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

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REPORTS

TO THE READER

Briefing Session on the FDA's Procedures and Practices. The following papers were delivered at a Food and Drug Law Institute Briefing Session on the FDA's procedures and practices held on March 24 and 25, 1977 in Washington, D. C.

The procedural regulations promulgated in May, 1975, include a device by which interested parties can obtain formal advice from the FDA on a number of subjects—advisory opinions. *William Van Brunt,* in his article, "Advisory Opinions," outlines the method for filing such a request, and then goes on to discuss the type of problems that would warrant an advisory opinion. Mr. Van Brunt is Associate Counsel in the legal department of the Hershey Foods Corporation. The article begins on page 304.

Subparts B and C of the FDA's procedural regulations promulgated under the Federal Advisory Committee Act are the subject of *Daniel R. Thompson's* article, "Public Hearings—A View From the Bar." He discusses the alternate forms of hearings provided by the Act and the provisions of each he considers likely to be successful. The requirements that must be met by petitioners filing complaints are also outlined in the article. He expresses concern regarding the FDA's attitude towards the use of cross-examination as a means of finding the truth. Mr. Thompson is a partner in the law firm of Bonner, Thompson, Kaplan & O'Connell. The article begins on page 312.

In his article, "Committee or Commissioner," *Alan R. Bennett* concentrates on Subparts D and E of the FDA's procedural regulations promulgated under the Federal Advisory Committee Act. Among the topics discussed are the regulations that apply to the committee as well as what constitutes an advisory committee. Mr. Bennett points out in the article, which begins on page 323, that some committees are established by law while others are initiated by the Agency for the specific purpose of resolving a particular problem. Mr. Bennett is an attorney with the law firm of Weil, Gotshal, and Manges.

In "The FDA's New Forms of Public Hearing—Choosing Among the Alternatives," *Joel E. Hoffman* discusses Subparts B, C, D and E of the Agency's procedural regulations. He points out that only one form is authorized by the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, although other forms are also valid and, depending on the specific case, may be more appropriate. The differences between the hearings as well as the advantages and disadvantages of each are discussed in the article, which begins on page 330. Mr. Hoffman is a partner in the law firm of Wald, Harkrader and Ross.

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Advisory Opinions

By WILLIAM VAN BRUNT

Mr. Van Brunt Is Associate Counsel in the Legal Department of the Hershey Foods Corporation.

I HAVE BEEN CAREFULLY following the adoption of the new procedural regulations since their first promulgation on May 27, 1975. Here we are in 1977, thanks largely to the efforts of the American College of Neuropsychopharmacology, to discuss these new administrative procedures and practices.

My topic is section 2.19[1] of the new administrative regulations of the Food and Drug Administration (FDA), dealing with advisory opinion requests.

These new advisory opinion regulations detail the mechanism by which interested parties, the public and the regulated industry alike, can obtain formal Agency advice on a wide variety of issues, as to which the FDA will thereafter be bound.

They also make it perfectly clear that advice rendered by Agency employees, other than in compliance with this Section, will be considered to be informal counsel which is not binding on the Agency. Therefore, it follows that any opinion I may proffer in regard to the application of these regulations is just as binding on the FDA as any opinion offered by this eminent panel at this time.

[1] Subpart A was initially codified at 21 CFR Secs. 2.1-2.25 on March 22, 1977 (42 *F. R.* 15553). As part of a complete recodification of Subpart A, it was reorganized and recodified at 21 CFR 10. The new section numbers are provided in the footnotes. Sec. 2.19 is now 10.85.

I am certain that we are all interested in how this new mechanism for obtaining a formal opinion will work in practice. Looking at it from the regulated industry's point of view, it would be nice, each time we have difficulty in reaching a determination on a matter coming within an arguably ambiguous section of the Federal Food, Drug, and Cosmetic Act or the FDA's regulations, to be able to obtain a ruling quickly and simply from the FDA. Think of all the work and worry it would save us. On the other hand, looking at it from the viewpoint of the Administration, is it fair to require an agency, charged with the responsibility of protecting the health and safety of the public, to devote a substantial amount of its resources to answering the multiplicity of questions which can arise with respect to laws as broad and encompassing as the statutes under which the FDA has jurisdiction and which govern the conduct of industries as large and complex as the food, drug, cosmetic, device and associated industries?

Scope of the FDA's Functions

Let's look and see how the Administration has, based on its experience with the Act, drawn this line.

The FDA has had considerable experience with providing interpretive guidelines. Early advisory opinions, in the late 30's and early in the middle 40's, were frequently issued as trade correspondence (some of which has been formally revoked and which I would assume is largely outdated). From time to time, the FDA did issue decisions designated as advisory opinions.

More recently, Agency guidance has been codified in the Agency's compliance policy guides manual (a document which can often be a very valuable tool when attempting to interpret and apply the law and regulations to a new fact situation). Interpretive guidance has been provided in preambles to new regulations. Under Section 2.19, it is clear that these interpretive aids will be binding on the FDA.

Perhaps the most plentiful source of advice has come from direct contact and correspondence with various officials of the FDA charged with the responsibility of applying the law. Unlike the other mechanisms for obtaining the guidance of the Food and Drug Administration, the FDA takes the position that it will not be bound by the informal advice of Agency officials. The FDA takes the stance that such advice is not necessarily given in a systematic and co-

ordinated fashion and the FDA believes that the risk that such advice is incorrect has always been borne by the regulated industry.

Format for Requesting an Advisory Opinion

Now that we have a mechanism for obtaining formal rulings from the FDA, how does one set about seeking the Agency's counsel? The format for requesting an advisory opinion is set out in Section 2.19(b) of these regulations. Appropriately, the prayer for relief should be entitled "a request for an advisory opinion," directed to the FDA hearing clerk.

The regulations require a concise statement of the issues and questions raised and a complete statement of the relevant facts and law, whether favorable or unfavorable to the requestor's case. This will require, in some cases, the attachment of raw data, and copies of articles from pertinent reference sources. For reasons I will develop later, I would also urge that you explain in your request, if it would not be obvious otherwise, why the question raised presents a policy issue of broad applicability. Finally, if timing is an appropriate factor, I would request a response by a specific date and explain why it is essential that the question be resolved by the date specified. Of course, each request must be filed in quadruplicate.

What are the proper subjects of an advisory opinion request? It is easy to generalize. I believe that it is proper to ask the FDA for an interpretation or clarification of any present law, regulation or guides it may have adopted. Because, among other reasons, there is no guarantee of the opportunity to comment on an advisory opinion request, I would opine that the FDA will not generally entertain advisory opinion requests when the substance of the request would come within another formal mechanism requiring the filing of a petition which is normally listed in the *Federal Register*. I assume that the FDA will always wish to insure that those persons having a right by statute to comment or participate in the Agency's determination, prior to a final resolution of the matter, are not excluded.

These regulations state specifically that the Administration will not entertain requests for specific labeling or product approvals. The regulations also state that an advisory opinion request will not be granted on matters clearly governed by a prior opinion or present regulation. However, in the latter instance, the net result will be

the equivalent of what the requestor seeks, and that is a formal statment of the Agency's position on the precise questions raised.

These regulations do not require that one seek the Agency's advice before engaging in the action which is the subject of the advisory opinion request. It is not improper to ask the Agency's advice with regard to present practices. Obviously in this case you should be certain that you do not invite something other than an advisory opinion. I am sure that a response which stated that your request is not the proper subject of an advisory opinion request—however, we are referring this matter to a United States attorney for action—would be rather unsettling.

It is clear, as far as the FDA is concerned, that the primary consideration, with regard to whether a question is deserving of an advisory opinion response, is whether or not the matter raised is one of general applicability. What does this mean? One thing it means is that the FDA has made a determination that it will devote its resources to respond to an advisory opinion request when its ruling will have significant precedential value. As one official has put it, a request raising an industry-wide concern is the *quid pro quo* necessary for the Agency to devote the time, manpower and resources necessary to respond carefully and systematically to such inquiries. There is merit in this view. However, I hope that the Agency will not lose sight of the fact that, from time to time, ambiguities and conflicts in the law or in the regulations will create isolated problems of significant concern to a regulated company or a small segment of an industry. These may not necessarily be problems having application to potentially large numbers of cases, but may certainly raise problems of importance from a monetary, health or safety viewpoint. In such cases, I hope that the Administration will not lose sight of the formal advice it gave in the preamble to Section 2.19 which states that "where a particular inquiry is of broad applicability or importance, the Agency will commit its resources to providing its best institutional judgment on a matter through an advisory opinion." I am certain that the public, the regulated industry and the Agency alike, wish to insure that the law is correctly interpreted and followed so that the public health and safety is protected and that consumers are not forced to bear undue costs, as a result of some of the vagaries which may arise in a body of law as complex and comprehensive as the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

Exceptions to Granting of Advisory Opinions

As I noted earlier, the FDA has taken the position that it will not grant an advisory opinion request on a matter related to a specific product, ingredient or labeling question. I would hope that where such questions may relate to a generic class of products, ingredients or labels, the Agency will entertain such questions.

Notwithstanding the fact that the matter raised is one of general applicability and would otherwise qualify for an advisory opinion request, Section 2.19 provides that the FDA need not respond where an opinion cannot reasonably be given on the matter involved. I assume that this exception would apply where the question is too indefinite or hypothetical and the subject matter is so complex that the opinion itself would have to be too qualified and general to be of any assistance. I would assume that situations may also arise where the question, though one of broad applicability, does not raise an issue significant enough for the Agency to devote the manpower required to develop a response. Obviously the FDA has responsibilities in addition to that of issuing advisory opinions.

The regulations also provide that the FDA may decline to issue an advisory opinion where it believes that the public interest would not be served. There may be instances where the precise issue raised by the request or an analogous matter will be pending before a court of law. In such circumstances, the FDA may very well determine that, since the issue is before the courts, it should await the court's determination, rather than issue an opinion which may be overturned.

Earlier I alluded to the fact that there is no guarantee of an opportunity to comment on an advisory opinion request. While such a request is a matter of public record, the FDA has advised that it will not file a notice of the filing of advisory opinion requests in the *Federal Register*. Furthermore, except when the response is published as a guideline or in a preamble to regulations, there is no requirement that the advice itself will be published in the *Federal Register*. Thus, it would appear that the opportunity to comment on a request or the FDA ruling may come after the fact. This may, to some extent, undermine the value of the right to comment. However, whether or not this will be the case depends on how widely these requests and opinions will be reported by the trade press.

Value of an Advisory Opinion

I have outlined the procedures for seeking the Agency's advice, but why seek an advisory opinion? An advisory opinion, when finally granted, will be the final ruling of the Agency. Action taken by the requestor or persons in a similar position in conformance with it will be insulated from legal action by the Agency, except in unusual situations involving an immediate and significant danger to health. (In those latter circumstances, the regulations provide that the FDA will take only civil enforcement action, contrary to the terms of its advisory opinions.) It is interesting to note also that the regulations provide that action undertaken or completed in conformity with an advisory opinion which has been subsequently amended or revoked shall continue to be acceptable except when contrary to a substantial public interest consideration or when the amendment or revocation states that continued action in conformance with the earlier opinion will be unacceptable.

Another reason for seeking an advisory opinion relates to Section 2.11(d)[2] of these new Regulations. Under this section, an advisory opinion will be considered to be final Agency action within the meaning of that section. In certain circumstances, such as where one has received informal opinions which indicate that following a contemplated course of action will run the risk of an enforcement action by the Administration and the matter is not free of doubt, obtaining a formal advisory opinion before engaging in the contemplated action, and then seeking court review, may be preferable to either foregoing the action altogether or engaging in it and risking substantial penalties.

Obviously there are going to be a great number of questions with which we will have to deal which cannot be the subject of a formal advisory opinion request. Where can you turn? The preamble to the regulations and the regulations themselves clearly leave the door open to seeking the informal advice of Agency officials. If it was not clear before, it is now clear that the FDA is taking the position that advice which is not given pursuant to Section 2.19 or which is otherwise issued as a guide or guideline shall not bind or otherwise obligate or commit the Agency to the views expressed.

[2] Now Sec. 10.45.

The FDA has consistently maintained an open-door policy. It is obvious that the Agency realizes the continuing need to keep the door open to two-way communication with the regulated industry and the public. I hope that the fact that it has been established by regulation that the informal opinions will not be binding on the Agency will not lessen the consideration and attention paid to such matters by officials of the Agency.

I read Section 2.19 of the regulations as cumulative, not exclusionary. When an advisory opinion request has been submitted to the Agency, I do not believe it is improper, at the same time, to seek an informal opinion. In circumstances where time is of the essence, and when, for reasons of the Agency's own priorities, a formal opinion cannot be issued within the time needed, an informal opinion which may indicate the way the final decision will go, will be invaluable.

As circumstances, science and regulations change, it will often be necessary to amend or revoke advisory opinions previously granted. The regulations state that notice of such change shall be given in the same manner in which the notice was originally provided for in the *Federal Register*. They further specify that this notice will be recorded as part of the file on the matter in the office of the hearing clerk. As I read these regulations, once you receive an advisory opinion, you will be apprised of any changes, no matter which method is followed, so long as you dutifully follow the *Federal Register*. This does not mean that others who have taken action in conformity with an earlier advisory opinion will necessarily be put on notice of any changes. Since it is possible that notice of such changes may not be published in the *Federal Register,* it will be incumbent upon those who rely on advisory opinions to regularly check the file in the hearing clerk's office.

Conclusion

I thought I would try to bring examples of some advisory opinion requests here. When I recently checked the docket I learned that none had yet been filed, which is not surprising considering the fact that most of us wait to act under new regulations until the Food and Drug Law Institute has laid it all out for us.

The regulations do provide that the Agency may, in its discretion, handle any request for an opinion as an advisory opinion request and I understand that a request has been or may soon be

filed on the issue of whether soft contact lenses are a drug or device. It is clear that this issue is one of general applicability, though I cannot say for certain whether there may be a more appropriate mechanism for raising this issue which would insure public comment before it is finally determined. You may want to follow the manner in which the FDA will handle this issue.

What does Section 2.19 really mean? It does not appear that Section 2.19 will serve to permit the regulated industry to obtain Agency rulings on the myriad of small problems which arise as products, ingredients, science, consumer needs and regulations change and develop. However, where the FDA believes the issue or problem has broad applicability or is important, it will provide a ruling. I do hope that this new provision will serve as an important adjunct to the prior practices of the Agency and that the Agency and its employees will continue to controvert that old saw about free advice, be it formal or informal. **[The End]**

COMMENTS SOUGHT ON NEW DRUG REGULATION PANEL REPORT

Information and views on the recommendations contained in the final report of the Review Panel on New Drug Regulations have been invited by the Food and Drug Administration (FDA). The report, now available from the Agency, concludes that, while the system of new drug regulation is fundamentally sound, the system's implementation procedure needs substantial improvement. The FDA, the report states, has been neither pro- nor anti-industry in its review and approval of new drugs. As directed by the Secretary of Health, Education, and Welfare, the Commissioner of Food and Drugs will review the Panel's recommendations and identify the actions he will take to implement recommendations with which he agrees. The Commissioner has also been directed to consult with public interest groups, consumer organizations, affected industries, and others in reaching his final decisions. So that the FDA will not have to delay action on programs already under development until all aspects of the reports and recommendations are complete, the Agency may, in the near future, implement or propose rules to implement certain Panel recommendations. The FDA will, however, consider for later action in response to its request for information and views any comments received. The last day for submission of comments is August 15, 1977.

CCH Food Drug Cosmetic Law Reporter ¶ 41,946

Public Hearings— A View From the Bar

By DANIEL R. THOMPSON

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THE PURPOSE OF THIS PAPER is an attempt to understand the Food and Drug Administration's (FDA's) recently finalized public hearing regulations, Subparts B and C.[1] This is a task that may sometimes seem comparable to deciphering the famous Rosetta Stone, which was written in Egyptian hieroglyphics and Greek. The FDA calls its modern equivalents "preambles" and "response(s) to comments," many of which appear to be written in some exotic language. It took many years to decipher the Rosetta Stone, and I suspect we may be facing a long period in learning to practice under the FDA's new hearing procedures.

I have been working for some months now under the old procedures contained in 21 CFR Part 2, Subpart F, which the FDA described, when proposing the new Subpart B in September of 1975, as "substantially out of date" (40 *F. R.* 40683), a comment I fully endorse. However, I will comment on the new rules, attempting to forecast which portions will work, which will not, and how they will work.

Let me begin by discussing, briefly, not the principal evidentiary procedures of Subpart B, but rather Subpart C, the Public Hearing Before a Public Board of Inquiry regulations. Subpart C was the first portion of the Administrative Practices and Procedures Regulations to be issued in final form, June 28th, 1976. In my judgment,

[1] On Tuesday, March 22, 1977, the FDA recodified the procedural regulations (42 *F. R.* 15553). The textual citations are outdated and the new section numbers are provided in footnotes. Subparts B and C are now Parts 12 and 13.

these regulations definitely fall into the category of regulations that probably will not work well.

In general, the Subpart C Public Board of Inquiry regulations provide what the FDA calls "an alternative to a formal trial-type hearing" in the form of "a scientific inquiry rather than a legal trial."[2] The justification for this alternative rests entirely upon two assumptions by the FDA.

The first of these is that lawyers are at best unnecessary, and sometimes a handicap, to searching out the truth and ascertaining the facts. As the Agency puts it, "(a)ccordingly, . . . there will be little, if any, need for participation by attorneys in the proceeding."[3] Similarly, the FDA seeks to preclude "other legalistic procedures," including one such procedure our founding fathers thought worthy of embodying in the Constitution, the right to confrontation and cross-examination.

The second erroneous assumption underlying Subpart C is that scientists, in contradistinction to lawyers, are interested in nothing more than searching out the truth in a disinterested manner. The fact is that scientists have no fewer prejudices, are not necessarily less committed to particular sides of a controversy in advance of seeing the evidence, than any other professional person. They may line up on one side or another for beliefs of their own just as readily as anyone else.

Moreover, scientific truth is no easier to identify than legal truth. Appropriately, scientists are not able to say without qualification that a particular substance or product is safe or not safe, that a test is well-designed and provides useful information or not, or that particular types of testing are necessary or not. Regulatory decisions obviously involve a mix of science, law and public policy, and while it is understandable that the FDA would seek a relatively quick, informal solution to the question of hearing format, I believe that limiting the participants to trained scientists will not necessarily result in satisfactory regulatory decisions.

Board of Inquiry Approach

Aside from the fact that I find these underlying assumptions to be incorrect, its procedures leave much to be desired. Let's begin with the necessity for such an approach. Subpart C procedures can be invoked in three situations: When the Commissioner decides this

[2] 41 *F. R.* 26636.

[3] 40 *F. R.* 40706.

is in the "public interest", when FDA regulations so provide, or when a party waives its right to an evidentiary hearing in favor of a Board of Inquiry and the Commissioner approves this choice.[4]

Under the first of these, there are no standards imposed as to when the Commissioner will invoke such a Board. Thus, the application of Subpart C is likely to be erratic and arbitrary, as evidenced by the fact that the Commissioner avoided the procedure entirely when he recently reviewed the Red-40 safety question. If there are no standards for the Commissioner's selection of cases, its use will not create public confidence in the procedure.

It is difficult to judge the utility of the second of these situations at the present time, since the preamble to the proposal notes that "no agency regulations currently provide for the right to a public hearing before a Board of Inquiry."[5] We must simply wait to see how the Commissioner implements this alternative.

Finally, in my judgment, a party challenging an FDA decision would be making a serious mistake in giving up the right to a formal hearing for the Board of Inquiry approach, since the procedures provided in Subpart C seem designed to limit a party's ability to expose weaknesses in the other side's case.

This begins with the selection process for the three-member Board, which is done by the Commissioner from lists submitted by the FDA Bureau, the petitioner, and other parties.[6] The weakness lies in the fact that from the lists submitted by the Bureau and the petitioner, the Commissioner selects only one member. The second member comes from the lists submitted by other parties, and the Commissioner selects the third member, who is the chairman.

This procedure will be acceptable when the Bureau has granted a petition which is then being challenged by another manufacturer or a public interest group, for example. In those circumstances, the Bureau and the petitioner could be in agreement, and one witness from their lists might make some sense. Presumably the second member would represent the opposition, and there would be a neutral chairman.

But it is unsatisfactory in the more common situation, where the petition is denied, and the petitioner is the party invoking the Board of Inquiry. Assuming a consumer group intervenes in such a proceeding, the Board would consist of one member from the Bureau

[4] Sec. 2.200(a)-(c) (now Sec. 13.1 (a)-(c)).

[5] 40 *F. R.* 40705.

[6] Sec. 2.202 (now Sec. 13.10).

of Foods and petitioner lists, one from the other parties' list, and one chosen by the Commissioner. It is quite possible that the petitioner would have had no member nominated by it on the Board. Moreover, in situations where only the petitioner and the Bureau are involved in a hearing, the effect of the regulations is to have a two-member Board.

It seems to me that it would have been simpler and more logical to have the Commissioner select one member from nominees submitted by those supporting the petition, one from those opposing, and a third member. I strongly suspect that actual practice under Subpart C will force some modification of the selection procedures.

Procedure of the Board

The second problem I see with the Board of Inquiry after the Board's selection is its procedures. While a number of these are also common to Subpart B formal evidentiary hearings, such as the requirement that a private party submit all damaging evidence on pain of losing his right to a hearing, several are unique to the Public Board procedures.

These include the lack of opportunity to challenge the admissibility of data or other information,[7] a flat prohibition upon raising objections while the opposing side is presenting its viewpoint,[8] and an effective preclusion of cross-examination, stemming from the fact that parties merely suggest questions to the Board to be asked of their opponents.[9]

The goal of such procedures is that, in the FDA's words, the "proceedings of a Board shall be conducted in the manner of a scientific inquiry rather than as a legal trial."[10] But we have learned through centuries of British and American legal experience that the testing of views and facts through confrontation is the most effective way to determine the truth. Scientific truths are no different from other truths in this respect. The FDA's efforts to remove the adversary procedure from what is, in fact, an adversary situation is misguided and unlikely to succeed in the long run.

With that brief treatment of Subpart C behind us, it is useful to discuss in some greater detail the Subpart B[11] procedures applicable to what the FDA denominates as formal evidentiary public hearings.

[7] Sec. 2.206(d) (now Sec. 13.30(d)).
[8] See footnote 7.
[9] Sec. 2.206 (c) (now Sec. 13.30(c)).
[10] Sec. 2.206(a) (now Sec. 13.30(a)).
[11] Now Part 12.

These apply to a wide spectrum of FDA actions, which are referred to in Section 2.100.[12] Most of these, however, involve the right to a hearing under 21 U. S. C. 371, the formal hearing section of the Federal Food, Drug, and Cosmetic Act.

Submission of Hearing Request

The FDA begins its hearing regulations with a rather restricted view of when a party has the right to such a hearing. While acknowledging that the Congressional intent in modifying Section 701(e) was to "require a hearing . . . upon receipt of objections and a request for a hearing" (40 F. R. 40698), the FDA adopts a posture which makes it difficult for a party to obtain a hearing.

This intention is implemented by substantial new provisions adding to the requirements that must be met before a hearing will be granted.[13] Thus, the statutory requirement that a party specify with particularity the parts of the order objected to, "stating the grounds therefore," is interpreted by the FDA to mean that a person must provide:

"a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held."[14]

In addition, the party must submit copies of any documentary material and a "summary of the nondocumentary testimony to be presented by any witnesses relied upon."[15]

There are, of course, statements in the preamble that a party need not reveal his entire case in his request for a hearing, but only so much as is necessary to show a genuine factual issue is present for resolution. Realistically, however, one would be extremely unlikely to hold back factual materials and expert testimony when he knows that the FDA would decide—according to criteria as yet unspecified—that he had not submitted enough to justify a hearing.

The practical pointer is that even greater importance rests upon drafting an effective request for hearing, with the greatest possible degree of specification for each hearing issue, since the FDA will deny any separate objection if sufficient facts are not pled in support of it,[16] even if other issues warrant hearings.

The material submitted must show that (1) there is a genuine and substantial issue of fact, and (2) that this issue can be resolved

[12] Now Sec. 12.1.
[13] Sec. 2.112 (now Sec. 12.22).
[14] Sec. 2.112(a)(5).
[15] Sec. 2.112(a)(5)(1)(11).
[16] Sec. 2.115 (now Sec. 12.28).

"by available and specifically identified reliable evidence."[17] Therefore, the moving party must identify with particularity, early in the proceeding, exactly what evidence will be sufficient to prove his case. This is a difficult task, indeed.

In addition, the factual issue to be resolved by this evidence must be adequate to justify the regulatory action sought, consistent with all statutory standards. Thus, there is a bias in the regulations in favor of summarily disposing of hearing requests.

There may be judicial review of the Commissioner's denial of a request for a hearing, or his partial denial as to some issues when he finds the issues severable from those on which a hearing is granted,[18] and the regulations specify what the content of the administrative record on appeal shall contain.[19]

Regulations Pertaining to Hearing

When a hearing has been ordered, the new rules provide for filing, within 30 days, of a "written notice of participation" in lieu of an appearance.[20] The notice must contain a statement of the party's interest, and a commitment to present evidence or testimony at the hearing. The intent behind these provisions appears to be to assure that all participants justify their presence in the proceeding.

The new regulations add broad authority to remove persons from participation in a hearing.[21] The FDA makes it clear that violation of provisions of the regulations, including particularly requirements or orders going toward submitting or disclosing information adverse to a person's case, may result in the person's losing his right to participate in the hearing. Insufficient participation in the hearing can also lead to imposition of this sanction.[22] In either case, there exists a right of appeal to the Commissioner,[23] but no provision for judicial review.

More serious than these requirements is the FDA's new requirement involving disclosure of data by the participants.[24] There are at least two major flaws in this section, one of which may well be of Constitutional proportions.

First this section requires the head of the Bureau involved to file the "administrative record" with the hearing clerk before the

[17] Sec. 2.113 (now Sec. 12.24).
[18] Sec. 2.115(d)(3) (now Sec. 12.28 (d)(3).
[19] Sec. 2.115(a).
[20] Sec. 2.130 (now Sec. 12.40).
[21] Sec. 2.131(g) (now Sec. 12.45(g)).
[22] See footnote 21.
[23] Sec. 2.131(g).
[24] Sec. 2.153 (now Sec. 12.85).

notice of hearing is published. This administrative record may not include all the documents that a party would have the Bureau designate; the Bureau head is to omit material which is, in his judgment, "not relevant" to the issues. In the absence of discovery rules, this may be the time for the party adverse to the government to exercise his Freedom of Information (FOI) rights.

The regulations do require that the Bureau head submit, along with a "narrative statement of his position" and the "type of evidence he intends to introduce in the hearing,"[25] all the data "unfavorable to his position. . . ."[26] If carried out this would indeed be a salutary change in FDA procedures. However, the comments to the regulation point out that this requirement:

"does not extend to documents reflecting the Agency's internal deliberative process, *e.g.*, documents expressing the point of view of agency employees . . . even though such documents are contained in an administrative file relating to a matter that is the subject of the hearing."[27]

The essence of this is that the FDA will reveal only "facts," not opinions, even though the distinction between the two may be slim or hard to make.

The second objection has to do with the obligation to disclose imposed on the moving party, and all other parties to the hearing. They must disclose all data detrimental to their position within 60 days of the hearing notice.[28] Failure to do so completely "shall constitute" a waiver of the right to further participation, and if done by the party requesting a hearing, shall waive his right to the hearing.[29]

There is at least one infirmity in requiring a person, on pain of losing his right to contest agency action, to submit all related factual data in his files adverse to his position. Making a person offer data showing, for example, why a given product should not be marketed as a condition to permitting him to market it could be a serious inroad into any reasonable concept of due process.

To illustrate, it is not at all unusual for a petitioner, in matters which may result in a hearing, to submit material to outside experts for purposes of evaluation. Should a particular expert report that there are deficiencies in any aspect of the presentation, presumably that would have to be disclosed to the FDA and whether the observation was valid or resulted from the use of deficient methods of analysis or poorly controlled tests. Here we could also encounter

[25] Sec. 2.153(a)(4).
[26] Sec. 2.153(a)(2).
[27] 41 *F. R.* 51714.
[28] Sec. 2.153(b).
[29] Sec. 2.153(d).

the thin line between fact and opinion; but where the sanction for guessing wrong is loss of the hearing, one is naturally hesitant to decide not to make such reports available.

Right to Cross-Examination

The FDA also seeks to further modify the adversary process by severely limiting the right to cross-examination. Two particular sections of the regulations do this. In one, the Commissioner requires "written cross-examination" as the usual procedure in FDA hearings.[30]

This means that witnesses will not be tested on the firing line where their demeanor, knowledge of the subject, and ability to deal with inferences from their remarks all can be tested. It tends to encourage the offering of a minimum of information useful to the cross-examining party.

Second, while oral cross-examination is not precluded, it will be granted only where the party shows (1) that in the absence of oral cross-examination the party will be unable "to adduce testimony required for a full and true disclosure" of the facts, and (2) that he "will be prejudiced" by denial of the request.[31] Such showings will have to be tied to the particular situation, and not simply reflect the general inadequacies of written cross-examination. They will be hard showings to make.

Moreover, the preamble indicates that *any* cross-examination, written or oral, is to be permitted "only when other means of developing the evidence are not sufficient."[32] In other words, cross-examination will be allowed only in sharply limited circumstances, set forth generally in Section 2.154(c). The hearing officer is to consider, in ruling on a request for oral cross-examination, whether: (1) permitting additional direct testimony would be preferable; (2) there are guarantees that the testimony may have been truthful; (3) the testimony of the party to be cross-examined is important to the factual issues; (4) any disagreement involves facts or inferences from the facts; (5) the testimony is related to the issues in the hearing; and (6) whether cross-examination would "expedite the hearing."

In my judgment, the person who should make these kinds of decisions is counsel for the adverse party, not the hearing officer. Such decisions as to whether the testimony can be answered by

[30] Sec. 2.154(b) (now Sec. 12.87(b)).
[31] Sec. 2.154(b)(1)(11).
[32] 41 *F. R.* 51715.

redirect or cross-examination, whether it was truthful, and whether it relates to the issues are matters for counsel's evaluation.

Unfortunately, it may take a considerable amount of experience and effort at trying to live with this approach to cross-examination before the FDA gives up and returns to more traditional procedures, if ever. We can trust, as well, the judgment and good sense of the hearing officer to lean in favor of the familiar forms of cross-examination. The point, though, is that a party should not be in the position of having to ask for, and justify, such a basic and necessary right as cross-examination.

My final negative criticism is that the regulations do not provide for usual discovery procedures. Possibly, the Commissioner believes that he lacks the authority to include discovery provisions absent some specific authority to do so. But if he may compel a private party to turn over adverse items in its possession, he may surely provide for the traditional and familiar forms of discovery, modified if necessary to suit the administrative rather than judicial hearing.

Indeed, permitting discovery would appear consistent with the announced purposes of these rules to further discover the truth through disclosure of evidence and positions well in advance of the actual hearings. Unfortunately, the provisions of the regulations provide no opportunity to probe the FDA's case except insofar as the Agency itself chooses to put it in the record. For example, there is no procedure for uncovering material in FDA files if that material consists of opinions. Permitting discovery would rectify this, and thereby substantially improve the hearing process.

Improvements Inherent in the New Regulations

While my comments have been largely critical of the new regulations, there are a number of improvements upon the existing regulations, and areas where the FDA has done a good job in spelling out procedures that have been in some doubt.

First, the regulations make explicit the fact that requesting a hearing is not a precondition of judicial review.[33] There may well be situations where a particular FDA action on a petition is influenced by legal considerations that the petitioner disagrees with, but where there are no disputed factual issues. In such circumstances, counsel could file objections but either not request a hearing, or expressly

[33] Sec. 2.116 (now Sec. 12.30).

waive it. The FDA's action on those comments then produces an order ripe for adjudication under Section 701(f) of the Act, without the need for going through a hearing process.

Second, I am inclined to believe that while oral cross-examination is vital to an effective fact-finding process, oral presentation of direct testimony may not be necessary. Written direct testimony may well expedite the hearing. Moreover, it encourages counsel to prepare and coordinate their case thoroughly, and makes available well in advance of cross-examination the opposing side's direct evidence. This should in turn substantially improve the quality of the cross-examination.

There are, of course, some defects in the procedure. In fact, counsel, rather than the witness, may end up having a greater hand in preparing the testimony than is common with oral direct. However, this is likely to result in testimony being focused more narrowly on the specific matters for decision.

Third, the regulations specifically state that the hearing officer can add to, or delete, issues as they are set forth in the notice of hearing. This is an important power because as the hearing progresses, additional issues may well come to the fore, and the parties should not be restricted to those issues formulated long ago. This is particularly true since the Bureau contesting the hearing normally determines what the issues will be. The possibility that these can be redetermined by an impartial hearing officer is most desirable.

Finally, the regulations generally strengthen the power of the hearing officer,[34] and expand the purposes of the prehearing conference.[35] Both these changes may contribute to a fairer hearing by giving the officer the authority to take actions that clearly will expedite the hearing.

One of the deficiencies of the old hearing regulations has been the FDA's repeated assertions that certain things cannot be decided by the hearing officer, but are instead matters for the Commissioner. This position has been asserted with regard to discovery, to obtaining government witnesses, and in several other situations. The FDA seems to have felt that it should not be bound by the hearing officer's concept of its obligations to live up to a fair hearing; perhaps the additional powers will be helpful in rejecting such assertions in the future.

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[34] Sec. 2.140—2.2, 144 (now Sec. 12.60, .62, .70, .75, .78).

[35] Sec. 2.158(a)(2) (now Sec. 12.92 (a)(2)).

Conclusion

In sum, there are benefits in these new regulations which should improve the hearing process. But there are four major areas where changes are, in my judgment, urgently needed. These are:

(1) the limitations on the right to a hearing, in particular the requirement that a party disclose virtually its entire case in order to justify a hearing;

(2) the requirement for submitting any unfavorable evidence without the right to exercise judgment, particularly in light of the substantial penalty (disqualification) if this is not done;

(3) the limitations upon the right of cross-examination; and

(4) the absence of discovery procedures in the regulations.

[The End]

MARKETING OF OTC DAYTIME SEDATIVES WILL BE DISCONTINUED

All over-the-counter daytime sedatives will be removed from marketing as the outcome of a rulemaking proceeding that the Food and Drug Administration (FDA) will begin this summer, according to FDA Commissioner Donald Kennedy. In a statement presented on June 21 to the Senate Subcommittee on Monopoly and Anticompetitive Activities, Kennedy indicated that the drowsiness caused by daytime sedatives presents a significant risk to users who need to be alert. The only antianxiety effect of daytime sedatives is the drowsiness produced by antihistamines, Kennedy stated.

In February of this year, the OTC Sedative and Sleep-Aid Panel concluded that OTC daytime sedatives present an unacceptable risk, but most members recommended that marketing of the products continue pending further studies. Kennedy stated that the FDA's adoption of the panel's minority position that the ingredients in daytime sedatives are not generally recognized as safe and effective does not preclude a reconsideration, based on additional evidence (if any exists), of the merits of the products. Kennedy stated that the panel majority will endorse the FDA's upcoming action.

CCH Food Drug Cosmetic Law Reporter, No. 755

Committee or Commissioner

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Subpart D of the FDA's Procedural Regulations[1]

ADVISORY COMMITTEES in some form have existed at the Food and Drug Administration (FDA) and its predecessor agencies for many years—at least since 1897 when Congress, in its wisdom, established the Board of Tea Experts who meet once a year to provide advice on which teas are fit for consumption in the United States. It is only relatively recently however that the number and types of advisory committees have grown substantially; now there are advisory committees providing the Agency with advice in nearly every area of its authority, from over-the-counter (OTC) drugs to radiation standards for color televisions.

Both Congress and the Agency have reacted in somewhat contradictory fashion to this proliferation of committees. On the one hand, Congress has often criticized the FDA's reliance on advisory committees as a subterfuge by which the Agency can delay taking regulatory actions and shift the responsibilities of decision-making to others. On the other hand, Congress has, on several occasions, most recently in the Medical Device Amendments,[2] required the FDA to set up additional advisory committees.

For its part, the FDA has viewed committees as a method for obtaining advice from leading experts on important regulatory matters, but has not hesitated to disregard their advice when the advisory committee's views differ from the Agency's.

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[1] On Tuesday, March 22, 1977, the FDA recodified the procedural regulations (42 *F. R.* 15553). The textual citations are outdated and the new section numbers are provided in footnotes. Subpart D is now Part 14.

[2] P. L. 94-295 (May 29, 1976).

In order to place some limits on the growing number of *ad hoc* committees providing advice, not only to the FDA but at all federal agencies, Congress in 1972 passed the Federal Advisory Committee Act (FACA).[3] The Act defines advisory committees and their functions and obligations, and requires a finding before an advisory committee is established, that its establishment is in the public interest.

Procedural Regulations

The FACA defines an advisory committee as any group "established or utilized in the interest of obtaining advice or recommendations," and provides that any group meeting that definition must comply with the terms of the Act, including obtaining a charter defining its purpose from the Office of Management and Budget (OMB), conducting periodic meetings, and, except in very limited circumstances, conducting its meetings in the open. While the statutory definition seems rather straight-forward, it has given rise to a number of questions. If, for example, the FDA meets with an industry group on a pending regulatory matter, and the industry group, as it is likely to do, makes certain recommendations to the Agency on what it should do with its pending regulatory matter, has that group acted as an advisory committee? Are Department and OMB clearance and public meetings and transcripts therefore necessary? The answer is, it depends.

In *Food Chemical News v. Davis*,[4] the Bureau of Alcohol, Tobacco and Firearms (BATF) met informally with representatives of consumer groups and the alcoholic beverage industry to discuss labeling proposals, prior to the appearance of any proposal in the *Federal Register*. The meeting was closed to the public. Food Chemical News sued, claiming, that the meetings were advisory committee meetings and had to be open. The court ruled in favor of Food Chemical News, holding that the industry and consumer groups were advisory committees, and prohibited BATF from holding further meetings behind closed doors.

On the other hand, in *Consumer Union v. HEW*,[5] a trade association requested a meeting with the FDA to discuss an industry sponsored voluntary cosmetic safety review program. Consumer Union sued, claiming that the trade association was acting as an agency advisory committee whose meetings had to be open. The court

[3] P. L. 92-463 (Oct. 6, 1972).
[4] 378 F. Supp. 1048 (DC DofC 1974).
[5] 409 F. Supp. 473 (DC DofC 1976), appeal pending.

denied Consumer Union's claim, noting that the FDA had not called the meeting to discuss a pending regulatory matter, and, in fact, the Agency was merely reacting to the trade association initiated and administered program.

The procedural regulations at 21 CFR 2.300[6] clarify this situation. As a general rule, an advisory committee is any group that is not composed solely of federal government employees that meets regularly at the Agency's request to provide advice or recommendations. Meetings called on an *ad hoc* basis at the request of outside parties to provide the FDA with data or information or to seek the FDA's advice are not advisory committee meetings. Between these two clear-cut positions are many other situations which may be deemed to be advisory committee meetings. Generally speaking, routine meetings or discussions between the Agency and outside parties are not advisory committee meetings, and the regulations so provide. However, since important consequences can flow from being found an advisory committee, I would suggest checking the regulations before meeting with the Agency, particularly if those meetings are to be on any regular basis.

The regulations at Section 2.340[7] list the standing advisory committees that have been established by the FDA, have received OMB charters, and meet regularly to provide the Agency with advice on a wide range of matters. Some of these committees, like the device classification panels, have been established by law; others, like the OTC panels, have been established by the Agency to assist in the resolution of particular problems. It is important to keep in mind that these committees provide advice but their advice is not legally binding on the Agency, which retains under the law ultimate responsibility for decision-making. Nevertheless, these advisory committees do have vast influence, often outside the FDA, on other agencies, the courts and the public.

Selection of Committee Members

Who serves on these advisory committees? There are several answers to this question, depending on the type of committee involved. As a general rule, the regulations make clear that the advisory committees are to consist of a fair cross-section of views on any particular matter. Committees which advise the FDA on policy, such as the National Food and Drug Advisory Committee, are com-

[6] Now Sec. 14.1.

[7] Now Sec. 14.100.

prised of members representing different interests, such as manufacturers, consumers, and agricultural interests. However, insofar as technical advisory committees are concerned, Section 2.330[8] requires that voting members of the advisory committee be cleared as special government employees, who have no personal financial stake in the outcome of any matter and have no significant relationship to the manufacturer or seller of a product regulated by the FDA. As a practical matter, this means that voting members of technical advisory committees cannot come from industry, but must come from the academic or medical communities. The regulations also provide for non-voting industry and consumer liaison members. The regulations provide that non-voting members are not to represent their particular company or organization, but rather should represent all interested persons within the class they have been chosen to represent. Non-voting consumer members have access to trade secret data only if they are cleared as Special Government Employees. The regulations provide that non-voting industry representatives are not to be given any access to trade secret data under any circumstances to avoid even the appearance of potential conflict of interest.

Sections 2.331 and 2.332[9] outline the procedures used by the Agency for nominations of voting and non-voting advisory committee members. Given the importance advisory committees have assumed at the FDA, I would strongly suggest that if you are interested in the work of a particular committee, you utilize these procedures to participate fully in the selection process.

Grounds for Closed Meetings

Advisory committees present a couple of problems to industry in addition to the usual one of convincing the committee of the merits of a particular position. Not so long ago, a good portion of advisory committee meetings were closed to the public; recently, however, in response to court decisions and a change by Congress in the FACA, the grounds for closing advisory committees have been sharply reduced. The regulations, in the Preamble and in Section 2.318[10] spell out the grounds for closing an advisory committee meeting. As a general rule, they will be closed only for the review of certain draft regulations, where open meetings would result in the unwarranted invasion of personal privacy, where investigatory files are to be discussed, and for the discussion of trade secrets and confidential com-

[8] Now Sec. 14.80.
[9] Now Secs. 14.82 and 14.84.
[10] Now Sec. 14.27.

mercial information. They will not be closed for general discussions of procedures or requirements applicable to classes of products or the presentation of any other data. The most important change from previous FDA procedure is that committees may no longer be closed during their deliberations.

The decision to close a meeting must be made by the Commissioner with the concurrence of the Chief Counsel's office. If you believe that data you wish to present to an advisory committee is trade secret data, do not simply show up with it at the meeting and expect the session to be closed at your request. Instead, as soon as you know that your product is to be discussed at an upcoming advisory committee meeting, you should consult the Agency's FOI regulations[11] to see if any data you wish to discuss are entitled to trade secret protection. If it is or if there is a question about it, you should contact the Agency employee on the committee, and explain the nature of your problem. Get a ruling in advance, with enough time for the Agency to publish a notice in the *Federal Register* explaining the reasons for closing the meeting, as it is required to do by the regulations and the law.

It should be noted that the regulations require that all advisory committee meetings be transcribed. While the FDA will not release the transcript of closed portions of meetings, it will release minutes of closed meetings. It is always possible that litigation seeking the release of the transcripts will ensue.

Scope of Committee Authority

Another problem that has arisen with respect to advisory committees concerns the tendency of some of them to exceed the strict letter of their authority, as set out in their charters, and take on issues which may not be directly before them. One recent example has been the OTC panels where individual panels have extended their review beyond labeling and have gotten into advertising as well. The implications of such action for the pending Federal Trade Commission Trade Regulation Rules on OTC drug advertising is fairly obvious.

The regulations provide that where a person feels that an advisory committee has exceeded its authority or acts improperly in any way, he may petition the Commissioner, under Section 2.319.[12] If the Commissioner determines that there was a violation, he shall

[11] Now Part 20.

[12] Now Sec. 14.7.

grant "appropriate" relief. It is somewhat difficult to imagine how "appropriate relief" will be translated into actual practice. You should, however, be aware of the procedure, and utilize it where you feel an advisory committee has acted improperly.

In summary, advisory committees operate in nearly every area of the FDA's activities; if you have any significant dealings with the Agency, you will find yourself before one sooner or later. In order to protect your rights, and make the most effective presentation of your views, you should become familiar with Subpart D.

Subpart E

Subpart E[13] provides the framework for public hearings before the Commissioner. Such hearings are essentially legislative in nature—that is, they permit interested persons to testify before Agency officials on matters of interest without any of the trappings of a judicial proceeding. There is no judge, no rules of evidence, no objections and no cross-examination. You simply state your case, and answer whatever questions the Agency officials conducting the hearing might have. This type of hearing is really sort of an oral version of notice and comment rulemaking.

The regulations provide that a public hearing is available in three situations:

(1) Where the Commissioner determines such a hearing is in the public interest. This is not likely to occur in a dispute between the FDA and a company over a particular product. It will most likely occur where an issue has broad public policy or health consequences. The recent good laboratory practices hearing, which I understand was well received, is an example of this situation, as is the upcoming hearing on the impending saccharin ban.

(2) Where specific regulations require it. Currently, the only regulations requiring a Subpart E hearing are the OTC regulations which provide that after the panel issues a report, but before the Agency takes final action on it, the report must be the subject of a Subpart E hearing.

(3) Where a party entitled to a formal Subpart B hearing *waives* that right.

[13] Now Part 15.

A Subpart E hearing will be granted only if all of the parties entitled to a formal hearing have waived that right. Like Subpart B,[14] the granting of a hearing stays the regulation in question. Unlike a formal hearing, however, a Subpart E hearing is quick, lasting a few days at the most, and the Agency will not introduce any evidence itself.

Given the Agency's reluctance to hold formal hearings, due in part to the massive expenditure of time and resources involved, you may be more likely to get a Subpart E hearing. While you lose some of the procedural protections afforded by formal hearings, such as the right to require the Agency to affirmatively make its case before, and the benefit of a decision by, an independent Administrative Law Judge, Subpart E does provide interested parties with the ability to state their case directly to Agency decision-makers, who are often isolated from your real concerns.

A Subpart E hearing is initiated by notice in the *Federal Register*. In addition to stating time and place of hearing, the notice will define its scope. In some cases, such as review of OTC monographs, the hearing will be limited to an already compiled administrative record.

The hearing is presided over by the Commissioner or his designee and other FDA personnel. Witnesses may bring any other person with them and submit written comments for inclusion in the record. The record is kept open for 15 days after the hearing, so that you may submit additional written material addressing any issues that may have arisen at the oral hearing.

As stated, the hearing is informal. No questions from the audience are permitted; the only questions are from FDA personnel.

Because Subpart B is more traditional, there is no doubt a reluctance to use Subpart E. However, it should not be ignored. There will certainly be situations where you feel your interests are best served by quick, direct presentation of your case to Agency decision-makers without need for the blizzard of paper and complex legal procedures that accompany more traditional hearings at the FDA. **[The End]**

[14] Now Part 12.

The FDA's New Forms of Public Hearing— Choosing Among the Alternatives

By JOEL E. HOFFMAN

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ONLY ONE TYPE of public hearing is expressly authorized by the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act (APA)—the formal evidentiary hearing, presided over by an independent Administrative Law Judge. The merest mention of this process reduces most staff members of the Food and Drug Administration (FDA) to a state of pathological terror, as if they personally had been frightened at the moment of birth by a horror movie contraption created from living, vitamin-fortified peanut butter.

This creates something of a dilemma for the FDA. The statute requires that contested factual issues presented by a variety of Agency proposals be resolved through a public evidentiary hearing. No amount of official rhetoric claiming broad authority to dispense with hearings can overcome that fact, as some courts have been willing to recognize.[1] Even where formal evidentiary hearings arguably are not required, there are limits on the Agency's authority to proceed without any hearing at all.[2]

Alternative Forms of Hearing

The new procedural regulations promulgated by the FDA contain, in Subpart B, extensive provisions to govern formal evidentiary

[1] *USV Pharmaceutical Corp. v. Secretary of HEW*, 466 F. 2d 455 (CA DofC 1972); *National Nutritional Foods Ass'n v. FDA*, 504 F. 2d 761 (CA-2 1974); *Edison Pharmaceutical Co. v. FDA*, 513 F. 2d 1063 (CA DofC 1975).

[2] See *Rutherford v. United States*, 513 F. 2d 1137 (CA-10 1976).

hearings. In addition, however, three novel alternative forms of hearing are established: the public board of inquiry in Subpart C, the public advisory committee in Subpart D, and the public hearing before the Commissioner in Subpart E. Taken together, they seem intended to provide a three-pronged escape route from the FDA's dilemma.

First, Subparts C, D and E provide decision-making mechanisms which the FDA evidently hopes the regulated industries (and perhaps consumer interests) will find more promising than the formal evidentiary hearing.

Second, the FDA implies in the preamble to the proposed regulations that an alternative form of hearing may be granted under particular circumstances. This would occur when a Subpart B formal evidentiary hearing is denied, and the private parties first waive their right to litigate the denial and thus save both sides from the risk of an all-or-nothing decision in the courts. In fact, the rule, as originally proposed by the FDA, was subject to the interpretation that only if all rights to challenge the denial of a formal evidentiary hearing were waived would the FDA even consider a request for an alternative form of hearing.

The American Bar Association's (ABA's) Section of Administrative Law filed comments objecting to this apparent prerequisite of waiver of judicial review. The final preamble to the regulations turns aside the ABA's objection by noting the FDA's discretion to grant an alternative form of hearing after a formal evidentiary hearing is requested and denied,[3] whether or not judicial review of the denial is sought. Neither the preamble nor the regulation states whether discretion will be exercised just as freely as when the petitioning party waives his claim of entitlement to a formal evidentiary hearing. The inducement to opt for one of the alternative forms in the first place is therefore not wholly absent.

Third, as an apparent *raison d'etre* for providing alternative forms of hearing, is the claim that such proceedings would be legally sufficient in some circumstances where a hearing cannot wholly be denied. The preamble to the proposed regulations asserts that "[u]nder recent case law, it is clear than an alternative form of hearing could, in many instances, be required even without the consent of the parties."[4]

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[3] Preamble to Subpart C, 41 *F.R.* 26636, at 26638 (June 28, 1976).

[4] 40 *F.R.* 40682, at 40701 (Sept. 3, 1975).

How this can be squared with the requirements of the APA, which was enacted precisely for the purpose of imposing a uniform hearing procedure in all cases "required by statute to be determined on the record after opportunity for an Agency hearing,"[5] is nowhere explained. This need not trouble us today, however, as hope evidently springs eternal in the FDA's collective breast; for the time being the Agency professes reliance on a supposed likelihood that parties "would readily agree to the form of hearing that would resolve the issue most expeditiously."[6]

Choosing The Appropriate Form

Whatever the reasons for the FDA having established the new alternative forms of hearing, in every proceeding before the Agency, their availability will present the question of which one to pursue. My assignment is to discuss the factors which should go into this choice.

Suppose that one fine morning your *Federal Register* includes a notice of opportunity for a hearing, or a so-called "final" regulation on which a hearing may be requested, that threatens your interests. How to decide which of the four available forms of hearing to request? What are the benefits and disadvantages of each form?

Unfortunately, at this early stage of life under the new regulations, there are very few data on which a decision could rationally be based, and most of the available evidence is anecdotal in the extreme. Only a few general guidelines can be suggested.

It seems clear that your choice of a form of hearing must depend heavily on the facts of the particular case. *First,* be certain that you have identified your objective—is it to win before the Agency, or are you counting on subsequent success in court? *Second,* what is the nature of the issue in your case—is it a narrow factual dispute, or a question of working out a desirable regulatory policy? Is the issue scientific, or one of "who did what to whom?" And, if the issue is scientific, is the science with you or against you? *Third,* what is the context of the case—are you off the market and trying to get on, or on the market and trying to stay there? Are there opponents in addition to the Agency? Are they consumer groups or are they competitors?

[5] 5 U.S.C. Secs. 553, 554.

[6] 40 *F.R.* 40682, at 40701 (Sept. 3, 1975) (preamble to proposed Sec. 2.117, now 21 CFR Sec. 12.32).

The decision as to which form of hearing to choose should be made on the basis of the total mix of all these factors and more. In most cases, no one factor will be determinative. Experience under each of the new procedures will doubtless require constant reevaluation of their probable risks and advantages in the many different factual settings that will arise.

On the virgin face of the new regulations, each of the four available forms of hearing has some unique characteristics making it more attractive for some kinds of controversies than for others. Let me describe a few of the judgments you might make in this regard.

Formal Evidentiary Hearings

The first decision to be made in responding to a notice of opportunity for hearing or to a regulation subject to objection is whether to insist on your right to a Subpart B formal evidentiary hearing as opposed to one of the new alternative forms. The crucial factor here is the likelihood that, in your case, the FDA could make a denial stick if the denial were challenged in court. This is because, if history is any guide, the odds are overwhelming that a request for a formal evidentiary hearing will be denied.

In 1973, soon after the quartet of Supreme Court decisions that so greatly expanded the FDA's power to deny hearings,[7] Peter Barton Hutt explained at another Food and Drug Law Institute conference that the reason no hearings had been held on new drug withdrawals up to that time was that only the "absolutely clear-cut ineffective" drugs had thus far been considered. Things would have been different, he said, if the Agency had begun its review of pre-1962 drugs with the "probably effective" drugs.[8]

That was in 1973. Today the FDA still has failed to grant a single evidentiary hearing in a new drug matter except when ordered to do so by a court.[9] Food and color additives have fared better.

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

[8] *1973 Court Cases Involving Rulemaking: Implications for Federal Regulation—Morning Question and Answer Session*, 28 FOOD DRUG COSMETIC LAW JOURNAL 718, 725-26 (Nov. 1973).

[9] Hearings have been granted only on Lutrexin (see *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973)); DES for beef cattle (see *Hess & Clark v. FDA*, 495 F.2d 975 (CA DofC 1974)); Corthyrobal (see *Edison Pharmaceutical Co. v. FDA*, 513 F.2d 1063 (CA DofC 1975); and Laetrile (see *Rutherford v. United States*, 542 F.2d 1137 (CA-10 1976)).

but only where effectively removed or kept from the market pending the requested hearing.[10]

If you conclude that the FDA is likely to prevail against a procedural challenge to the denial of an evidentiary hearing, the comparative risk/benefit calculus in choosing a form of hearing is heavily weighted toward opting for one of the alternative forms. It would be hard to imagine a situation where some kind of hearing would not be better than no hearing at all.

This does not apply, of course, if you are a petitioner seeking FDA approval of your product, and the opportunity for a hearing is being offered not to you but to adverse parties seeking to prevent a favorable outcome. The regulations do not give a petitioner like you a veto if the objecting parties are willing to accept an alternative form of hearing. The regulations contain an undertaking, however, to take into account the views of an affected petitioner as to the appropriateness of granting an alternative form of hearing.[11] In these circumstances, it may be worthwhile to insist that if a hearing is to be held at all, only the hated formal evidentiary hearing will do.

As noted above, the regulations hold out an opportunity to request your second choice after a formal evidentiary hearing is denied. It therefore might be suggested that if a formal evidentiary hearing would in fact be preferable to any of the alternative forms, the probability that the FDA could defend the denial of a hearing should not affect your choice. This would be a reasonable conclusion in situations where the FDA is genuinely in doubt as to what its final determination of the merits should be, or is anxious to legitimize its intended action by developing support from a prestigious board of inquiry or advisory committee.

In other situations, however, the FDA is likely to agree to one of the alternative forms of hearing only as a compromise, to avoid litigation over a denial. A post-denial request for an alternative form may well be viewed by the Agency as no more than a "heads I win, tails you lose" proposal. In short, if you want to live by the sword, be prepared to die by the sword.

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[10] See *Monsanto Co. v. Gardner*, No. 77-1245, (CA DofC), decided March 18, 1977 (reversing the denial of a hearing prior to revocation of a food additive regulation for acrylonitrile beverage bottles).

[11] 41 *F.R.* 51706, at 51711 (Nov. 23, 1976) (preamble to Sec. 2.117, now 21 CFR Sec. 12.32).

Even if in your case a formal evidentiary hearing would be granted, if not by the FDA then by a reviewing court, you must still decide whether to request one of the alternative forms. This requires an analysis of the comparative strengths of the four possible choices in light of the facts of your case.

The formal evidentiary hearing is of greatest value when the data relied upon by your opposition are suspect, and cross-examination of the person responsible for conducting a study might show unreported departures from the protocol or lapses in adherence to approved techniques. It may be true, as the FDA was once fond of saying, that no amount of examination or cross-examination can make an inadequate or uncontrolled study into something it is not.[12] But even a modicum of well-conducted cross-examination can help determine whether a study was, in fact, adequate and well-controlled as advertised.

Similarly, conclusions purportedly drawn from data may depend on unstated premises or faulty reasoning not apparent on the face of a report. Or they may have been drawn in ignorance of other data that would require the conclusions to be changed. Where these are the dominant issues in your case, the formal evidentiary hearing may be the best method for resolving them.

An inevitable disadvantage of the formal evidentiary hearing, on the other hand, is that the Administrative Law Judge is at best a generalist in science and medicine. To be sure, this can be a great strength of any fact-finding process—that a party can prevail only by persuading an intelligent, inquisitive human mind without preconceptions and with no unstated but unprovable assumptions. And it is worth remembering that if you cannot convince an Administrative Law Judge because he or she is insufficiently expert, you may have even more difficulty convincing the federal district court or court of appeals.

Public Board of Inquiry

In many cases, however, the facts are so technologically complex, and so sophisticated an approach is required, that a public board of inquiry chosen under Subpart C would be more likely than an Administrative Law Judge to reach a desired result. This opportunity can probably be realized under the new regulations without

[12] See *Upjohn Co. v. Finch*, 422 F. 2d 944 (CA-6 1970).

substantially foregoing the benefits of the adversary hearing as a fact development process.

The new regulations expressly contemplate that public boards of inquiry will "function as tribunals."[13] It is true that the regulations also state that "the proceedings shall be conducted in the manner of a scientific inquiry rather than as a legal trial."[14] But even cross-examination (although carefully not so labeled) is authorized by Subpart C where the board of inquiry chairman "determines that this will facilitate resolution of the issues."[15]

The principal difference between a public board of inquiry and the traditional evidentiary hearing, in terms of procedure, seems to be that under Subpart C "[n]o participant may interrupt the presentation of another participant for any reason."[16] But this would be avoided in a well-run formal evidentiary hearing as well, if direct testimony were required to be submitted in writing in advance, and if all objections to admissibility were required to be made in the same manner. By virtue of the APA, moreover, the rules of evidence are inapplicable in a formal evidentiary hearing before an Administrative Law Judge.[17] As for objections to admissibility under the APA mandate that "irrelevant, immaterial or unduly repetitious evidence" be excluded, there is a popular saying among some Administrative Law Judges that no one was ever reversed for letting something into the record.[18]

The fact that the members of a board of inquiry are scientists rather than lawyers will not in and of itself make the proceeding less adversary or even less formal. Similar tribunals, called Atomic Safety and Licensing Boards, are utilized by the Nuclear Regulatory Commission (NRC) in hearings on nuclear facility construction and operating permits.[19] Those proceedings are not the models of elevated scientific discourse for which the FDA seems to yearn. The usual adjudicatory procedures apply, and their value has been well proven even (or perhaps especially) where the triers of fact are scientific

[13] 41 *F.R.* 52148, at 52152 (Nov. 26, 1976) (preamble to Sec. 2.330(f), now 21 CFR Sec. 14.80).

[14] Sec. 2.206 (41 *F.R.* 26641 (June 28, 1976) now 21 CFR Sec. 13.30). See also 40 *F.R.* 40682, 40706 (Sept. 3, 1975) (preamble to proposed Sec. 2.206) ("[I]t is anticipated that there will be little, if any, need for participation by attorneys in the proceeding").

[15] Sec. 2.206(c), *supra* note 14.

[16] Sec. 2.206(d), *supra* note 14.

[17] 5 U.S.C. Sec. 556(d).

[18] See also Remarks of Administrative Law Judge Donald A. Campbell at the 1974 ABA National Institute on Federal Agencies and the Public Interest, 26 *Ad. L. Rev.* 504-10 (1974).

[19] See Sec. 191 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. Sec. 2241.

experts. As the Chairman of the NRC's Atomic Safety and Licensing Appeals Panel recently said:

". . . [T]he annals of NRC licensing proceedings are replete with instances in which either skillful cross-examination by counsel (or a technical interrogator) or questions posed by the board itself have brought to light serious infirmities in the foundation of the conclusions which have been reached by an expert on a matter of large safety or environmental importance. It might be added that, in some instances, the conclusions thus undermined were those of the NRC staff—as set forth in its safety evaluation report, final environmental statement or written testimony."[20]

Public Advisory Committee

Sometimes your goal in requesting a hearing may be not so much to prove a fact, or to document a conclusion, as to establish a scientific consensus in support of your position. Here, the public advisory committee may be the most appropriate procedural vehicle. Subpart D of the new regulations makes clear that, as required by the Federal Advisory Committee Act (FACA), the members of a public advisory committee must reflect a diversity of viewpoints on the subject of its advice.[21] A favorable advisory committee report should carry particular weight with the FDA (and subsequently in court) for precisely this reason.

Another consideration that might incline you to opt for a public advisory committee hearing rather than a public board of inquiry would be a need for familiarity with the regulatory background of your issue, or for continuity in dealing with a series of similar issues. The advisory committees utilized under Subpart D are likely to be the FDA's standing advisory committees, if only because of the FACA requirement that the creation of every new committee be justified. Although a public board of inquiry should be as expert as any advisory committee, its *ad hoc* character may give it difficulty in applying the regulatory perspective that comes with experience, as well as give you difficulty in bringing the members up to speed.

On the other hand, the advisory committee assigned to hear your case may have no members with expertise bearing precisely upon the particular issues involved. The membership of a public board of inquiry can be tailored precisely to fit the requirements of the case it is to hear.

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[20] "The Role of Atomic Safety and Licensing Boards and Appeal Boards in Reviewing NRC Staff Technical Conclusions," Remarks of Alan S. Rosenthal Before the Atomic Industrial Forum, Feb. 7, 1977.

[21] 41 *F.R.* 52148, at 52152 (Nov. 26, 1976) (preamble to Sec. 2.330(f), now 21 CFR Sec. 14.80).

Finally, there is the obvious tactical point that it would be disingenuous not to mention. The public board of inquiry has only three members, while an advisory committee is likely to include a significantly larger number of experts. You have that many more chances to persuade a majority when you are before a public advisory committee.

Hearing Before The Commissioner

The final form of a hearing offered by the new regulations in lieu of a formal evidentiary hearing is in Subpart E, called a hearing before the Commissioner. The first thing to be said about this alternative is that the hearing may not be before the Commissioner at all. The regulations are explicit that one or more staff members may be designated to hear the proceeding, except where a more specific provision requires the Commissioner to preside personally.[22] This was done in the recent good laboratory practices hearing held before senior officials of the Bureau of Veterinary Medicine, the Bureau of Medical Devices, and the Office of the Chief Counsel.

The preamble to Subpart E stresses that separation of functions—the separation of the decision-making function from the advocacy function of Agency staff—will not apply in hearings before the Commissioner or his designee.[23] This is necessary, the preamble explains, so that the Commissioner is not deprived of advice from the staff members "best informed about a particular matter." The principal advantage in a Subpart E hearing thus may be to bring out on the record, in the form of findings and conclusions forming a tentative Agency decision,[24] the detailed views and arguments of the staff members advising the Commissioner.

This opportunity may be highly important in a case where the factual controversy can be presented without cross-examination of either side's witnesses, and the policy component of the dispute predominates. Even where the Commissioner personally conducts the hearing, to have a tentative decision that can be tested and rebutted in a focused manner can add greatly to your chances of ultimately persuading the Agency of your position. Such a hearing before the Commissioner and two senior FDA officials was held on the tentative final monograph for over-the-counter antacid drugs,

[22] Sec. 2.403 41 *F.R.* 48262 (Nov. 2, 1976), (now 21 CFR Sec. 15.30).
[23] 41 *F.R.* 48258 (Nov. 2, 1976).
[24] See Sec. 2.117(f) 41 *F.R.* 51723 (Nov. 23, 1976), (now 21 CFR Sec. 12.32).

and reportedly gave the parties a good opportunity to focus the issues for the decision-makers.[25]

Conclusion

In this aspect, as well as many others that will arise in applying the new system of procedural options, one truth should always be kept in mind: It may be possible to get an agency temporarily reversed for errors in procedure, but history demonstrates that, on the merits, there is almost nothing an agency cannot do within the general area of its authority, sooner or later, if procedural foul-ups are avoided. When given your choice of procedures, the one to choose is inescapably the one by which a record can be created in your case that in the end is most likely to persuade the FDA of the soundness of your position. **[The End]**

NEW LABELS, WARNINGS PROPOSED FOR OTC PAIN RELIEF DRUGS

Major labeling restrictions, including significant warnings, for the two major over-the-counter pain-and-fever relief drugs, aspirin and acetaminophen have been proposed by the Food and Drug Administration (FDA). Changes recommended by the FDA's Advisory Panel on OTC Internal Analgesic and Antirheumatic Products include warnings against taking aspirin at the same time as certain prescription drugs or during certain months of pregnancy. Concerning acetaminophen, the Panel found no basis for claims that this ingredient is safer than aspirin and urged labeling to warn against the danger of liver damage from overdose. The Panel also proposed that the FDA prohibit all claims for relief of arthritis or rheumatism on aspirin products because consumers should not self-treat these diseases.

On the basis of these recommendations, the agency is proposing the conditions under which these pain drugs are generally recognized as safe, effective, and not misbranded. While noting that the proposal is intended to elicit comments from the public to assist the FDA in developing an official policy on these products, Donald Kennedy, Commissioner of Food and Drugs, predicted without qualification that the Panel's report will lead to more explicit labeling and essential new warnings that will make it easier for consumers to select and use pain-and-fever relief products without physician supervision.

Comments on the proposal must be filed by October 6, 1977; reply comments must be filed by November 7, 1977.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,971

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[25] See O'Keefe, Daniel F., "A Fine New Twist—A Brief Commentary on the Commissioner of Food and Drugs' First Oral Hearing," 29 Food Drug Cosmetic Law Journal 116 (March 1974).

VITAMIN/MINERAL RULES TO TAKE EFFECT IN 1979

The effective date of the regulations governing the labeling and composition of dietary supplements containing vitamins and minerals has been postponed by the Food and Drug Administration (FDA) until July 1, 1979. The National Nutritional Foods Association, the National Association of Pharmaceutical Manufacturers, and the Solgar Co., Inc., had petitioned the FDA for a stay of the effective date pending judicial review; a petition for review of the regulations and for a modification of the effective date, or in the alternative for a stay, has been filed in a U. S. court of appeals. In addition to requesting the stay, the petition to the FDA pointed out the lack of conformance between the effective date of the vitamin/mineral rules and the uniform effective date for food labeling regulations.

The FDA extended the effective date to conform to the uniform effective date, but did not grant the stay. The Agency said that if judicial review is still pending on July 1, 1978, the former effective date, petitions for further postponement of the effective date would be considered.

The new effective date should provide ample time for judicial review, according to the FDA, and for companies to bring their products into compliance if the rules are sustained. Voluntary compliance with the regulations is already permitted.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,969

ANIMAL DRUGS CONTAINING HEXACHLOROPHENE TO REQUIRE NADAs

Animal drugs containing hexachlorophene will require approved new animal drug applications (NADA). Topical preparations containing not more than 0.1 percent hexachlorophene as a preservative are not affected by the new rule promulgated by the Food and Drug Administration (FDA). The Agency stated that there is no adequate data to establish that such drugs are safe and effective and that there is no information on the potential risk to persons who administer animal products containing the drug at levels higher than 0.1 percent, who are exposed to animals on which these drugs have been used, or who consume edible products of treated animals. NADAs for hexachlorophene-containing drugs must be submitted to the FDA by September 29, 1977. The interim marketing of such drugs may continue until the application has been approved, has been found not approvable, or until an existing approved application has been withdrawn. Any hexachlorophene animal drug for which a NADA has not been submitted will be deemed adulterated after September 29.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,694

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