rests with the Agency. Under device legislation, precisely the opposite prevails—a significant departure.

Presto. Agency authority in the field of device Good Manufacturing Practices exceeds the current authority the Agency exercises in drug Good Manufacturing Practices. This extension of authority was recently referred to as "legislative leapfrogging" which is the best description I have heard to date.

Anticipating activity in this area, the Inter-Association group designated working subcommittees to prepare GMP drafts. After preparation, subcommittees will interface with appropriate personnel in the Bureau of Medical Devices and Diagnostics in an attempt to reach consensus with regard to device Good Manufacturing Practices.

Initially, thoughts were directed to an umbrella set of GMP's, encompassing the entire population of medical devices. It is rapidly becoming obvious that such a task may be virtually impossible because of the diversity in the many thousands of devices being distributed and used.

Categories of Devices

At this point, a meeting was held with the Bureau after which it was decided that subcommittees would explore the feasibility of

proposed Good Manufacturing Practices according to defined categories.

Tentatively, the categories are:

... Dental Materials

... Implants

... In Vitro Diagnostic Reagents

... Mechanical and Electro-Mechanical Devices

... Sterile Disposables, and

... A General or "All Others" Category

In one category, such as sterile disposables, a draft has been submitted to the Bureau, and active discussions are being pursued.

Prepared drafts for the other categories will be submitted within the next few months, and joint meetings should result in consensus. At this point, I should interject that these drafts are being prepared by a sampling of representatives knowledgeable in the particular category of devices involved. This effort is being coordinated by the Inter-Association.

It would be utopian to expect that the finished documents will be completely satisfactory and free from ambiguities, regardless of whether a document is umbrella in nature or whether it is a group of documents reflecting device categorization.

An umbrella document could literally "blow one's mind." Imagine, if you will, how one document could satisfy the requirements of Good Manufacturing Practices for devices which range from tongue depressors and surgical curtains to heart valves and instruments involving sophisticated mechanization. In some cases, manufacturing may involve batch processing, in others, serialization. One manufacturing lot, like an instrument model, might entail a year's production; on the other hand, a lot of some polymer implants might be less than one day's production.

If a lot is one machine costing $60,000, what about finished sample and component retention? It is difficult to perceive how an umbrella set of GMP's can be devised which would adequately serve the needs of the Agency, industry and, more importantly, the consumer.

By the same token, device categorization, as the vehicle, is no less difficult. Let us discuss the field of implants for the moment.

Implants conceivably include products such as diaphragms, contact lenses, heart valves, steel bone plates, and the like. Were it not for a category of dental materials, dental fillings could be categorized as implants. A heart valve requires production under rigidly controlled conditions in a clean environment to assure safety and reliability. In contrast, steel bone plates and contact lenses are essentially produced in machine shops in unclean environments with contaminants such as cutting oils.

I realize that I have raised questions for which no suitable answers exist. However, this is the situation, and the Agency must deal with it.

One final point, the original Act (as applied to drugs) *did not* grant the Agency authority to require complaint files. When regulations for drug GMP's were promulgated, the Agency seized the opportunity to incorporate provisions requiring retention of complaint files. Current bills (passed or pending) on medical devices *do* contain provisions requiring manufacturers to maintain complaint files. Good Manufacturing Practices for devices should not include provisions pertaining to complaint files, because (among other things) complaint files are not rightfully part of a manufacturing system. Device legislation explicitly permits the Agency to require complaint files, but it should be accomplished by means other than GMP's.

Factory Inspection

The Kennedy bill amends Section 704 of the Act to authorize factory inspection of medical device establishments. This particular section (in essence) was amended by merely inserting the term "medical devices" after the term "drugs" or by the addition of other relevant language where appropriate. Therefore, the authority granted for the inspection of medical device establishments is identical to that granted for inspection of drug establishments.

Virtually the same criteria apply to both. For example, inspection does not extend to (a) financial data, (b) sales data, (c) personnel data (other than qualifications), etc.

There has been scant interpretation by the courts relative to the limits of an inspection. The statute (21 U. S. C. 374) provides the sole guidelines. Based on precedent, it is apparent that inspectors will

be entitled to see batch production records and master formulas of prescription medical devices.

I should emphasize that device inspection will differ little, if at all, from drug inspection. The inspector should appreciate the distinction between drugs and devices and conduct his inspection accordingly.

Finally, FDA's Inspection Operations Manual (IOM) is now publicly available consistent with the "goldfish bowl" approach now in vogue at the Agency. Device manufacturers should obtain Section 542 of the Manual, which tells the inspector how to determine GMP compliance.

Records and Reports

Section 516 of the Kennedy bill authorizes the Agency to require manufacturers to establish and maintain records and make certain reports available to the Secretary as the Secretary may require by general or special regulation.

In the absence of a medical devices law, the requirement may still be imposed because of an administration bill which was recently submitted to Congress. The Agency has proposed that Section 702(C) of the Act be amended so that anyone operating a device establishment:

"... must establish and maintain such records, make such reports, and provide such information as the Secretary may, by reasonable regulation, require . . ."

This proposal is intended to give the Agency access to all complaints and reports of adverse reactions in the files of device manufacturers—access which is presently not permitted.

If and when this proposal is adopted, I cite it as another example of the Agency exercising authority exceeding the intent of Congress. The General Counsel's Office at FDA would undoubtedly disagree.

Prescription Device Advertising

The Senate bill amends Section 502 of the Act dealing with prescription drug advertising. As in factory inspection, the identical provisions which have been applied to drugs would also apply to devices.

All prescription device advertising must include an established name for the device, a full description of all components or the for-

mula showing quantitatively each ingredient, and a description of side effects, contraindications and effectiveness.

These provisions do not include printed matter determined "labeling" as defined in Section 201 (M) of the Act. Section 201 (M) defines labeling as:

"All labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

Thus excluded is printed matter such as the immediate package label and the package insert.

Under the Kennedy bill, the FDA would have sole authority to regulate prescription device advertising. Problems which could be encountered range from the reasonable to the ridiculous. In the case of a heart valve, a list of ingredients may be of some value to the physician whereas a list of components for an X-ray machine would be meaningless.

In closing, I am reminded of more than one occasion where a member of the Agency has expressed that industry activity is not to be confused with progress. I submit that the other shoe fits—activities of the Agency and Congress, likewise, are not indicative of progress. **[The End]**

DECLARATORY, BUT NOT INJUNCTIVE, RELIEF PROPER AGAINST SEIZURE

The U. S. District Court did not have jurisdiction to enjoin a Food and Drug Administration seizure prior to the institution of seizure proceedings, but it did have jurisdiction to declare whether the products to be seized were within the definition of "food" in the Federal Food, Drug and Cosmetic Act, according to the U. S. Court of Appeals for the First Circuit. Manufacturers of paper food-packaging materials challenged the announced intention of the FDA Commissioner to seize materials which contained more than 10 p.p.m. polychlorinated biphenyls and which were shipped in interstate commerce after September 4, 1973. The seizure provisions of Section 304 of the Act were intended to provide speedy protection of the public from dangerous articles in interstate commerce, and, consequently, they require that a seizure not be enjoined pending judicial resolution of other issues. However, Section 304 does not preclude District Court jurisdiction to grant declaratory relief on the basis that materials to be seized are not subject to the provisions of the Act.

Natick Paperboard Corp. and Crown Paperboard Co., Inc. v. Weinberger, et al., CA-1, CCH FOOD DRUG COSMETIC LAW REPORTER

Advisory Committees at FDA—A Legal Perspective

By DAVID H. HICKMAN

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MANY ADMINISTRATIVE LAWYERS have concluded, after the court decisions in the drug quartet and the *Octane Posting* case, that any effort by the private bar to construe statutes is an exercise in futility. They believe the courts to have decreed that only federal administrators have been endowed by their creator with the right and the ability to divine legislative intent.

Without the cloak of this new species of administrative expertise, one must approach with some concern the task of attempting to place the Food and Drug Administration's (FDA) use of advisory committees in a legal perspective. The subject matter appears unavoidably to require an effort at statutory interpretation, involving the Federal Advisory Committee Act of 1972,[1] and the relationship between it and the statutes governing conflicts of interest[2] and Freedom of Information.[3]

The difficulties encountered in applying the Federal Advisory Committee Act to the expert committees most frequently utilized by FDA,[4] are best understood in terms of the Act's genesis. Two primary concerns led to Congressional hearings on advisory committees in the late 1950's: first, the escalating number of advisory committees in the federal government; and, second, the possibility that committee members were using their positions to forward special

[1] Pub. L. No. 92-463, 86 Stat. 770. The Act took effect on January 5, 1973.

[2] 18 U. S. C. § 202, et seq. (1970).

[3] 5 U. S. C. § 552 (1970).

[4] FDA does utilize some committees for advice on broader policy matters (*e.g.*, the National Advisory Food Committee and the National Advisory Drug Committee), but these are far exceeded in number by committees convened to provide specific scientific or medical advice.

interests.[5] The latter apprehension was associated with the increasing use of so-called "industry advisory committees" composed of representatives of the industries being regulated.

Guidelines for Committee Formation

The strong Congressional interest expressed led to the issuance of Executive Order No. 11007[6] in February, 1962, prescribing guidelines and requirements governing the formation and use of advisory committees in the Executive Branch. Without detailing those requirements, it is noteworthy that a distinction was drawn between "advisory committees" and "industry advisory committees," with the latter defined as those committees composed predominantly of industry representatives. In addition to the requirements applicable to all advisory committees, "industry advisory committees" were subjected to a requirement that verbatim transcripts be kept of all meetings. That requirement, however, as well as the operating requirements generally applicable to advisory committees, could be waived by the head of the department or agency to whom the committee reported.

The Executive Order apparently wrought little change in the use of advisory committees, and Congress again turned its attention to them in the 91st and 92nd Congresses.[7] Both the hearings and the various legislative proposals focused on continued proliferation of committees, and the concern that undue influence on government policies was exerted by committees composed of industry representatives operating behind closed doors.

The strongest critics of advisory committees would have legislated with substantial specificity the requirements which they thought would resolve the problems. Thus, for example, one bill would specifically have required the inclusion of "public members"—pre-

[5] *See* Hearings on H. R. 3378 Before the Special Studies Subcomm. of the House Comm. on Government Operations, 85th Cong., 1st Sess. (1957).

[6] Hearings on "Presidential Advisory Committees," Before the Special Studies Subcomm. of the House Comm. on Government Operations, 91st Cong., 2nd Sess. 10-12 (1970).

[7] *See* Hearings on "Presidential Advisory Committees," Before the Special Studies Subcomm. of the House Comm. on Government Operations, 91st Cong., 2nd Sess. (1970); Hearings on S. 3067, Before the Subcomm. on Intergovernmental Relations of the Senate Comm. on Government Operations, 91st Cong., 2nd Sess. (1970); House Comm. on Government Operations, "The Role and Effectiveness of Federal Advisory Committees, H. R. Rep. No. 91-1731, 91st Cong.; 2nd Sess. (1970); H. R. Rep. No. 92-1017, 92nd Cong., 2nd Sess. (1972); S. Rep. No. 92-1098, 92nd Cong., 2nd Sess. (1972); H. R. Rep. No. 92-1403, 92nd Cong., 2nd Sess. (1972).

sumably what we now call consumer representatives—on every advisory committee. The legislation which emerged was a compromise which stated its requirements much more generally. Thus, rather than establishing detailed formulas for committee membership, the Act imposes the more generalized requirement that there be "fair balance" in the membership of committees.

Many of the difficulties presented by the Act for an agency like FDA result from the fact that it draws no distinctions among the various types of advisory committees utilized by government. As a result, requirements that were doubtless imposed with a view to controlling the use of "industry advisory committees" are equally applicable to the scientific advisory committees most frequently employed by FDA. This failure of Congress to recognize very fundamental distinctions among advisory committees and the functions they serve may present serious obstacles to FDA in its effective future use of such committees.

Generally, the Act seeks to achieve its objectives by requiring:

(1) that the need for advisory committees be reviewed and substantiated;

(2) that the public be given access to advisory committee meetings and to the documents they consider and prepare;

(3) that membership on all advisory committees be "fairly balanced" in terms of the points of view represented and the functions to be performed; and,

(4) that committees act independently, and only in an advisory capacity.

Ensuring Active Advisory Committees

To achieve the first objective—ensuring that advisory committees were really performing a useful function—three distinct measures were undertaken. First, the Act requires that the President submit an annual report to Congress on existing advisory committees and their operations. The first report, running to four volumes and weighing in excess of 21 pounds, listed more than 1,400 advisory committees and their members. The supplemental index alone runs to almost 1,000 pages. Needless to say, contrary to the case with some Presidential compilations, there was no stampede by the publishing houses to get it out in paperback. Whether this exercise will, in fact, produce a review of the need for some committees, or the sheer burden of the task will tend to discourage their creation, remains to be seen.

The second effort was to create in the Office of Management and Budget (OMB) an ongoing responsibility for the supervision of advisory committee creation and operation. OMB appears essentially to have declined this responsibility and has indicated that it will look to the agencies to regulate themselves.[8] The OMB function is of some interest, however, as it included a requirement that guidelines for implementation of the Advisory Committee Act be issued. In January of 1973, extensive proposed guidelines were published, including examples of how various of the Act's requirements were interpreted by the Department of Justice and OMB.[9] However, in publishing its final guidelines in April of this year, OMB retreated from the detailed approach taken in the original proposal and offered only very cursory guidance as to implementation of the Act.[10]

The third effort at control was directed at the agencies themselves. They are prohibited from creating any advisory committee unless it is found to be in the public interest and it has a very detailed charter prepared describing its composition and functions. In addition, there is a statutory self-destruct mechanism; all committees will automatically terminate after two years unless specifically extended.

It does not appear that these requirements have had any impact in curtailing the use of advisory committees by FDA, but it may readily be concluded that FDA's continued, and, indeed, expanded use of advisory committees does not conflict with the purposes of the Act. In imposing the review and supervision provisions of the Act, Congress was concerned with the massive expenditures associated with committees that existed in name alone, or whose reports "were ignored or forgotten."[11] FDA advisory committees, on the contrary, are generally created to provide advice to the Agency with respect to specific current regulatory activity. Their advice, whether heeded or not, is made part of the record on which policies are implemented.

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[8] Testimony of Frederick V. Malek, Deputy Director, Office of Management and Budget, in Hearings Before the Subcomm. on Budgeting, Management and Expenditures of the Senate Comm. on Government Operations, February 5, 1974.

[9] Notice, "Advisory Committee Management-Administrative Guidelines and Management Controls," 38 Fed. Reg. 2308 (1973).

[10] "[Circular No. A-63 Rev.]-Advisory Committee Management-Guidance," 39 Fed. Reg. 12389 (1974).

[11] S. Rep. No. 92-1098, 92nd Cong., 2nd Sess. at 3 (1972).

In fact, a primary criticism of FDA's current heavy reliance on advisory committees takes quite the opposite thrust. It is argued that FDA gives too much weight to committee advice, and that committees are performing functions which should properly be undertaken by the FDA staff. Commissioner Schmidt has responded that the committees are merely amplifying the staff efforts, particularly in areas where highly specialized expertise is required, and thereby enabling FDA to undertake much more comprehensive regulatory programs.[12] To the extent that the committees are properly managed and administered, and their advice subjected to agency review, this position appears well taken.[13]

Seeking to Avoid Bias in Committee Composition

The provision requiring "fair balance" in advisory committee membership is doubly obscured by the legislative drafting. First, it is located in the portion of the statute entitled "Responsibilities of Congressional Committees," and is presented as one of five basic requirements of any *legislation* establishing or authorizing the establishment of an advisory committee. In what appears to be a statutory afterthought, it is then provided that "to the extent they are applicable" these guidelines must be followed by agency heads and other federal officials in creating an advisory committee.

No guidance is offered by the statute as to the degree of deviation from the guidelines intended to be permitted by the qualifying phrase, and the Conference Report simply states that the guidelines "shall" be followed.

Perhaps the most reasonable reading of the section is that, except to the extent that they involve uniquely Congressional functions, the guidelines are to be applicable to all agency advisory committees. On this reading, those provisions relating to appropriations, or permitting deviations from the general requirements of the Act relating to public access to information would not be applicable because they involve legislative functions which only Congress can

[12] Testimony of FDA Commissioner Schmidt, in Hearings Before the Subcomm. on Budgeting, Management and Expenditures of the Senate Comm. on Government Operations, March 6, 1974.

[13] The Panel on Chemicals and Health of the President's Science Advisory Committee recommended that FDA should employ an "Advisory Board of Review" consisting of members from outside government to sit "in connection with each important regulatory decision." *Chemicals & Health*, Report of the Panel on Chemicals and Health of the President's Science Advisory Committee at 7 (1973).

perform. All other sections, including the requirement of "fair balance," would, however, be applicable to agency advisory committees.

The second problem resides in determining what is meant by "fair balance." The statute states that advisory committee legislation must:

"Require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee."[14]

On its face, this language appears to present some unique problems in the use of expert technical committees of the variety most frequently employed by FDA, which the Agency does not appear to have resolved.

For example, a committee convened to advise on the appropriate regulatory status of a broad class of drugs—like the advisory committees on over-the-counter drugs—would not appear to be "fairly balanced in terms of the points of view represented" if it has no spokesman for the scientific views of OTC manufacturers. This position was recognized in the Draft OMB Guidelines, which interpreted the fair balance requirement as follows:

"The membership of a committee necessarily depends on its functions. For example, the membership of a committee whose sole function is to consider scientific questions may be limited to scientists. However, an effort should be made to include scientists representing different points of view and different types of employment (university, industry, etc.)."[15]

The requirement that there be fair balance in points of view represented may be particularly acute with respect to committees like those involved in the OTC Review, where the legal standard of evaluation—general recognition of safety and effectiveness—looks to a consensus of those qualified to evaluate the questions presented. At present, the OTC review committees have no formal industrial representation. They do have both industry and consumer liaisons, who may express their views in panel meetings, but who do not possess the most critical element for input into the advisory process, voting membership on the committee. The point is not simply that their votes are not counted, but, more importantly, that their comments may have little impact on committee members, because they do not have peer status.

[14] Pub. L. No. 92-463, § 5(b)(2), 86 Stat. 771 (1972).

[15] Notice, supra n. 9 at 2308 (¶ 8). The final OMB guidelines simply require that the Agency indicate to OMB how it intends to meet the "fair balance" requirement.

Conflicts of Interest

The use of industry representatives on advisory committees must, of course, be consistent with the federal criminal law on conflicts of interest.

In relevant part, the "conflicts law" prohibits personal and substantial participation by a special government employee, through recommendation or rendering of advice, in any "particular matter" in which he, his immediate family, a partner, or a business with which he is connected or has an arrangement concerning prospective employment, has a financial interest.[16]

These provisions of the federal law were enacted in 1962. One substantial consideration leading to their enactment was a determination by Congress that existing laws were, in some respects, unnecessarily prohibitive. Thus, it is observed in the Report on the bill from the House Committee on the Judiciary that:

"It is also fundamental to the effectiveness of democratic government that, to the maximum extent possible, the most qualified individuals in the society serve its government. Accordingly, legal protections against conflicts of interest must be so defined as not unnecessarily or unreasonably to impede the recruitment and retention by the government of those men and women who are most qualified to serve it."[17]

Obviously, delicate questions of interpretation are presented by the conflicts of interest statute, as well as by the relationship between that statute and the directive on fair balance in the Federal Advisory Committee Act. These questions are not susceptible to broad resolution, and will have to be dealt with on a case-by-case basis. However, they are clearly not irreconcilable.

Conflicts might be avoided if the special government employee withdrew from any discussions or deliberations in which a potential conflict might arise. On the other hand, once his bias had been clearly revealed to other members of the committee, "fair balance" might best be served by permitting him to participate in the deliberative process and, perhaps, simply by excluding him from voting on the recommendations to be made.

Moreover, the conflicts law itself provides a mechanism by which participation by the employee could be effectively achieved without exposure to criminal liability. If the special government employee informs the official responsible for appointment to his position of the nature of his activity on behalf of the government, makes full dis-

[16] 18 U. S. C. § 208 (1970).

[17] H. R. Rep. No. 748, 87th Cong., 1st Session at 6 (1961).

closure of his financial interest and receives in advance a written determination from the official that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the government may expect from him, he is exempted from the exposure to criminal liability which he otherwise could face.

Consistent with the statute, the *President's Memorandum* on "Preventing Conflicts of Interest on the Part of Special Government Employees" indicates that the power of exemption may be exercised if the government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization.[18]

Achieving Fair Balance

Careful attention must be given to the conflicts of interest statute in utilizing industry representatives on advisory panels. In resolving the questions that may arise, it should be kept in mind that Congress, in revising the conflict laws, sought to permit the government access to those individuals who were most capable and knowledgeable in a particular field, and, in fashioning the Federal Advisory Committee Act, directed that advisory committees should have balanced representation, to avoid the bias of any single segment of society dominating the advice received.

Moreover, achieving fair balance requires much more than simply ensuring that conflict of interest laws are not transgressed. Bias cannot be measured by financial interest alone. An academician, for example, may be free from any conflict of interest in terms of monetary gain, but may have an even greater personal stake in committee action because of his known commitment to a particular theory of a disease mechanism or the pharmacodynamics of a drug. His academic prestige may rest on the outcome of the committee's deliberations.

The problem may be aggravated if, in an area in which scientific opinion is in flux, the Agency seeks the greater prestige it believes associated with established names, who have grown up with, if not generated, the ideas now being questioned. It may be particularly acute where a panel's assignment is broad, and other panelists readily subscribe to the veteran's asserted expertise, devoting their primary efforts to other matters of similar interest to them.

[18] "Preventing Conflicts of Interest on the Part of Special Government Employees," *The President's Memorandum of May 2, 1963* at 8.

An academician may also lack the clinician's intimate familiarity with drug needs and performance in the field. Clinicians, in turn, may have little sensitivity to consumer needs in home medication for minor discomforts which may not readily be translated into the well-defined disease conditions they encounter, diagnose, and treat in the clinic. In addition, the relative abilities and personality characteristics of the panelists may also be critical to the form and substance of a committee's advice.

It is clearly in the interest of all concerned with the regulatory process—industry, in terms of obtaining a fair evaluation of data, and the public and FDA, in terms of being assured of the objectivity of the advice received—that a careful screening process be employed in the selection of committee members. That process must be one that will reveal any biases and interests that might influence the decision-making process. Unfortunately, such a procedure does not appear to have been employed effectively in all instances, and some committee members have taken public postures on questions to be put to the committee that suggest, at best, that they will not be open-minded in their deliberations. When such bias is evidenced by an already appointed committee member, it should be incumbent upon FDA, at the least, to take extra precautions in its supervision of committee activities to ensure that the committee, as a whole, exercises a balanced judgment.

Public Access to Committee Operations

There is irony in the fact that the portions of the Federal Advisory Committee Act which have, to date, generated the greatest public debate and resulted in litigation are those governing public access to documents and to the deliberative process. Transcripts, even of advisory committee meetings, are in great demand in Washington.

The extent to which FDA may effectively be able to employ advisory committees in the future may depend upon the resolution of legal questions involving the interrelationship of the Federal Advisory Committee Act and the Freedom of Information Act as the two statutes govern the ability of an agency to close advisory committee meetings to the public, and deny access to transcripts of closed sessions.

The openness requirements of the Federal Advisory Committee Act represent a compromise between a strong Congressional interest

in subjecting advisory committee operations to public scrutiny, with a particular view to preventing the secret advancement of private interests, and the position urged by several federal agencies that, in some areas, requirements that all meetings be open to the public would so inhibit free discussion among committee members as to foreclose effective utilization of those most expert in a particular field. Thus, the broad declaration of Section 10(a) that "each advisory committee meeting shall be open to the public" was made inapplicable by Section 10(d) to meetings which the head of the agency to which the committee reports "determines is concerned with matters listed in Section 552(b) of [the Freedom of Information Act]." Section 552(b) delineates the categories of documents that an agency may legally refuse to disclose to the public under the Freedom of Information Act. The Federal Advisory Committee Act apparently contemplates that minutes or transcripts of closed meetings will not be subject to disclosure,[19] because it requires that when a committee conducts closed sessions, it must report at least annually on its activities in a fashion consistent with the policy of the Freedom of Information Act.

The debate and litigation have focused on whether or not advisory committee meetings may be closed to the public pursuant to Section 552(b)(5), which protects from disclosure intra- or interagency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency, on the theory that the discussions to be held, if reduced to writing, would be subject to protection. FDA has articulated this position as a legitimate basis for closing meetings in its general regulation on advisory committees, with the justification that it is essential to protect the free exchange of the views and judgments of the individual members and to avoid undue interference with agency or committee operations.[20] It regularly employs the justification to close portions of advisory committee meetings.[21] The OMB Draft Guidelines also made specific provision for closing portions of advisory committee meetings on a determination that the oral discussions to be held, if reduced to writing, would be exempt from disclosure under Section 552(b)(5). The final guidelines, however, are silent on the subject.

[19] Section 10(b) makes Section 552(b) of the Freedom of Information Act generally applicable to documents made available to or prepared for advisory committees.

[20] 38 Fed. Reg. 11119, at 11120 (1973).

[21] *E.g.*, 39 Fed. Reg. 7442, at 7444-45 (1974).

A Technical Legal Debate

The legal debate is technical. Section 552(b)(5) refers to documents. There was no need for reference in that Act to conversations, because they may obviously be held at any time in private by agency employees, and the disclosure aspects of the Act, to which Section 552(b) creates exemptions, gave no right to access to oral deliberations within an agency. The logic of the exemption as it applies to agency documents is to permit a free and frank exchange of ideas among agency employees. The logic must extend to expert advisory committees if they are to provide effective assistance to the agency. Committee members are no less susceptible to inhibition than agency employees. They are acting, in effect, as special employees of the agency and should be as free as other agency employees to evaluate and discard ideas which they may ultimately conclude are groundless, without being subject to greater public criticism than other agency employees would experience.

The legal position that the Federal Advisory Committee Act supports this use of the exemption is not without foundation. Section 10(d) exempts from the public access requirement meetings which the agency head determines are "*concerned* with matters listed in Section 552(b)." (Emphasis added.) Although this language does not provide a distinct resolution of the problem, it clearly suggests that Congress intended something broader than simply matters which were "subject to" the 552(b) exemptions. In view of the representations made to Congress of the need to close some meetings to promote a free exchange of ideas, and the indication in the Senate Report that the reference to the Freedom of Information Act was included to meet objections raised to openness of all meetings, it may reasonably be concluded that this use of the exemption is justified. Moreover, any other reading of the Act would lead to the anomalous result of granting protection to the transcripts of meetings but permitting access to the meetings themselves.

Two district court decisions in the District of Columbia have declined to accept this position, but the factual situations presented were quite dissimilar from those presented by FDA's use of expert committees.[22] Moreover, the Court of Appeals for the District of Columbia, in a suit brought under the Freedom of Information Act

[22] *Gates v. Schlesinger*, 366 F. Supp. 797 (D. C. 1973); *Nader v. Dunlop*, 42 U. S. L. W. 2284 (Dec. 4, 1973). The distinctions are well-drawn in the government's *Memorandum in Support of Defendant's Motion to Dismiss or For Summary Judgment, Smart v. FDA* (D. C. N. D. Cal., No. C-73-0118-SW) at 42-43.

has recognized that exemption (b)(5) may extend to documents prepared by outside consultants. In reaching this conclusion, Judge Bazelon observed that:

"The Government may have a special need for the opinions and recommendations of temporary consultants, and those individuals should be able to give their judgments freely without fear of publicity."[23]

The issue was raised in terms of the availability of transcripts of closed sessions of FDA advisory committees in the *Van Smart* case, and the question of closing committee meetings on the basis of Section 552(b)(5) extensively briefed by the government. In a broadly phrased bench decision in favor of FDA, District Judge Schnacke concluded:

"Advisory committees are policy-determining groups whose deliberations are entitled to protection. The Freedom of Information Act was never intended to invade the privacy of discussions of this sort."[24]

The technical problems of closing advisory committee meetings have been considerably exacerbated by the final OMB Guidelines under the Act. They require a specific request from the committee to the agency head for closing a meeting, to be given 30 days in advance of the meeting. Initially, this appears an inappropriate allocation of responsibilities, because it is the Agency, not the committee, which is responsible for most matters justifying the closing of a meeting, as, for example, the fact that material containing trade secrets will be reviewed. Viewed in this context, the "requirement" appears to be a recognition of the authority to close meetings because committee members wish the opportunity for a free exchange of ideas. The situation would be further complicated, however, should an agency require advice on an emergency basis. While the requirement that notices of meetings be published in the *Federal Register* at least 15 days in advance of the meeting provides for shorter notice in emergency situations, no such provision is made for waiving the requirement of a 30-day advance request to close the meeting.

Independence and Advisory Capacity of Committees

The final areas for consideration—the independence and advisory capacity of committees—also demand careful exercise of judgment by the Agency.

The Act requires, again in the section on "Responsibility of Congressional Committees" which is to be followed by agencies "to the extent they are applicable," that legislation creating a committee:

[23] *Soucie v. David*, 448 F. 2d 1067, 1078 n. 44 (D. C. Cir. 1973).

[24] Reporter's Transcript, *Smart v. FDA* at 5 (D. C. N. D. Cal., No. C-73-0118-SW, April 19, 1974).

"contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment."[25]

The abuse to which this is directed—use of committees to reinforce policies developed within the Agency by influencing or persuading the committee to "sign on"—is not uncommon, and there is some evidence that FDA may be perpetuating the problem.

Efforts to avoid this problem must be carefully weighed, however, to avoid the equal evil of the inadequately supervised committee that becomes involved in issues beyond its mandate or expertise or fails properly to address the questions on which it is intended to advise. The prohibition against influence is not a prohibition against instructing the committee as to its proper role, and maintaining administrative surveillance to ensure that the committee stays on course.

In fact, this latter objective is reflected by the several portions of the Act requiring clear definitions of committee purposes, the creation of an Advisory Committee Management Office in the agency to exercise control and supervision over committee establishment, procedures and accomplishments and the requirement that a representative of the agency chair or attend each meeting of a committee, and give prior approval to the holding and agenda of each meeting. If FDA is to effectively utilize its advisory committees, it appears that at least in some instances closer supervision of activity in terms of the charge given will be required. Clearly this can be achieved without dictating results.

The related mandate of the Act is that advisory committees be advisory only, and that the responsible agency make the final decision. At least in terms of its exposure on the Hill this is frequently a Catch-22 situation for FDA—which is accused of abdicating responsibility if it accepts the advice rendered, and of ignoring the best thinking on the subject if it does not follow the advice received. On occasion both accusations may even be leveled in the same hearing.

To some degree the advent of the Peter Preamble has ensured that agency review of advisory committee recommendations will be undertaken, at least where they are directly related to agency action which takes the form of regulations. There is considerable merit, in this respect, in the procedure followed with the recommendations of the first OTC panel to complete its assignment, which were published

[25] Pub. L. No. 92-463, § 5(b)(3), 86 Stat. 771 (1972).

for public comment prior to evaluation by the Commissioner. An opportunity was thereby afforded all interested parties to call to the attention of FDA those provisions thought to require revision prior to FDA's evaluation, thereby assisting it in focusing on controversial aspects of the advice received prior to the establishment of its own position and regulatory proposal.

It appears inevitable that FDA will most frequently follow the advice of its scientific committees, particularly when their raison d'être is the need for highly specialized expertise not available from the agency staff. Crediting the scientific knowledge of these consultants, however, does not relieve the agency from the fundamental burden of applying the law to the facts or carefully reviewing the basis of committee advice and ensuring that the appropriate legal standards are applied in taking regulatory action. That review is mandated by the Act.

Conclusion

Among the most important questions which remain unanswered is the impact on the ultimate regulatory process of a failure to comply with requirements of the Federal Advisory Committee Act. Failures to comply with specific requirements can be challenged as they occur, as has been the situation with the denial of public access to some meetings, and the courts can require the agency to comply with the Act. However, are the Act's mandates subject to what would be essentially collateral enforcement by being made the basis of an attack upon the ultimate regulatory action of the agency?

Any effort to resolve that question would necessarily involve conjecture, and is beyond the scope of these remarks. However, it does appear that the strength of such a case would depend upon the particular requirement not observed and upon the surrounding facts of the regulatory action. It appears that the strongest, if not an indispensable element of any such case, would be a demonstration that the agency had acted solely on the advice of the committee, without any independent review by the regulatory authority. So long as the agency could demonstrate that it had not relied solely upon the advice of the committee in taking action, it is difficult to conclude that failure to observe requirements of the Federal Advisory Committee Act would so taint the administrative process as to form the basis for successful court challenge of ultimate regulatory action.

[The End]

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