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Food·Drug·Cosmetic Law JOURNAL

Papers Presented at the Food and Drug Law Institute's Pharmaceutical Update V

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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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Milton A. Bass, a member of the law firm of Bass & Ullman, discusses the distinctions between substantive and interpretive regulations in relation to the FDA's use of its regulatory authority. Mr. Bass focuses on the *National Nutritional Foods Association v. Weinberger* decision and also reviews other cases which are significant to this topic. The article is titled "Is the Substantive-Interpretive Issue Really Dead?" and it begins on page 448.

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Is the Substantive-Interpretive Issue Really Dead?

By MILTON A. BASS

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IN *National Nutritional Foods Association (NNFA) v. Weinberger*,[1] the Court of Appeals for the Second Circuit ruled that actions by the Food and Drug Administration (FDA) under Section 701(a) of the Federal Food, Drug and Cosmetic Act were "substantive" and binding upon the public. In addition, the Court held that judicial review of these regulations was governed by the arbitrary or capricious standard found in 5 U. S. C. Section 706(2)(A). In light of this decision, the question as to the continued viability of the distinctions between substantive and interpretive regulations has been raised in many quarters. It is felt by some that the definitive ruling by the Second Circuit should close the book on the procedural and substantive

[1] *NNFA v. Weinberger*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 38,003, 512 F. 2d 688 (CA-2 1975). Efforts by the FDA to regulate vitamin, mineral and health food industries have recently spawned a whole series of cases involving the NNFA. See also *NNFA v. FDA*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 41,078, 491 F. 2d 1141 (CA-2 1974) and CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 41,191, 504 F. 2d 761 (CA-2 1974); *NNFA v. Weinberger*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 41,016, 366 F. Supp. 1341 (DC SD NY 1973) and CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 41,127, 376 F. Supp. 142 (DC SD NY 1974); *NNFA v. Schmidt*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 41,035, 367 F. Supp. 889 (DC SD NY 1973).

aspects of Section 701(a) Agency action under the Federal Food, Drug and Cosmetic Act.

Prior to analyzing this question, it is imperative that we define the terms under discussion. By substantive agency action, we mean rule-making under an express grant by Congress for the purpose of establishing regulations which have the binding effect of law. Under Section 701(e) of the Act, Congress has provided for such regulations with respect to numerous FDA activities. Incorporated into the grant of authority to the Agency are detailed and specific procedural and substantive protections to assure a full development of the factual issues involved, along with ultimate judicial review by a United States Court of Appeals under the "substantial evidence" standard.[2] Regulations issued under these statutory procedures are binding and, in enforcement actions brought by the Agency, these regulations have the force and effect of law.[3]

Agency Interpretations

On the other hand, by interpretive regulations, we mean agency interpretations of a statute or statements of policy as to factual matters which represent advisory opinions of the agency designed to inform the public as to how a particular statute will be enforced. By definition, these types of agency action are not binding on the courts and litigants can challenge their legal and factual validity in enforcement proceedings. This distinction has long been recognized by Congress, the courts and the commentators.[4] The crucial question with

[2] Sec. 701(f) and 5 U. S. C. Sec. 706 (2)(E).

[3] This proposition, although generally accepted, is by no means self-evident. See *United States v. Lord-Mott Co.*, 57 F. Supp. 128 (DC Md 1944); *United States v. Bodine Produce Co.*, 206 F. Supp. 201 (DC Ariz 1962). The binding nature of these regulations, however, is fully supported by the legislative history of the Act. See House Report 2139, 75th Congress, 3rd Sess. 1938 at p. 12, noting: "These regulations are not merely interpretive. They have the force of law and must be observed."

[4] See legislative history of Administrative Procedure Act, House Report No. 1980, 79th Congress, 2nd Sess., p. 18; Report of Attorney General's Committee on Administrative Procedure (1941); *Skidmore v. Swift & Co.*, 323 U. S. 134 at 140 (1944); *Gibson Wine Co. v. Snyder*, 194 F. 2d 329 at 331-332 (CA DofC 1951); *American President Lines, Ltd. v. Federal Maritime Commission*, 316 F. 2d 419 at 422 (CA DofC 1963); *O'Neill v. United States of America*, 281 F. Supp. 359 at 363 (DC Ohio 1968), aff'd. 410 F. 2d 888 (CA-6 1969); *Mateczak v. Secretary of HEW*, 299 F. Supp. 409 at 412, n. 4 (DC ED NY 1969); *Continental Oil Co. v. Burns*, 317 F. Supp. 194 at 200 (DC Del 1972); *Soriano v. United States*, 494 F. 2d 681 at 683 (CA-9 1974). See also Davis, *Administrative Law Treatise* Sec. 5.03-.05 (1958); 1970 supplement to Treatise Sec. 5.03-.04.

respect to determining the status of any agency action is the intent of Congress in enacting the specific regulatory provision under which authority is claimed by an agency.

The status of Section 701(a) Agency action has received surprisingly little judicial attention during the 37 years since the enactment of the statute in 1938. Undoubtedly, this was primarily the result of the long held view that interpretive regulations were, in any event, not subject to pre-enforcement judicial review. Instead, it was believed that they must await a concrete factual setting for adjudication in enforcement proceedings.[5] Consequently, issues as to the validity of Section 701(a) regulations could generally arise only in a context where a litigant was clearly entitled to a trial. Nevertheless, there is one known instance where this issue was presented and determined. In *United States of America v. Everett Fisheries, Inc.*,[6] the Court was presented with this issue. This case was a criminal action alleging that Everett Fisheries had violated the Act because it did not comply with the provisions of an interpretive regulation at 21 CFR 128a, subpart A which set forth detailed and precise requirements for the manufacturing and processing of smoked fish. The court ruled:

"[I]n each case the government must present its evidence so as to persuade the finder of fact *and the defense must have its opportunity to dispute* and that the judgment exercised by the Food and Drug Administration in promulgating regulation 128a, Subpart A is not to be given automatic and decisive effect in the case; rather, that the regulations in question are to be given just such effect as the trier of fact may consider that they deserve on the basis of the evidence in the case." (Emphasis supplied.)

This approach was thoroughly consistent with the notion that Section 701(a) regulations are *interpretive* as outlined above.

Pre-enforcement Judicial Review

The nature of the problem was completely changed by the decision of the United States Supreme Court in *Abbott Laboratories v. Gardner*.[7] That decision allowed pre-enforcement judicial review of

[5] See *Helco Products Co. v. McNutt*, 137 F. 2d 681 (CA DofC 1943); *Abbott Laboratories v. Celebrezze*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,206, 352 F. 2d 286 (CA-3 1966); *American President Lines, Ltd. v. Federal Maritime Commission*, 316 F. 2d 419 at 422 (CA DofC 1963).

[6] This is an unreported decision in 72 Cr. 109 (DC WD Wis, May 30, 1973), but referred to in *NNFA v. Weinberger*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 41,127, 376 F. Supp. 142 at 147, n. 7.

[7] 387 U. S. 136 (1967).

FDA action under Section 701(a). The Agency argued strenuously that such action was only interpretive and therefore not subject to judicial challenge. The Supreme Court ruled that, since the Agency action placed affected members of the public in the dilemma of either complying or risking severe enforcement sanctions, a sufficient controversy existed to allow judicial review.[8] As a result of *Abbott Laboratories,* new vistas of judicial review of agency action have been opened. Increasingly, agency pronouncements, including those under Section 701(a) of the Federal Food, Drug and Cosmetic Act, have been subjected to pre-enforcement judicial challenge. In the absence of the inherent right to a trial of an enforcement setting, the potential for a narrow scope of review was easily within the range of judicial consideration.

It is interesting to note how the vitamins A and D controversy developed along these lines. On December 14, 1972, the FDA published a notice in the *Federal Register* proposing prescription requirements for vitamins A and D in products which contained the vitamins in excess of 10,000 and 400 international units respectively. The Agency claimed that unspecified high dosages of the vitamins were known to be toxic and cited a list of articles in the literature regarding these vitamins.[9] The proposal evoked massive opposition from both industry and consumers. Analyses of the literature were submitted, all concluding that the levels proposed were unsupportable. Support of the Agency position was limited to letter endorsements without scientific analysis. Nevertheless, the Agency, relying on these endorsements from certain prestigious organizations and on its prior opinion, finalized its prescription requirement to take effect on October 1, 1973.

Despite the absence of substantial evidence to support the action, both the District Court for the Southern District of New York and, more recently, the United States Court of Appeals for the Second Circuit have deferred to the Agency's claimed expertise. The means by which this result was achieved was the holding that Section 701(a) regulations are substantive and subject to review only under the "arbitrary or capricious" standard of 5 U. S. C. Section 706(2)(A).

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[8] Interestingly enough, the Court stressed that factual issues were not involved in that case.

[9] 37 F. R. 26618 (Dec. 14, 1972).

Outside Experts

It is readily apparent that the consequences of this decision are enormous. If the Agency relies on outside experts in reaching a decision, it is difficult to see how that action can ultimately be characterized as "arbitrary or capricious" by any court. Since it is well-known that medical experts can easily be obtained for almost any side of any controversial proposition, it is difficult to imagine any meaningful judicial review in such an approach.

As already indicated, the Second Circuit's reliance on *Abbott Laboratories* clearly raises some questions. First, the Agency itself has made a complete about-face in its position, now arguing that the rules are subject only to pre-enforcement relief and can never be challenged in enforcement proceedings. Second, *Abbott Laboratories* dealt only with the question of standing to bring a pre-enforcement action and in no way sought to resolve the scope of review and independent status of these regulations. Similarly, other decisions of the Supreme Court[10] relied on by Judge Mansfield simply did not deal with this issue at all. In *Hynson,* the Court did no more than affirm the Agency's interpretation of the statute that no hearing was required to withdraw a new drug application (NDA) if the holder of the NDA had clearly failed to submit controlled studies required by the Act. This administrative summary judgment procedure was deemed inherent under the statutory requirements and not a separate outgrowth of Agency authority under Section 701(a) of the Act. Yet, the Second Circuit relied on this case for a determination that all Section 701(a) regulations are substantive and binding. In fact, the Supreme Court ruled only that a particular Agency interpretation of the statute was correct. *Bentex,* in turn, related to the Agency's primary jurisdiction with respect to determining new drug status under the Act. Surely, however, the Supreme Court in *Hynson* and *Bentex* never contemplated or considered the question of withdrawal of products from the marketplace, such as in the case of vitamins A and D, without any kind of evidentiary hearing, even though serious factual disputes and controversies as to the merits exist.

The problem has been that the FDA has been citing the *Hynson* and *Bentex* cases with great success for the general broad propositions of deference to the expertise of the Agency and an expansive inter-

[10] *Weinberger v. Hynson, Westcott and Dunning, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,930, 412 U. S. 609 (1973); *Weinberger v. Bentex Pharmaceuticals, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,932, 412 U. S. 645 (1973).

pretation of the Agency's powers under the Act. Clearly, it is this aspect of these cases which spilled over into the determination of the status of Section 701(a) regulations.

Congressional Intent

Although the Court of Appeals strongly emphasized judicial trends taking such a broad view, the essential question was overlooked and disregarded. Fundamentally, the inquiry should have been directed to the Congressional intent in enacting Section 701(a) and in considering the consistency of a substantive classification with the general structure of the Act. Those familiar with the provisions of the Act must find it strange that the Agency is required, under Section 403(j) of the Act, to hold a full evidentiary hearing for the purpose of establishing informational labeling on foods for special dietary use, while, at the same time, the imposition of prescription requirements could be accomplished without any evidentiary procedures or an evidentiary scope for judicial review. Indeed, under the Act, certification of antibiotics, the safety of food additives, approval of color additives and similar complex and crucial determinations are expressly made subject to formal evidentiary and due process procedures, including specific provision for detailed judicial review. In stark contrast, the Court of Appeals decision allowed the Agency to promulgate binding regulations without any of these procedures. In fact, Section 701(a) contains absolutely no procedures for the promulgation of regulations. The "Notice and Comment" procedure found acceptable by the Court of Appeals, is taken from the Administrative Procedure Act (APA), 5 U. S. C. Section 553, which was enacted some years after Section 701(a). It is certainly untenable to suggest that Congress originally, under Section 701(a), intended such regulations to have binding effect without specifying any procedures for their adoption. Such a result can only be reached if one adopts the difficult view that the APA was intended to dramatically alter the structure of the Federal Food, Drug and Cosmetic Act, by granting such substantive authority.

Resolution of this question, however, is not dependent on indirect, speculative assessment of the structure of the Act. The legislative history, in two respects, clearly shows the intent of Congress in limiting substantive authority to those situations where a hearing was required. In this respect, the House Report explaining the regulatory authority under the Act succinctly notes:

"§ 701 relates generally to regulations. In the case of regulations, the violation of which constitutes an offense, it is required that appropriate notice of a public hearing be given and that adequate time shall be given after the promulgation of a regulation before it becomes effective."[11]

An unofficial contemporaneous construction of the Act prepared by FDA officials also took the position that Section 701(e) procedures were intended to apply to all regulations of a character which increased or added to the statutory requirements.[12]

Legislative History

The most remarkable aspect of the Court of Appeals disregard of the legislative history is found in the specific legislative history of the prescription statute which was immediately at issue in *NNFA v. Weinberger.*

When Section 503(b)(1)(B) was first proposed in Congress it contained a provision whereby the Agency had the power to designate which drugs were to be placed on prescription status by employing procedures similar to those set forth in Section 701(e) of the statute. There was a right to a hearing, cross-examination and subsequent judicial review by the Court of Appeals under the "substantial evidence" standard.

The debates in the House of Representatives demonstrate beyond any doubt that Congress felt that even this was too much power for the Agency. Accordingly, an amendment, known as the O'Hara Amendment, was passed in the House of Representatives. It removed the power of the Agency to substantively determine prescription status.[13]

The United States Senate accepted the House amendments and passed the prescription statute without debate. The Senate Committee Report specifically referred to the Agency's recourse under Section 701(a) to issue interpretive regulations. In explaining the rationale for eliminating any substantive grant of authority the committee noted:

[11] Report No. 2139, House of Representatives, 75th Congress, 3rd Sess., pp. 11-12; Dunn, *The Legislative History of the Federal Food, Drug and Cosmetic Act*, p. 823.

[12] White, Sellers and Grundstein, *Administrative Procedure and Practice for the Department of Agriculture under the Federal Food, Drug and Cosmetic Act of 1938*, pp. 176-179, reprinted in 3 Toulmin, *Law of Foods, Drugs and Cosmetics*, pp. 1221-1223 (Second Edition, 1963).

[13] The debates took place on July 31 and August 1, 1951 and appeared in the Congressional Record at 97th Congress 9235-9243, 9321-9349. Only a full reading of these debates can give the true flavor of the vigorous Congressional opposition to any substantive grant of authority as well as the insistence on a *de novo* judicial inquiry as to the facts.

". . . It was felt that the statutory definition, together with the authority to make interpretive regulations, could bring an end to the existing confusion in drug labeling and that uniformity can be achieved through cooperative efforts of the drug industry and the Food and Drug Administration working under the statutory plan."[14]

In the Public Interest

In light of this clear legislative history, how can we explain the Court of Appeals ruling that Section 701(a) regulations are substantive? With all due respect, it is apparent that the Court strained to grant the Agency a substantive authority which the Court felt would be in the public interest. Actually, Judge Lumbard, although concurring in the decision, expressly noted that he was not at all confident that Congress intended the FDA to have substantive rule-making authority with respect to prescription drugs. Judge Lumbard was clearly troubled and his solution is the suggestion that the Court should apply the "substantial evidence" standard rather than the "arbitrary or capricious" standard of judicial review. The majority opinion, however, rejects the "substantial evidence" standard. The remaining question then is the underlying validity and propriety of the general approach of expanding, irrespective of a Congressional intent, the scope of Agency authority.

The question is by no means limited to the Federal Food, Drug and Cosmetic Act. In response to recent judicial holdings that the Federal Trade Commission (FTC) has similar substantive authority, Congress responded swiftly by enacting a specific hearing procedure for FTC regulations.[15]

Moreover, the new statute expressly distinguishes between interpretive rules and statement of policy and substantive regulations.[16] Congress, however, while specifying the "substantial evidence" standard of review for the substantive grant of authority to the FTC, deals only vaguely with interpretive rules and statements of policy. If the Second Circuit approach is followed for the FTC, it is not inconceivable that some Court might once again frustrate the Congressional intent by narrowly limiting the scope of judicial review for the informal agency action.

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[14] Senate Report No. 946, 82nd Congress, 1st Sess., pp. 4-5. In fact, the Committee report referred to such regulations as *interpretive* at least four times. Despite this clear language, the Court of Appeals relied on this Committee report and a few isolated words therein to support Congressional intent for substantive regulations.

[15] Sec. 18.

[16] Compare Sec. 18(a)(1)(A) with Sec. 18(a)(1)(B).

Ultimate Question

The ultimate question is, of course, what difference does it make? Can the courts be relied upon to provide meaningful review under the "arbitrary and capricious" standard? The simple answer is that review of a collection of comments submitted to an agency can never provide the court with sufficient background or a meaningful record to fully illuminate the propriety of agency action. This would be true even if the "substantial evidence" rule were to apply.

The significance of cross-examination cannot be overstated. It is a crucial tool, within proper limits, to help ascertain the facts and for the structure of a meaningful record. The vitamins A and D case is an excellent example of what the absence of cross-examination can mean. Comments were submitted in support of the Agency's position, some of which made statements indicating that particular individuals or organizations supported the placing of these products on a prescription status. No rationale or explanation was given in most cases for these views. Without cross-examination, there was no basis to demonstrate the invalidity of their factual premise. The Agency's attitude toward adverse comments received is also illuminating. Analyses submitted to the Agency were simply dismissed as "insufficient" to warrant a change in the FDA's opinion. In effect, this amounted to an administrative summary judgment upheld by the different courts even though there was a serious conflict and dispute as to the facts.

Erosion of Judicial Function

Before attempting to answer the question of whether the substantive-interpretive issue is dead, we must first ask what this issue means to industry. It may be that general counsel for a company has written a memorandum or discussed this problem with management using such language as "substantive," "interpretive," "arbitrary and capricious," "substantial evidence," "hearing," "cross-examination" and "due process." This litany, a la Lenny Bruce, unfortunately does not paint a meaningful picture of the significance of this problem to the pharmaceutical company and the executive in the pharmaceutical company. What this question really means is that one day a pharmaceutical company is going to receive a criminal indictment or a complaint in an injunction or seizure action initiated by the FDA. The executive is then going to call his counsel and begin to discuss preparation to defend the company against such charges. He might want to discuss with the attorney available scientific witnesses, studies, reports

and other steps which should be taken to prepare a proper and adequate defense. At that point, the meaning of this issue will become abundantly clear, because the executive of that company is going to be told by the counsel that all those words mentioned some time ago really mean that there is no such thing as going in to defend the company or its executives against these charges. Rather, they merely have to go into court to determine what kind of sentence or judgment is going to be issued. We are witnessing an erosion of both the judicial function and a significant cornerstone for the protection of the individual and industry.

The question of whether the substantive-interpretive issue is dead must be answered by saying that we could not accept this resolution unless we could imagine a judiciary which would automatically be suspicious and doubtful of any agency action conducted under the "Notice and Comment" procedure. As we all know, the approach of the courts is instead based upon a presumption of regularity and validity. Under such circumstances, the issue must be kept alive if there is to be any meaningful function for judicial review of agency action.

I trust that the bar, industry and commentators will not accept the result along these lines. The issue and problem is very much alive and must be resolved, if not in the Courts,[17] then certainly in Congress.

[The End]

INTER-AMERICAN BAR ASSOCIATION

Conference XIX of the IABA will be held September 27 through October 3, 1975 in Cartagena, Colombia. The central theme of the meeting is "Juridical Aspects and Documents Relating to Latin American Economic Integration, Including Those Relating to the Andean Pact." Committee XIX—Food and Drug Law, has as its topic: "Up-dating annual study of food and drug laws in the Americas." For registration and invitation, please write John O. Dahlgren, Esq., Secretary General, Inter-American Bar Association, 1730 K Street, N.W., Washington, D. C. 20006.

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[17] A petition for a writ of certiorari was filed in the Supreme Court of the United States on May 2, 1975 in the case of *NNFA v. Weinberger, supra.*

Overview of Some Recent Developments in the Drug Field

By VINCENT A. KLEINFELD

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AS IS ALMOST ALWAYS THE CASE as far as the Federal Food, Drug and Cosmetic Act and the Food and Drug Administration (FDA) are concerned, legislative decisions are sometimes made by the Agency, and fascinating (in a grim way) opinions rendered by the courts. Occasionally, although not very frequently, an opinion written by a federal judge in the food and drug area is well-reasoned, well-analyzed and well-articulated. This unusual opinion is not predicated, as are so many others, almost entirely on the immediate decision of a court to sustain whatever the FDA has done, leading to the issuance of strange and often shoddy opinions. One of the exceptions is the *National Nutritional Foods Association (NNFA) v. FDA* opinion,[1] where the court reviewed the vitamin regulations. Although some lawyers may differ with some of the conclusions reached and language enunciated by the United States Court of Appeals for the Second Circuit, the scholarly opinion of Judge Friendly demonstrated that he had obviously done his homework and had performed a tremendous job in reviewing the record of the vitamin and special dietary food hearings.

To go back somewhat, we are all familiar with the position taken by many, particularly in the government, that the fantastic two-year hearings on these subjects were somehow the fault of industry and

[1] *NNFA v. FDA*, CCH Food Drug Cosmetic Law Reporter ¶ 41,191, 504 F. 2d 761 (CA-2 1974).

basically constituted an attack on the whole process of promulgating food standards. It appears that these ill-fated hearings may be responsible in large part for the philosophy of the FDA that there should practically never be any hearings at all, with respect to both drugs and foods. If there are no hearings, the government will not be wasting its time in permitting cross-examination of its witnesses. After all, how can one have the temerity to cross-examine prestigious experts with doctorate degrees? It can be said to those in the government who are of the firm opinion that cross-examination of government witnesses is not advisable and is only a waste of time, that the proposed vitamin and special dietary food regulations, obviously ill-conceived and out-of-date before the conclusion of the hearings, would have been the law of the land if they had not been stayed by the filing of objections and the holding of hearings. The importance of this can best be realized by an examination of the original regulations and those which were finally issued and judicially reviewed.

Regulations Sustained

The United States Court of Appeals for the Second Circuit, through Judge Friendly, did not automatically uphold all the final regulations. Many had thought that this would occur by reason of the fact that it has happened so frequently in the past. It was also believed that since two years had been expended at the hearings, no reviewing court would take the trouble to analyze the record and consider, in a judicial manner, the many important problems raised. Most of the regulations were sustained by the court, but a number were sent back to the FDA for further consideration and others were held to be invalid. An important ruling of the court was its mandate that the FDA consider further whether additional combinations of vitamins and minerals should be authorized and whether greater potencies of vitamins and minerals should be permitted. In addition, since the trial examiner had unduly restricted cross-examination of an extremely important witness, the court directed the FDA to reopen the hearings so that the witness could be fairly cross-examined. For these reasons, the regulations were stayed by the court. The Supreme Court refused to grant certiorari.

In discussing the provision of the regulations which provided that a product with more than 150 percent of the recommended daily allowance of a mineral or vitamin would be classified as a drug, the FDA stated that this would not necessarily require a prescription. I retain

my doubt with respect to the accuracy of that statement. In any event, the FDA decided not to build a better record on this point and reversed its original position.

Vitamin A

Milton Bass will discuss the opinion of the United States Court of Appeals for the Second Circuit in *NNFA v. Weinberger.*[2] This involved the Section 701(a) regulation classifying as prescription drugs all preparations of vitamin A containing more than 10,000 international units per dosage form. All I will say is that, in my opinion, it is almost incredible that anyone who would carefully read and analyze the five-year legislative history of the Federal Food, Drug and Cosmetic Act (putting aside the legislative history of the Durham-Humphrey Act) would conclude that Section 701(a) conveyed authority to the FDA to issue substantive regulations. The reasoning of the Court of Appeals is difficult to follow but, as far as the 1938 Act is concerned, the Supreme Court had apparently resolved the problem in *Hynson, Westcott and Dunning*[3] and related cases. In any event, one interesting query is whether the courts will rule similarly in the event of a criminal prosecution of a corporation and its officials, based on a Section 701(a) regulation. In my view, this is not a closed question.

FOI Act

Recently, the Food and Drug Law Institute sponsored an excellent meeting on the FDA's Freedom of Information (FOI) Act regulations.[4] Consequently, I just wish to make one or two points. It is most important to realize that the entire philosophy of the FDA concerning what is confidential or a trade secret, or what information from a new drug application (NDA) may be obtained, has completely changed. The Agency has pointed out that, formerly, it retained about 90 percent of its records as confidential. Now, it makes available roughly 90 percent of its records. My guess is that, in view of the manifest intent of the government to disclose everything it possibly can, that 90 percent will be changed to 95 percent. It is interesting to note that drugs covered by effective NDAs were considered so sacrosanct in the past that the FDA would not even advise any-

[2] See article on page 448.

[3] *Weinberger v. Hynson, Westcott and Dunning, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,930, 412 U. S. 609 (1973).

[4] See 30 FOOD DRUG COSMETIC LAW JOURNAL 311 and following (June 1975).

one as to whether a drug on the market was covered by an effective application. It seems to me that the regulations are so vast and comprehensive that a company should now be very careful before it submits any voluntary information. In almost every instance, it should obtain a ruling from the FDA in advance that the company's opinion that certain information is confidential or a trade secret is accepted. As we know, merely marking something confidential will be of no avail. I should think, also, that a request for information by an inspector should be given even more careful consideration than was given in the past to avoid disclosure by the FDA under the new FOI policy.

An interesting question arises with respect to information which is not submitted voluntarily but is required to be submitted. It seems to me that, in this situation, there may be a difference of opinion between the company and the FDA as to whether certain material constitutes a trade secret or confidential information. The company should, in some way, endeavor to determine in advance what the FDA's position is. If one cannot conclude that the FDA will consider certain information to be confidential, an immediate approach to the courts may be undertaken.

Frankenstein Monster

After the passage of the Drug Amendments of 1962 and the creation of the drug efficacy study implementation (DESI) panels, I spoke at a drug meeting. I stated that the FDA may have created a Frankenstein monster since, if the prestigious scientists chosen by the Agency to constitute the panel found that a product was effective (the pre-1962 NDA having been permitted to become effective by the FDA as far as safety was concerned), the product could reasonably be said to be generally recognized as safe and effective (GRASE) by qualified experts. Therefore, it would no longer be a new drug.

I used the term "Frankenstein monster" because at that time, before the FDA started gyrating in this area, practically every drug and many devices and cosmetics were being called new drugs. It would have been a simple task for the FDA to come to the conclusion that a finding of effectiveness by a panel (with the caveat that in certain instances bioavailability would have to be demonstrated) rendered the product an old drug. And, as the Agency has said in the past, the Act requires current good manufacturing practices (GMPs) for all drugs. But that straightforward approach would have been

anathema to the FDA at that time. The Agency would not have the more extensive authority over "old" drugs as it had over new drugs. And there were many traditionalists in the Agency who believed that practically all drugs (and most devices and cosmetics) should be considered new drugs. Nevertheless, it was apparent to the government that something had to be done. Consequently, it created the concept of abbreviated new drug applications (ANDAs).

Research Work

A fascinating subject indeed is those mysterious ANDAs. For many years after the passage of the Federal Food, Drug and Cosmetic Act in 1938, it was the firm opinion of the FDA that, even if many others had submitted the requisite data to the Agency and had obtained effective NDAs, any subsequent manufacturer of the product would have to repeat, at great expense, the same research work as its predecessors had performed. This may have been predicated on Section 301(j) or Section 505 of the Act, or on both. In any event, the government's original position appears to have been bottomed in part on a well-intended desire to protect a manufacturer who may have spent considerable sums in research in order to obtain approval of an NDA.

As I see the situation, the FDA determined to utilize the concept of ANDAs not for new drugs, but for old drugs—drugs which were, in fact, GRASE. I venture to guess, however, that many FDA officials were distressed because of this tremendous wedge into the traditional stand of the government.

At one time, the FDA announced that some few drugs might, by some major miracle, be old drugs. In the *Federal Register* of May 28, 1968, the government published a statement concerning drugs which had been cleared previously through new drug procedures for which "approved new drug applications are not now required as a condition for marketing." The proposal referred to a listing, under certain conditions, "of drugs for human use that do not now require an approved new-drug application." This seeming obeisance to the statutory definition of a new drug never got off the ground.

William Allen White once said that consistency is a paste jewel that only cheap men cherish. Many pejorative adjectives and adverbs have been hurled at the FDA, sometimes with reason. Since the passage of the Drug Admendments of 1962, however, the Agency

can hold up its head proudly and plead innocent to any indictment of consistency.

Early in 1972, the FDA stated that:

"The determination whether a drug is generally recognized as safe and effective for any conditions is complex and not an absolute or one-time determination. The judgment requires consideration of the composition of the drug in terms of its reproducibility and reliability, as well as the indications for its use. Since product reproducibility and reliability require adherence to the conditions of current good manufacturing practice, including when applicable, assurance of bioavailability, there are few if any times that an expert judgment can be reached without full knowledge of factors that affect product composition. This consideration alone means that new-drug approval will be required in essentially all cases . . . . The Food and Drug Administration believes that before a manufacturer or distributor introduces a product to the market, whether or not the same or a similar product is already marketed by another firm, a request for review and comment on the proposal should be submitted. Information submitted should include a complete statement of the composition (active and inactive ingredients and assurance of product reliability), the labeling, and an adequate summary of the medical documentation on which the manufacturer or distributor and his expert advisers have reached a decision that the composition of the drug is such that it is generally recognized as safe and effective for the conditions for which it is to be prescribed, recommended or suggested in its labeling."

The statutory definition of a new drug had not and has not been repealed. As indicated, however, the government was not going to permit a drug and similar products found to be effective to be removed from new drug status. The answer was clear, again at that time. Many holders of effective NDAs were required to file supplemental NDAs; the manufacturers of similar products were generally required to file ANDAs without separate proof of efficacy. This was awkward because the government, from the passage of the Act, had firmly held that a drug manufacturer could not rely on the clinical work performed by a drug manufacturer who had in the past secured an effective NDA without the latter's permission. This long-standing policy determination was outweighed by the policy determination to keep control of drugs which were really old drugs. If the "me too" drugs were, in fact, new drugs, under the long-established position of the FDA, they had no right to be approved on the basis of what glaringly appeared to be incomplete NDAs.

Contemporaneous Construction

I once pointed out that it has been said that he who is certain that the FDA does not have the authority to assume a legal position it is taking may be falling into the error of the scientist who proved

that the winged area of the bumblebee was too small to support the creature in flight. Nevertheless, consistency is not an unmitigated evil, and it would appear that industry has a right to rely on public pronouncements of the government as to its construction of the Act, particularly with respect to regulations. The United States Supreme Court, in the "imitation jam" case, adverted to the importance of the government's "contemporaneous construction" of statutory provisions.

Section 201(p) of the Act clearly defines "new drug" as a drug the composition of which is such that it is not GRASE for the uses for which it is promoted, or a product the composition of which is such that, as a result of investigations, it has become so recognized, but has not otherwise been used to a material extent or for a material time. At one time, in the fairly recent past, the FDA announced that a drug would become a new drug if, in part, some manufacturing procedure was changed. A proposed Statement of Policy published in the *Federal Register* of February 23, 1971, happily entitled, "New Drugs on the Market Without Approved New Drug Applications," appeared, again at that time, rather fantastic in its implications, particularly since there was a clear threat of criminal prosecution of those who differed with the government. The proposal stated in part:

"In implementing the conclusions of the Drug Efficacy Study and identifying all marketed drugs affected by this review, it is apparent that large numbers of drugs have been, and continue to be, introduced to the market without clearance through the new-drug procedures and without the manufacturer or distributor having reached an understanding with the Food and Drug Administration that new-drug approval is not required. These include products with new formulations, new manufacturers, new manufacturing procedures, and new or revised claims. Most, if not all, of these products are new drugs and should have been cleared through the new-drug procedures prior to marketing."

Competitive Products

And the Commissioner declared, in the February 23 *Federal Register*, that:

"The Food and Drug Administration believes that before a manufacturer or distributor introduces a product to the market, whether or not the same or a similar product is marketed by another firm, a request for review and comment on the proposal should be submitted. Information submitted should include a complete statement of the composition (active and inactive ingredients and assurance of product reliability), the labeling, and an adequate summary of the medical documentation on which the manufacturer or distributor and his expert advisors have reached a decision that the composition of the drug is such that it is generally recognized as safe and effective for the conditions for which it is to be prescribed, recommended, or suggested in its labeling."

There have been some strange recent happenings in the muddled NDA-ANDA field. Frequently, the holders of NDAs found them-

selves in a worse position than those who were marketing the same products without even the submission of ANDAs. In one situation recently, the holder of an NDA complained about competitive products being on the market without any FDA clearance, and adverted to a delay which had occurred concerning the company's submission of a supplemental NDA. The response was that that type of drug had been transferred from one division to another and that some required data had been submitted later. The FDA then concluded (as if there were no alternative to the position it was taking) that there were some situations where the holder of an NDA might, for some time, be under greater restrictions than those marketing the product without NDAs or ANDAs and without suffering the delays such an NDA holder had to face. The FDA opined that this was just too bad and that some day this would change. This was not an isolated instance.

In another situation, a strange position was taken by some FDA officials. A company's product was covered by an effective NDA and a number of companies were marketing a similar product without an NDA and an ANDA. The company submitted a supplement (required because of a proposed change in facilities), and received a reply that the change might be approved but that the officials wanted an additional warning to be placed on the labeling of the company's product. When the company conferred with the FDA about the new warning, the company requested that the FDA notify competitors that they also would be required to utilize the new warning. The officials' bland reply was that they could not do so (this was nonsense) and would not do so. When the company asserted that this would be a most unfair thing for the FDA to do, the cheerful answer was that the Agency could not do anything about the "me too" products. But it did have the complaining company in its grasp because the company possessed an NDA and the officials would not approve the supplemental NDA unless and until the company had agreed to accept the warning.

Monograph Approach

The NDA-ANDA wheel was turned quite a bit in a speech last year by a highly placed FDA official. The speech made clear that the monograph approach to regulating prescription drugs would be definitely pursued. It was explained that the monographs will specify the conditions under which the drug may be marketed without prior FDA clearance. The selection of drugs suitable for monographs will

be made "on the basis of their generally recognized safety and effectiveness, experience in the use of the drug, extent of use, and the accuracy and availability of specifications and methods of analysis to assure their integrity and safety." The speaker pointed out that the monograph approach could cover at one time all the issues concerning whether a drug is a "new drug" or "old drug." Manufacturers may comply with the monograph, or daringly seek to obtain approval of an NDA for a drug which is not in accord with the monograph.

As was to be expected after the 1973 Supreme Court opinions, the speaker pointed out that, once a monograph is made final, the FDA will proceed against a noncomplying drug on the charge that the drug fails to meet the monograph and not on the charge that the drug is not safe and effective or is an unapproved new drug. The FDA official concluded by stating that, "In summary, the new approach to the regulation of prescription drugs by the establishment of drug monographs is not, after close examination, a significant departure from the old approach." Of course, this depends on how far back one goes in determining what is "old." Certainly, if we go back to the halcyon days of old, when some mild attempt was made in some instances to adhere to the provisions of the Act and its legislative history, I would venture to say that there have been certain "significant departures."

Strategic Endeavor

At long last the wheel seems to have completed its turn. The hegira has been performed. The "Memorandum in Opposition to Plaintiff's Motion for a Preliminary Injunction" in the Hoffmann-LaRoche suit is the amazing document which did this. The memorandum is the choicest example of the Machiavellian "end justifies the means" approach since the Pentagon papers and the famous tapes. It states, with candor, that the ANDA regulations were issued not with the design to enforce them but as a strategic endeavor to keep drugs in some hazy new drug area until the FDA was in a position to make a straightforward approach to the new drug problem, to at least attempt to comply with the new drug provisions of the Act.

The memorandum finally reveals that there are a number of drugs on the market without approved NDAs or ANDAs, that they are GRASE and "simply put, they are no longer new drugs. . . ." The admission is then set forth that the FDA has recognized this for some time, "but has failed to publish a comprehensive document in

the *Federal Register* setting forth an enforcement policy and proposed procedures for regulating these 'old' drugs." Why not? The memorandum then clearly lets the proverbial cat out of the bag. It declares that the FDA realized that it was not feasible administratively, necessary for public protection or "consistent with the definition of 'new drug' in Section 201(p) of the Act, to require either a full or an abbreviated NDA for all human prescription drugs found to be safe and effective." Then the rather staggering admission is made that "there was apprehension, until it was proved unfounded by the four Supreme Court decisions handed down in June 1973, that the only way that the agency could assert adequate regulatory control over any drug would be to classify it as a 'new drug.'" I question that. In other words, let us issue regulations (not intending from the outset to enforce them), and leave the entire drug industry in utter confusion. The justifications are set forth, but they do not change the fact that public positions were taken for a considerable time which the FDA did not intend to follow in many instances. This action of the Agency was explained by admitting that where a drug was found to be effective by a National Academy of Sciences-National Research Council panel, was widely recognized by experts and texts as safe and effective, and presented no bioavailability or special manufacturing problem, "the possibility of proving in a court that the drug product is a new drug, requiring an approved full or abbreviated NDA, is remote." In other words, the product no longer came within the definition of "new drug."

Shifting Positions

As indicated, I pointed this out in a paper many years ago. I should think that a government agency should have proceeded with the same frankness. Again, the memorandum admits that "the requirements of an abbreviated NDA were initially imposed for the purpose of retaining regulatory control over these [generic] drugs until the agency could formalize regulations prescribing conditions under which old drug status would be conferred to these drugs." I see nothing in the Act or in the 1973 Supreme Court decisions which permits the FDA to state that old drugs are new drugs until the Agency can straighten out its shifting positions and comply with the law. The memorandum makes the following fascinating declaration:

"What is inconsistent, and plaintiff has identified this issue, are the notices announcing that abbreviated NDAs may be submitted for approval. In these notices the agency has said the entities in question are regarded as new drugs.

The statement was made for purposes of retaining interim regulatory control until such time as old drug monographs could be published." (Emphasis supplied.)

It would indeed be pleasant to give industry the authority to prosecute a government agency, together, of course, with all its officials who shared responsibility, by action or inaction, in the furtherance of the illegal transaction. At least, industry should have the privilege of issuing regulatory letters demanding compliance with the law.

Marketing of Prescription Drugs

In any event (at least as of now), the fascinating memorandum declares that the FDA intends to follow an interim enforcement policy with respect to the marketing of human prescription drugs covered by DESI notices. This policy, to be published in the *Federal Register,* will state the grounds upon which the FDA will and will not institute enforcement action for lack of a full or an abbreviated NDA.

Then, the FDA will publish proposed regulations under which drugs shown to be safe and effective may be marketed without abbreviated or full NDA approval. These proposed regulations will set those conditions which, in the FDA's opinion, are essential to a determination that a drug is GRASE and does not require a full or abbreviated NDA: labeling in compliance wtih the DESI notice; submission of reports; compliance with the GMP regulations; and, in certain cases, bioavailability data. Any noncomplying product would be a "new drug." Also, comprehensive procedures governing the establishment of old drug monographs for human prescription drugs will be published.

When the great history of the FDA is finally written, before all the old-timers have passed on (I hope to a more peaceful area, perhaps to their just desserts), the history may be divided into two eras, BPH and APH (before Peter Hutt and after Peter Hutt). I hope it endeavors to explain how the law changed so substantially without legislative consideration or action. **[The End]**

Publicity as a Regulatory Tool

By RICHARD S. MOREY

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I HAVE APPROACHED this topic with some trepidation for several different reasons.

First, I am in the unenviable position of having to follow the senior member of our law firm on the platform.[1]

Second, we are all waiting for the speaking debut of the Food and Drug Administration's (FDA's) new general counsel, Richard Merrill.[2] Some will say that there is not much more that he can do beyond what Peter Hutt has already done. But when Peter first assumed the job, there were similar comments. It was felt that he could hardly go further than William Goodrich in terms of expanding the FDA's legal authority. So we will have to wait and see.

My greatest problem with this assignment, however, is that my basic thesis runs directly contrary to all recent trends in food and drug law. I am making the reactionary suggestion that the Agency be bound by constraints set forth in its governing statute.

Many have followed with great interest the recent debate between Peter Hutt and the food and drug bar as to whether the Federal Food, Drug and Cosmetic Act is a "constitution" or a narrow grant of power which must be strictly construed. Generally, Peter's position is that the Agency can do anything that Congress has not prohibited it from doing in advance. Based on the Agency's use of publicity, which flies in the face of such a statutory prohibition, there is some question whether even that single restraint on the Agency's action is recognized in practice.

My main area of concern in this paper is adverse publicity directed by the FDA against products which it regulates under the

[1] See article on page 458.

[2] See article on page 478.

Federal Food, Drug and Cosmetic Act. To start, such publicity is a legitimate and useful regulatory measure which is recognized by the statute. Its use, however, is restricted by the statute to certain well-defined situations where there is need for this powerful sanction. It was never intended to be used routinely by the Agency for relatively trivial problems where there is no justification for affirmative publicity in terms of the public's need to know.

Class III Recall

To illustrate the sort of situation I am talking about, in which the use of publicity is unjustified, there was a recent Class III recall involving rancidity of approximately 15,000 candy bars made by a well-known manufacturer. A Class III recall is defined as a "routine situation in which the consequences to life (if any) are remote or non-existent." The company agreed to recall this product on the basis that the bars had developed a "slight off-taste" that did not pose a health hazard. For some reason, however, this minor incident was made the subject of FDA publicity and was reported, among other places, in the *Wall Street Journal.*

At this point, I should emphasize that my complaint relates to *affirmative* issuance of publicity by the Agency. This is to be distinguished from making information available to those who seek it under the Freedom of Information Act or the routine inclusion of such information on the FDA's weekly recall list. While some question might be raised as to the FDA's legal authority to issue the recall list, this probably could be justified under the Agency's right to report on the results of its investigations. In any case, this is certainly far different from the affirmative use of a press release or public announcement specifically condemning a particular product.

In passing, I note that the recall list is more troubling for other reasons. One serious problem is that the list of products on the recall list is often out-of-date. Sometimes they appear so long after the event as to give the impression that there is a second separate problem with the same product. Also, the recall list fails to distinguish adequately between an actual recall in which the return of the product to the manufacturer is contemplated and so-called "stock checks" and "field corrections." There have been some recent improvements in this latter regard but, regrettably, the recall list still too often confuses rather than clarifies the situation.

Adverse Publicity

The FDA's present use of adverse publicity is inescapably linked to another nonstatutory regulatory technique used by the Agency against allegedly defective products—the recall. There have been recent proposals to amend the Act to provide the FDA with statutory recall authority. Such an amendment might change the dynamics of this situation, if enacted. But this does not appear likely in the near future.

Publicity is linked with recalls as far as the FDA is concerned for two basic reasons. First, if the manufacturer agrees to a recall, the use of either Agency or manufacturer-generated publicity may be necessary to recover the products subject to the recall. Generally, publicity is the only available means of recapturing products which have passed beyond the manufacturer's distribution system into the hands of the ultimate consumer. Second, and more important for the purpose of this discussion, the *threat* of adverse publicity is one of the most effective means which the FDA has of persuading a recall by a manufacturer who does not believe a recall is justified.

For several reasons, the possibility of adverse publicity by the Agency is usually a most potent factor in securing a recall. To the extent that this publicity reaches the ultimate consumer, the market for the product under attack may be temporarily, and in many cases permanently, destroyed. Also, there are important secondary effects. For example, large customers such as drug wholesalers and food chains made aware of the FDA's position, may start rejecting the product in anticipation of expected consumer reaction against it. And, in the medical situation, practitioners may cease to use, recommend or prescribe the product for fear of malpractice claims, regardless of their opinion of the merits of the product.

Warning Releases

The threat of FDA publicity thus can often yield a recall of a product, whatever the manufacturer's view as to the justification of the FDA demand for the recall. Few manufacturers are ready to stand up to full dress Agency treatment involving televised press conferences and widely disseminated "warning" releases. There is even the possibility of a suggestion that the manufacturer is not bowing to the Agency's demands and is recalcitrant and unfeeling about the public welfare.

To illustrate the possible problems with FDA publicity, I will give short descriptions of two instances involving, by hindsight at least, unfortunate uses of publicity by the Agency.

In November 1959, just as the peak annual season for the sale of cranberries started, the FDA discovered that some cranberries grown in Washington and Oregon had been sprayed with aminothiazole, a pesticide which in very high doses had been shown to induce cancer in rats. Cranberries grown in the rest of the United States were not involved, and it ultimately turned out that less than one percent of the nation's cranberry crop was subject to any aminothiazole hazard. Also, scientists considered that the likelihood of harm to humans from even the contaminated cranberries was, at most, speculative because only low-level, short-term exposure was involved. In any case, Secretary of Health, Education and Welfare Flemming held a highly publicized press conference on November 9, 1959 and urged the public not to eat the contaminated cranberries. Because of Secretary Flemming's vagueness as to the status of cranberries not grown in Washington and Oregon, and because of the difficulty of determining where particular cranberries were grown, the effect of the Flemming announcement was to almost completely wipe out the entire national market for cranberries in 1959. Lingering effects were felt for several years thereafter although there was no hazard whatever from aminothiazole except for a very small portion of the 1959 crop. The injustice of the FDA publicity to the cranberry growers was apparent to the Congress which eventually indemnified the growers to the tune of approximately nine million dollars.

Botulism

Another incident occurred in late 1971, in the wake of the publicity about botulism in a can of Bon Vivant soup. On October 29, 1971, the FDA issued an "urgent warning" that Stokely-Van Camp french-style sliced green beans might similarly be contaminated with botulism. The release was based on preliminary tests performed by another government agency. Subsequently, confirmatory tests demonstrated that botulism was not involved and the FDA had to rescind its warning against the Stokely products on November 1, 1971, two days after it was originally issued. Significantly, the Agency indicated in withdrawing its warning that it would act the same way again in similar circumstances.

These incidents are not intended to represent *typical* FDA use of publicity. They illustrate extreme situations in which, by hindsight,

the use of publicity was unjustified. My purpose in describing these incidents is simply to show the potential for unjustified harm inherent in the FDA's use of publicity.

Another factor worth noting as to FDA publicity is a relatively recent development. This is the situation in which an alleged hazard is first apprehended elsewhere. Then, consumer, political, or competitive pressures are brought to bear on the FDA to initiate or endorse publicity directed to the public about the claimed hazard. Examples are numerous and include cyclamates, DDT, monosodium glutamate, and Red No. 2. For our purposes it is not necessary to decide whether these various substances are or are not hazardous. It is enough that many of these alleged hazards are seriously disputed and open to some doubt, and that the FDA's decisions as to use of publicity in these instances were subject to often severe pressure toward use of its publicity mechanism.

Notices of Judgment

Turning to the FDA's statutory authority to issue publicity, Section 705(a) of the Federal Food, Drug and Cosmetic Act requires publication of "Notices of Judgment" in each case under the Act in which judgment is rendered. Section 705(b) of the Act states:

"The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department."[3]

Considering both the language of the statute and the relevant legislative history, the operation of Section 705 could hardly be clearer. The FDA is required to publicize any *judgments* rendered by the courts under the Act and also is authorized to report its investigations. It is further authorized, in strictly limited circumstances involving "imminent danger to health" or "gross deception of the consumer" to direct publicity at specific foods, drugs, cosmetics or medical devices. The standards set by the words "imminent danger" and "gross deception" are high, moreover, and indicate that Congress did not intend the FDA to lightly issue publicity directed at specific products.

The Agency has, on occasion, suggested that the second sentence of Section 705(b), relating to reporting on investigations is all the authority it needs to issue adverse publicity against specific products. But this is reading this single sentence of an integrated statutory

[3] 21 U. S. C. 371(b).

scheme completely out of context. In light of the legislative history and the rest of Section 705, this sentence plainly refers to dissemination of objective reports, statistical analyses and scientific articles, not to adverse publicity intended to affect the status of specific products. Logically, unless the first sentence of Section 705(b) is read as a limitation on FDA authority to issue publicity, the second sentence is surplusage. Thus, the rule that a statute must be interpreted so as to give meaning to all of its parts would be violated by this suggested FDA interpretation.

Imminently Hazardous Products

Nor is the FDA's suggested interpretation of Section 705(b) consistent with the Congress' continuing concern with adverse publicity as evidenced in the recently enacted Consumer Product Safety Act. Section 6(b) of that Act, like Section 705(b), restricts disclosure of adverse product information except for "imminently hazardous" products and in other limited circumstances. Section 6(b), moreover, provides for consultation with interested persons before release of adverse information and for formal retraction of erroneous disclosures.

There have been only three reported cases interpreting Section 705. *Hoxsey Cancer Clinic v. Folsom* held that Section 705 was constitutional but did not rule directly on the meaning of this provision. In *United States v. Diapulse,* the court held that while it had the requisite power to restrain publicity by the FDA, no prejudicial publicity had been disseminated. However, it is unclear whether this ruling was based on Section 705 or on the court's inherent power to deal with unfair pretrial publicity. The recent *Abbott* case, of course, dealt solely with pretrial publicity and is not directly relevant to a consideration of Section 705.

I will describe in some detail the third case involving Section 705. *United States v. International Medication Systems, Ltd. (IMS)* was an action by the FDA for preliminary and permanent injunction against IMS and several corporate employees charging a number of violations of the Act. The principal charges involved alleged failure of the IMS plant to comply with current good manufacturing practice (GMP) requirements.

Two days of evidentiary hearings were held on the FDA's motion for a preliminary injunction prior to May 10, 1973. In these hearings, the Agency relied upon a number of violations of GMP found during an inspection of the IMS plant in December 1972, in January

1973 and in earlier inspections. IMS' defense was essentially that any improper practices present in the plant during those FDA inspections had since been corrected. On May 10, 1973, the court refused to grant the FDA's motion for preliminary injunction. It pointed out that the FDA was not aware of the then present conditions at the IMS plant and that, if the corrections claimed had in fact been made, injunctive relief was not warranted. The matter was left that the FDA would proceed with another inspection of the IMS plant and report to the court on June 11, 1973 as to whether it still sought injunctive relief. The court made it clear, however, that the FDA might at any time prior to June 11, 1973 seek a temporary restraining order if it believed that conditions at the IMS plant justified such relief.

Potential Hazard

On May 31, 1973, the FDA informed IMS that it wished to discuss the recall of IMS products. A representative of IMS met with the FDA on June 6, 1973. At that meeting, the FDA representatives indicated that, if the Agency's demand for recall was refused, the Agency would inform the nation's hospitals that a public health hazard was presented by IMS products due to the alleged GMP violations. IMS refused this demand on the basis that it involved essentially the same issues before the court in Los Angeles and, in any event, was unjustified. Thereafter, the FDA, on June 9, 1973, sent a letter to the nation's approximately 7,000 hospitals warning against use of IMS products. Most significantly, the letter stated that the sterility of some IMS units was compromised and that the products presented "a potential hazard to the public health."

On June 11-14, 1973, the court in Los Angeles held further evidentiary hearings on the status of the IMS plant and IMS products. On June 15, 1973, the court denied the FDA's motion for preliminary injunction on the ground that, while some violations of GMP at the IMS plant in the past had been shown, they had been corrected and, in any case, were not of a nature requiring injunctive relief.

Powers in Equity

Most significantly, the court also found that the FDA had violated Section 705(b) of the Act in sending its letter to the nation's hospitals. Exercising its powers in equity, the court announced that it would order the FDA to issue a second letter to the same hospital

addressees reporting the court's ruling and specifically the finding by the court that:

"IMS was not shown to be guilty of violation of good manufacturing practices to the extent that its products represent a potential hazard to the public health."

Subsequent to this ruling by the court, however, IMS and the FDA reached an agreement under which IMS withdrew its request to the court for relief under Section 705. The court's written order thus merely denied preliminary and permanent injunctions and did not contain any affirmative relief under Section 705, as contemplated in the court's oral statement on June 15, 1973.

The *International Medication* case is important as the first case in which the limitations placed on the FDA by Section 705(b) have been explicitly recognized by the courts. It is perhaps equally important for its ruling that a party wronged by FDA publicity may be entitled to affirmative relief in the form of further FDA publicity ordered by the court to correct the harm done by illegal and unjustified earlier publicity. Although subsequent events precluded appellate consideration of these rulings, at least one federal court has found startling vitality in Section 705.

Need for Publicity

Turning for a moment from legal to policy considerations, there are excellent reasons for cutting back on the FDA's use of publicity. It would be a mistake to regard the public interest as always favoring dissemination of publicity, even based on questionable facts. Without even considering the interest of the manufacturer, there are important reasons why the Agency's use of publicity should be limited to carefully validated cases involving a serious and immediate threat to health. As mentioned earlier, publicity is the only effective way to remove from the marketplace the rare, truly dangerous product which reaches the consumer and is beyond tracing through the normal distribution system.

If a product can readily be traced to all the ultimate consumers, as would be the case for prescription products, the need for publicity would seem to be minimal. Indeed, it might unnecessarily alarm patients who could be better informed through their physicians. Most articles regulated by the FDA, however, cannot be traced effectively after they leave the manufacturer's control and enter our complex distribution system. In these circumstances, a dramatic public warning, in the name of the FDA, is the only way to limit or halt consumption before it is too late.

The importance of this vital role of FDA publicity cannot be overemphasized. It should not, in any way, be jeopardized by other FDA use of publicity. It is possible, however, that the constant stream of relatively minor product defects announced by the Agency has this effect. The consumer can become jaded by these trivial complaints and not prepared to act in case of a real emergency. Also, an ill-advised major announcement, like the cranberry or Stokely-Van Camp statements, has an adverse effect on the Agency's credibility when it later turns out to be wrong, even if the Agency was justified in making the announcement. Again, the consumer is deprived of the full benefit of an FDA warning in a critical situation because of prior doubts cast on the Agency's credibility. This possibility alone would seem to justify caution by the Agency even in potential life-threatening situations.

The Agency's present position, however, appears to be as stated in the press release retracting the Stokely-Van Camp botulism false alarm:

"There are times when the public interest demands action before the scientific case is complete. The decision always must be made in favor of consumer protection."

I submit that there is at least some question whether the overall public interest favors this "shoot from the hip" policy.

Careful Reassessment

The FDA's long-standing failure to adhere to the statutory restrictions on its issuance of adverse publicity cannot be justified. The Agency's present policy deserves careful reassessment within the Agency, as well as by Congress and all interested persons. This is so particularly in light of the recent Administrative Conference Recommendation on Adverse Agency Publicity, which was accompanied by a report critical of the FDA's use of publicity, and the *International Medication* decision which I have described. Rash or indiscriminate use of adverse publicity is inconsistent with the Agency's basic mission as well as unjustly harmful to those wrongfully indicted. The standards set in the statute and reaffirmed both in the Administrative Conference Recommendation and in the recently enacted Consumer Product Safety Act strike the best possible balance among the conflicting interests to satisfy "consumer protection" in the broadest sense. **[The End]**

Administrative Rule-Making

By RICHARD A. MERRILL

Mr. Merrill Is Assistant General Counsel of the Food and Drug Division of the Department of Health, Education and Welfare.

I CONFESS TO SOME APPREHENSION about appearing at this Update, which mounted as the day approached and my tenure as a private citizen grew shorter.[1] But I draw comfort from the fact that, for a few more days, I can elude your toughest questions by taking refuge in phrases such as "I have not had a chance to consider that" or "That was done before I came."

It would be foolish of me not to acknowledge that some of you have come to find out how—or whether—my views differ from those of my predecessor, Peter Hutt. To begin with, I like to sleep occasionally. And I have even been known to eat dinner at home—sometimes, I must confess, late at night. There may be other differences that are even more dramatic.

Mr. Hutt has, however, taken measures to be sure that the transition is not too disruptive. One thing he did leave me was his annotated copy of the Federal Food, Drug and Cosmetic Act. There is no truth to the rumor that it resembles a French paperback, requiring a knife to open the pages. But it does contain some interesting marginal notations here and there, such as "Repealed, 21 C. F. R. Section —."

When my appointment was announced, I half expected to receive a note or two from old friends at Covington & Burling, congratulating me, condemning me, expressing condolences. Nothing came. However, I did receive one item which I cannot trace. It was a small package in a plain brown wrapper bearing no return address. Enclosed was an eraser.

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[1] Professor Merrill was appointed, effective June 1, 1975, Assistant General Counsel of the Food and Drug Division of the Department of Health, Education and Welfare. He succeeds Peter Barton Hutt in that office.

I could not properly ignore all matters of substance during this presentation, although it may appear that I am talking at a level of generality. Accordingly, I have recorded a few observations about an important issue of administrative law that bears directly on the responsibilities of the Food and Drug Administration (FDA). This issue is the Agency's authority to choose *between* rule-making *and* adjudication as modes of implementing the Act's substantive mandate.

One of the attributes of the job that attracted me is the FDA's role as an innovator of new regulatory approaches. I shall be candid; I share many of Peter Hutt's convictions about how the Agency should seek to enforce the law. In particular, I share his view that it is important for the FDA to explain in advance what it is trying to do and clarify how it intends to proceed. The necessity of doing this will force Agency officials to think through new initiatives *before* they are launched.

Regulation Through Rule-Making

Furthermore, I believe that regulation through rule-making affords numerous advantages—for the public, for the Agency, even for the industry. Therefore, it should continue to receive considerable emphasis. This does not mean that the FDA should not go to court to enforce the law. It should, and must, and will. And, no doubt, it will find itself in court as a defendant more frequently.

Many of the advantages that rule-making offers are obvious. It permits resolution of recurrent issues in a single proceeding. It produces requirements that apply prospectively, and affords manufacturers an opportunity to comply before they are subject to suit. It permits articulation of legal requirements with precision and clarity. It promotes evenhanded application of law and minimizes invidious choices among potential defendants. Thus, it helps assure that regulation does not sponsor competitive advantage. In addition, rule-making allows broader participation in the formulation of Agency policy. And it forces the Agency to defend its policies in general terms, rather than as *ad hoc* responses to what may be isolated or atypical problems.

Of course, adoption of rules also facilitates subsequent court enforcement by narrowing the issues in dispute. Sometimes a rule may so limit the scope of material dispute that it makes adjudication unnecessary. And it is precisely this potential of rule-making that makes it controversial. Such controversy is entirely understandable, but it

should not rest on impressions that rule-making is un-American or that rules that foreclose "trial" of issues are uncommon.

As rule-making by administrative agencies has become more fashionable, attention has focused increasingly on the procedures required for rule-making. Some of the debate seems to me to have obscured certain well-established principles, including the legitimacy of what has been termed "informal" or "Notice and Comment" rule-making.

Trial-Type Safeguards

The Constitution does *not* require government to provide trial-type safeguards when it formulates legal requirements that resolve and, thereby, foreclose subsequent contest of factual questions. Congress can, for example, pass a statute that makes diethylstilbestrol (DES) illegal on the ground that it is unsafe, without affording a trial to anyone on the issue of safety. An agency with rule-making power could, I submit, constitutionally do likewise. Indeed, most legal authorities would agree that even informal rule-making procedures are not constitutionally mandated.

This is not to suggest that rule-making procedures additional to those prescribed by Section 553 of the Administrative Procedure Act (APA) may not be required in many circumstances. Congress may prescribe more complex procedures, as it has done in several recent statutes, as well as, for some subjects, in Section 701 (e) of the Federal Food, Drug and Cosmetic Act. The APA itself requires formal rule-making where the operative agency statute mandates that rules be adopted "on the record after opportunity for an agency hearing," but not, apparently, otherwise. And a few recent appellate decisions have instructed agencies to afford greater opportunity for the development of factual issues than the APA minima are thought to afford. But all of the cases with which I am familiar—*International Harvester, Mobil Oil, Kennecott Copper*—have relied on provisions in the governing regulatory statute that have no counterparts in the Federal Food, Drug and Cosmetic Act.

I believe that, more often than not, "Notice and Comment" rule-making *can* afford adequate opportunity for the illumination of factual issues and produce a record that permits meaningful judicial review. Three steps in the process are critical. First, the Agency's notice must not only disclose clearly what requirements the Agency proposes to adopt; it must also identify the issues it intends those requirements to resolve. Further, it must at least advert to, if not

incorporate, the evidence which it believes justifies the result proposed. Second, comments by interested persons should conscientiously attempt to expose the specific errors of fact or judgment of which the Agency is thought to be guilty. Finally, the Agency has an obligation in its final order to respond to all material objections to its proposal and to explain why they do or do not warrant revision of its preliminary conclusions.

New Procedural Regulations

My impression is that the FDA has been very conscientious at Stage 3 and that its notices of rule-making, though by no means perfect, have been better than those of most other agencies. Furthermore, most of the substantial comments on proposed rules that it has received recently have seriously addressed merits of what it has been doing. The hyperbole has been left to subsequent litigation. The Agency's new procedural regulations should reinforce this pattern.

There may be occasions on which additional procedural mechanisms would be useful in exposing policy issues or factual disputes underlying a proposed rule. The new procedural regulations provide that the Commissioner, on request or on his own initiative, *may* go beyond "Notice and Comment" rule-making and prescribe additional procedures. These include: informal, legislative-type hearings; oral argument; reference to an advisory committee or board of inquiry; even trial-type hearings with cross-examination. I suspect you will see these procedures invoked during the next few years in the context of rule-making that is formally subject only to Section 553 of the APA.

Mr. Bass, like many others, has expressed concern that judicial review of informal rule-making cannot be serious review.[2] I think he is wrong. The applicable standard of review is, of course, the "arbitrary and capricious" text of Section 706 of the APA.[3] The "record" for review is the record assembled by the agency, not some new record constructed by a district court.[4] Notwithstanding these "restrictions," numerous recent decisions, principally by the District of Columbia Circuit, demonstrate a judicial willingness to scrutinize informal agency rules with surprising intensity.[5]

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[2] See article on page 448.

[3] See *Automotive Parts & Accessories Association v. Boyd*, 407 F. 2d 330 (CA DofC 1968).

[4] See *Camp v. Pitts*, 411 U. S. 138 (1973).

[5] See, for example, *National Tire Dealers and Retreaders Association v. Brinegar*, 483 F. 2d 1328 (CA DofC 1973).

Terms of Substance

I expect this trend to continue. Reviewing courts are likely to focus on the requirement in Section 553 that an agency's notice of proposed rule-making must state "either the terms of substance of the proposed rule or a description of the subjects and issues involved" as a basis for insisting that agencies fully disclose what they are considering and why. Similarly, the APA requirement that the rules ultimately adopted must include "a concise general statement of basis and purpose" can supply the textual basis for demanding a comprehensive discussion of all of the factual and legal issues exposed by the comments.

In the new procedural regulations, the FDA states that it will not attempt to go outside the rule-making record to support a challenged rule in court. This does not mean that the Commissioner may not rely on his personal experience or on Agency experts in *interpreting and evaluating* the data assembled and in deciding what policies the data support. But the Agency's final rule will make clear when this has occurred and explain what effects it has had.

Finally, I would not be surprised to find other judges following the lead of Judge Lumbard in his concurring opinion in *National Nutritional Foods*.[6] He suggests there that an Agency rule for which substantial evidence is lacking should be struck down as "arbitrary" or "irrational." Whether or not this is an appropriate integration of the statutory standards, I am confident that the FDA can live comfortably with the functional result. **[The End]**

[6] *National Nutritional Food Association v. Weinberger*, CCH Food Drug Cosmetic Law Reporter ¶ 38,003, 512 F. 2d 688 (CA-2 1975).

EEC Developments Affecting Products— Registration and Liability

By JEFFREY W. BARTLETT

Mr. Bartlett Is Director of International Legal Affairs of G. D. Searle International Company.

ONE OF THE ESPOUSED PRINCIPLES of the European Common Market is to promote the free flow of commerce among the various member states. Practices which effectively prohibit the movement of goods across borders are frowned upon as preventing the accomplishment of the objectives of the European Common Market. In this regard, it should be noted that pharmaceutical practices such as product registration, testing, advertising and social security reimbursement are considered to be artificial trade barriers restricting the free flow of goods. In order to end the partitioning effect of these practices and to bring about the free movement of goods, a range of draft proposals, one of which has been formally adopted, has been prepared by the European Common Market Commission. To date, there have been six proposals dealing with pharmaceuticals. They are:

(1) extension to all member states of the obligation for companies to obtain a preliminary authorization from National Health Authorities before introducing pharmaceuticals into the market, and the initial harmonization of the procedures and conditions for granting such authorization. This has been adopted as Council Directive 65/65;

(2) harmonization of the pre-marketing investigation procedures required to place a pharmaceutical on the market, the methods of quality control of pharmaceuticals by the producer,

and the manufacturer's supervision of manufacturing and marketing the product;

(3) recognition by the member states of the marketing license granted by other member states;

(4) harmonization of legislation as to publicity for pharmaceutical products; for example, advertising, promotion and the descriptive materials supplied with these products;

(5) approximation of national legislation relating to the types of coloring permitted in pharmaceuticals; and

(6) harmonization of provisions regarding analytical, pharmacological and clinical norms and protocols relating to pharmaceutical tests.

For a seventh item, it should be noted that the Commission is also investigating harmonization of legislation involving the dispensing of drugs, drug prices, veterinary preparations and drug costs of insurance programs. Of the six items listed above, only one, two and six are of significance at this juncture. In one case, the proposal has been adopted and, in the other, it is about to be formally adopted. However, before reviewing these proposals, it is necessary to understand, in a cursory manner, the procedure and the basis for drafting protocols.

Treaty of Rome

Article 100 of the Treaty of Rome creates the basic legislative authority for the approximation of national laws. This Article provides that the Council, by unanimous decision and on proposal of the Commission, will issue a directive for the approximation of such legislative and administrative provisions of member states as directly affect the establishment of the operation of the Common Market. However, before this occurs, the Assembly (European Parliament) and the Economic and Social Committee of the Common Market must be consulted in the case of directives, the implementation of which would involve the amendment of legislation in one or more member states. In other words, the European Commission files a proposal for harmonizing legislation with the Council of Ministry who reviews and adopts it, subject to review by the European Parliament and the Economic and Social Committee. These two latter groups may change the draft as they see fit. Afterwards, the draft is resubmitted to the Council of Ministry which then formally adopts the proposal as a directive. The key to the directives is that they are not law in themselves, but they require that national entities work

the requisite changes to bring their national laws into accord with any directive.

However, the directives do have a retroactive and prospective application. Because of this mechanism of approval of any proposal, it is understandable why few proposals have become directives.

Turning back to the actual directives themselves, the only directive formally adopted by the Council is Directive 65/65, dealing with branded pharmaceuticals. Basically, the directive provides that no proprietary medicinal product prepared in advance, sold under a special name and put up in a special way (for example, branded pharmaceuticals) may be put on the market in the member state unless the producer has been granted authorization by the competent authorities for marketing by the member state.

Medicinal Product

Medical product is defined as meaning:

(1) any substance or combination of substances *presented* for treating or preventing disease in human beings or animals;

(2) any substance or combination which may be administered to human beings or animals; or

(3) any substance or combination of substances which may be administered to human beings or animals with the view of making medical diagnosis or restoring, correcting or modifying physiological functions in human beings or animals.

In order to obtain authorization to market, an application must be submitted to the competent authorities of the member state. The application should be accompanied by the following information:

(1) name and address of the person responsible for placing the product on the market (distributor and importer), the distributor and, where appropriate, the manufacturer;

(2) name of the proprietary product (brand name or common name);

(3) composition by nature and quantity of all ingredients of the drug, exclusive of the empirical chemical formula;

(4) short description of the method of preparation;

(5) therapeutic indications, contra-indications and side effects;

(6) formulation and directions for use, method of administration and expected stability, if it is less than three years;

(7) testing methods (control) employed by the manufacturer (quantitative and qualitative analyses of the ingredients and of the finished products, and special tests such as sterility, presence of pyrogenic substances or presence of heavy materials);

(8) the results of physical, chemical, biological, microbiological, pharmacological, toxicological and clinical tests;

(9) mock-up of the sales presentation or one or more specimens, plus package leaflet, where one is to be enclosed;

(10) a document showing that the manufacturer is authorized in his own country to produce proprietary products; and

(11) any authorization for sale of the product in any third country or in another member state.

In the case of number 8, bibliographical data relating to the items may be submitted for branded pharmaceuticals already in use with sufficient experience as to the side effects in human beings, if the pharmaceutical contains active ingredients which are the same as the preparations currently in use or it contains known ingredients.

Authorization to Market

An application may be withheld for approval if it is found that the preparation is harmful under normal conditions for use, balancing risk to benefit. An application also may be withheld if it is found that the preparation does not have the therapeutic potency claimed, or if such potency is inadequately substantiated by the application or if the nature and quantity of the ingredients are not as stated. Decisions on authorization to market are not to take longer than 120 days from the day the application is submitted. In exceptional cases, this period may be extended an additional 90 days. Interestingly, by a special provision, the Council directive indicates that the authorization for marketing the preparation shall have no effect on the liability of the manufacturer (under ordinary law) or of the distributor (where appropriate).

Once the product is placed on the market, the member states may suspend or withdraw authorization to market *only* if it is found that the preparation is harmful under normal conditions of use, or if it does not have the therapeutic potency claimed or if the nature or quantity of the ingredients is not as stated. Therapeutic potency is deemed to be lacking if it is found that the branded pharmaceutical does not have any therapeutic effect.

As to labels and packaging, the directive indicates that pharmaceuticals must be labeled with the name of the product. The name may be a brand name. Immediately following the name of the preparation, the nature and quantity of the active ingredients per unit must be stated. The active ingredients may be expressed in percentages, according to formulation. The name or registered trading name and address of the distributor and, where more appropriate, the manufacturer, should appear on the label. Finally, the method of administration, the last date for use in the case of a product with a period of stability of less than three years, and special storage precautions must also be indicated where appropriate. All of the previous items must be placed on the product package and, where there is no package, on the container. The language on the packaging and on the container must be the language of the country in which the product is for sale. Failure to comply with the labeling requirements is also reason for health authorities to withdraw or suspend the authorization to market.

Missed Deadline

Although the initial step was taken with the formal adoption of the first directive, the member states, primarily Germany, missed the December 31, 1966 deadline to bring their national rules into line with those contained in the directive. The rationale given by Germany for not adopting the directive was that Directive 65/65 did not make sense without the adoption of the directive dealing with the approximation of legislative regulatory administrative provisions governing preclinical and clinical investigations of branded pharmaceuticals. However, once the Commission threatened to bring action under the Treaty of Rome against Germany for failure to fulfill its duties under Article 189 of the Treaty, the German government introduced legislation to reform its pharmaceutical laws, especially concerning registration requirements. Hence, Germany and, to a lesser extent, Denmark, which is also reforming its registration laws, are the key jurisdictions for the implementation of Directive 65/65.

At the same time, the Council of Ministry has been cognizant of the German concerns and has adopted and sent to the Assembly the second draft directives which should be discussed.

Substantively, the second directive requires the member states to adopt provisions so that the documentation and information required to be submitted under Directive 65/65 will be submitted by the applicants to experts in the member state having the requisite

degree of technical or professional qualifications. The object is to obtain preliminary review of the product before it is presented to competent authorities for approval for marketing. The experts are required to give their opinions on the testing methods provided for in the application of the manufacturer, relating to qualitative and quantitative analyses of ingredients, and the results of physiochemical, biological, microbiological and toxicological clinical tests made.

Competent Authorities

Once submitted after review by the experts, the competent authorities in the member states are to check the files submitted in accordance with Directive 65/65, in the time unit provided therein (no drugs). However, the authorities may demand that the manufacturer furnish additional information or tests. In addition, they may submit the product to a state laboratory or to a laboratory designed for testing pharmaceutical products to have the tests made by the manufacturer repeated. Interestingly, when the competent authorities avail themselves of the privilege to request additional information, the time limit provided for the first directive is suspended. Member states are also required to adopt provisions to obligate the holder of an authorization to market a product to furnish proof upon request that the product has performed well during control tests of the base product before and during processing, insofar as the tests are needed to ensure manufacturing compliance with the rules in force under Directice 65/65. Member states must adopt legislation to verify the tests and to, in exceptional and justifiable cases, do research themselves. If the holder of the authorization is unable to furnish proof that the tests have been made in compliance with the rules in force, then it is reason to, temporarily or permanently, stop production of the proprietary medicine. The delivery of the product is to be prohibited and the product withdrawn from the market when it is found to be harmful under normal conditions of use, or it does not have the therapeutic effect claimed, or such effects are insufficiently substantiated by the applicant, or the medicinal product does not contain the ingredients in the quantity stated on the container.

Any action taken by member states pursuant to this directive is required to fully set forth the precise grounds for the action. The person concerned must be notified of the action, together with the information regarding the remedies provided under the laws in force and the time limit in which an appeal may be taken. No decision

ordering a permanent or temporary discontinuance of manufacture or withdrawal from the market may be made for any reason other than those set forth in the directive.

Trade Barriers

This directive does not obligate the member states to automatically recognize an authorization to market in another state and, therefore, does not necessarily remove some of the trade barriers within the Common Market member states regarding pharmaceuticals. However, there is a related proposed draft directive, submitted on February 9, 1970, which would harmonize the standards and protocols for the biological, analytical and clinical tests referred to in Directive 65/65 and in the second directive. The purpose, of course, is to launch a more uniform adoption of testing procedures so as to eliminate national registration requirements as a form of trade barrier. Additionally, this directive would create a standing Committee of Medicinal Products, which would have as its primary function the responsibility for examining any questions concerning the operation of the second directive. The questions would be presented by the chairman of the committee, either on his own initiative or at the request of a representative of a member state. For a full outline of the nature of the test required, I recommend review of these proposals in CCH COMMON MARKET REPORTS.

These, then, would be the recent developments in the Common Market affecting registration of products within the Common Market. I think, in summary on this point of registration, it is fair to say that the regulatory climate in Europe will only get more severe as a result of the adoption of directives, as exemplified by the legislation in Denmark and Germany relating to the registration and approval of pharmaceuticals.

Product Liability

Let us now look at the question of product liability law within the Common Market. There are basically three conventions which could result within the European Common Market, each being sponsored by a different group—The Hague Conference, the Commission of the European Communities, and the Council of Europe. The Hague Convention determines the law applicable, in a conflict of law case, regarding suppliers' liability for damage caused by a product because of defect, misdescription or a failure to give adequate notice of the product qualities or its methods of use. The Hague Convention does

not deal with matters involving the claim of a transferee against his immediate transferor because the Convention believes that such a claim is not ordinarily a "product's liability" question but is usually a question of warranty or other contractual responsibility.

Article 15 of the proposed Hague Convention, however, provides that the Convention "shall not prevail over the Conventions in special fields to which the Contracting States are or may become Parties and which contain provisions concerning products' liability." Let us turn to the drafts relating to more substantive laws.

European Communities' Directive

The first of these drafts is the European Communities' draft directive, which provides that the producer of an article manufactured by industrial methods or of an agricultural product shall be liable even *without fault* to any person who suffers damage as a result of a defect in such article. A "producer" is defined as any person by whom the defective article is manufactured and put into circulation in the form in which it is intended to be used. An article is deemed defective if it is unfit for the use for which it was intended by the producer. Quite clearly, this liability is to be borne by the producer, irrespective of fault, that is, strict liability in the U. S. sense. The actual liability of the manufacturer depends solely upon the causal connection between the defect and the damage. The liability is imposed without regard to any contractual relations which may exist between the manufacturer and the injured party, that is, "privity requirement." However, contractual claims are unaffected by the directive. National law would remain unchanged and would apply to contractual laws.

A determination as to whether a defect exists depends on an objective comparison between the purpose assigned to the article and the fitness of the article for that purpose. Where the article is not fit for the purpose intended, a defect exists of the type as may result in liability for damage resulting therefrom.

Limit on Damages

Damage, under this draft, must include personal injury. Where only property damage is involved, the directive is not applicable. Questions of property damage are to be treated under national law relating to contracts and warranties.

In passing, it should be noted that economic loss is recoverable as part of the total damage where personal injury exists. The directive

provides for a limit on damages but, as yet, the actual amount has not been specified. However, even after a showing of damage, defect, and the causality between the two, a manufacturer will be liable under the directive only if it is engaged in large-scale production (industrial methods). Liability for the manufacture of individual items or special order items is excluded. It was felt by the drafters that, since such manufacturing requires special care, the principle of liability with fault would be sufficient. Moreover, liability is not imposed on subcontractors or for semifinished or intermediate products; the directive quite clearly indicates that only the person who puts the end product of a manufacturing process on the market is responsible for the product. A manufacturer puts the product in circulation when it is delivered to the initial purchaser, that is, passed out of control of manufacturing. Hence, since it is the manufacturer who determines the proper use of an article, any use contrary to that laid down by the manufacturer is at the risk of whoever makes improper use of the article.

By way of concluding this short discussion on the Commission draft directive, a statute of limitations period is provided for. Any claim must be brought within a "reasonable" period of time from the date the product was first used. In any event, the period is not to be longer than an, as yet, unspecified number of years from when the product was first put into circulation. In summation, liability is given without any consideration of the contractual relationships which may exist between the manufacturer and the injured party. Liability depends solely upon the causal connection between the defect and the damage. Once again, the national laws of the member states must be changed to be in accord with this proposed directive within eighteen months following adoption of the directive. It, in itself, is not a law.

European Convention

Regarding the draft European Convention of the Council of Europe, this imposes liability on a producer to pay compensation for death or personal injury caused by a defect in the product but, again, property damage is not covered. A product (all moveables, natural or industrial, whether raw or manufactured, but not immoveables) has a defect when it does not provide the safety the person is entitled to expect, with regard to all of the circumstances including the presentation of the product. The producer is one who manufactures the finished product or component parts, or who produces natural products. Unlike the European Commission draft proposal, however, the importer

of a product and any person who has presented the product as his product by causing his name, trademark or other distinguishing feature to appear on the product shall be deemed to be the producer and will be liable as such.

Where no identity is indicated, the supplier becomes liable. The philosophy, of course, of such a broad definition of producers is to give a consumer the largest number of possible parties against which to recover. If several persons are liable under the convention, each is fully liable (in solidum).

Burden of Proof

Once again, the drafters of this convention felt that the idea of fault or *culpa* in product liability cases, regardless of whether or not the burden of proof of fault lay with the plaintiff, was not a satisfactory basis for liability. Hence, the committee of experts responsible for the draft have adopted the principle of strict liability, that is, no proof of fault is required for products cases. As with the European Communities' draft directive, the draft European Convention creates liability without reference to the existence of a contract between the injured party and the responsible party. There is, therefore, no privity requirement. It simply requires the injured party to prove a defect which caused the damage.

The key to liability under the draft European Convention is contained in the word "defect," which is defined to include the concepts of safety and expectancy. Paraphrasing from the draft, a product is defective if it does not provide the safety a person is entitled to expect under all circumstances. The tests of safety and expectancy are to be objective and are obviously not to be used upon the expectation of an individual consumer or person. Interestingly, the drafting committee chose not to use the term "reasonable" in connection with expectation since it was felt that its use might diminish consumers' rights. Its use could require one to consider economic factors and expediency in manufacturing, two factors the drafting committee felt not appropriate to questions of safety. In short, "all of the circumstances" must be taken into account to determine if a defect exists. The draft specifically lists only one such circumstance—"the presentation of the product," which should be viewed as including not only incomplete or incorrect warnings or directions but also the absence of directives for use or warnings.

Development Risks

As to the question of safety, the convention imposes liability at the time the product is "put into circulation"—presumably for the first time. That means when it has been delivered to another person and not at time of use. The comments accompanying the draft indicate this concept was adopted so as not to distinguish development risks from other situations. Development risks are those covering damage that was unforeseeable and unavoidable in the state of scientific knowledge at the time when the product was put into circulation. In other words, the draft incorporates the philosophy that the risk of injury from developments should be borne by the community as a whole through the spreading of risk with insurance companies by the producers, that is, buy insurance when one puts the product on. However, a trier of fact would have some leeway with regard to development risks because the definition of defect would allow a time factor to be considered in any individual case, that is, "having regard to all the circumstances." Notwithstanding the incorporation of strict liability, a producer is not liable if it can demonstrate that the product has not been put into circulation (delivered to another person), or if it can be demonstrated that the defect causing the damage was nonexistent when the product was put into circulation, or that the defect came into being after it was put into circulation. If the injured person has, by his own fault, contributed to the damage, compensation may be reduced or disallowed, after consideration of all circumstances. The same is true if an employee of the injured party has contributed to the damage as well. As with the European Commission draft, the liability of the producer cannot be excluded or limited by any exemption of exoneration clause. The convention would not have application to producers' liability *inter se* or their right of recourse against third parties. The convention would not affect any rights which a person suffering damages may have according to the ordinary rules of law of contract and warranty liability.

Measure of Damages

Compensation under the convention would be limited to death or personal injuries and would not include compensation for property damage. As to the actual measure of damages, the convention leaves to the individual states the responsibility of categorizing types and measure of damages which can be claimed under the convention. This was a compromise on the part of the drafters to avoid difficulty in

gaining acceptance of the convention by the members. Finally, the drafters have left to the individual countries the option of whether or not there should be a stated maximum recovery for damages. The convention provides for a limit of DM $20,000 per occurrence and DM $30,000,000 per aggregate.

In summation, the principle and basis of the liability retained by the convention is that the producer must pay compensation for damages resulting in death or personal injury caused by a defect in his product. The injured person must prove the damage, the defect, and the cause linking the defect to the damage.

Victim's Fault

All that the producer can do is successfully defend by proving that the defect did not exist when the product was put into circulation or that the defect was after the product was put into circulation. The victim's own fault may completely or partially reduce the liability if all circumstances are taken into account.

If a conclusion can be drawn from this short presentation, it is that corporations operating within the European Economic Community (EEC) must be prepared to face stronger regulatory and legal constraints in Europe. The author has tried to simply present an overview of the more important changes in the EEC in the hope of awakening an interest in developments occurring overseas. **[The End]**

EUROPEAN FOOD LAW ASSOCIATION

The first international congress of the EFLA will be held September 26 and 27, 1975 in Parma, Italy, on the general theme, "International Food Standards and National Laws." For information and registration, please address European Food Law Association, 3 Blvd. de la Cambre, 1050 Brussels, Belgium. The EFLA was established in 1973 at the Institute of European Studies, Brussels University. The Secretary General is Mr. Alain Gerard, Lecturer at Brussels University, and Associate Editor for Europe of the FOOD DRUG COSMETIC LAW JOURNAL.

Safety, Efficacy and Quality Review in the United Kingdom

By J. V. R. MARRIOTT

Dr. Marriott Is Manager of Regulatory Affairs of Abbott Laboratories, Ltd.

TO PARAPHRASE TERENCE: *"Quot medicinae tot sententiae; suo quoque mos,"* which translates freely into "as many opinions as there are medicines, each a law unto himself." I hope to show you how this applies and how it aptly describes the approach that, apparently, will be made regarding the review of product licenses in the United Kingdom (U. K.).

But before I attempt to show this and because our U. K. law regulating the marketing of medicinal products is different from that of the United States, let me briefly describe the Medicines Act.

Slide 1:[1] Our present main interest is in the entitlement to licenses of right and, in the next item, the procedure for application for all licenses for new products. Before going into these, let us look at the structure of the Licensing Authority.

Slide 2: The Ministers delegate their responsibility to the Department of Health and Social Service, Medicines Division, at the peak of which sits the Committee on Safety of Medicines (CSM). The work of the medical, pharmaceutical and administrative reviewers is canalized through subcommittees to the Committee. The interaction with industry exists at all three levels. The Medicines Commission is a policy-making Committee which advises the Minister.

[1] Slides begin on page 499.

Slide 3: The Medicines Act established the right of pharmaceutical manufacturers to apply for a product license of right for those products already on the market before September 1, 1971. Most of these manufacturers had already submitted information to the voluntary Committee on Safety of Drugs (Dunlop Committee). The information that had to be supplied to the new CSM was only slightly different and not very comprehensive.

It occupied three to four pages of typescript with more blank space than text and was, you will agree, quite insufficient to assess the products on the three criteria of quality, safety and efficacy.

Manufacturer's License

But, you could not produce pharmaceuticals without a manufacturer's license, which involved a full description of plant, premises, methods of manufacture and control, and visits by inspectors. In this manner, therefore, the quality criterion was looked after in a general way. The safety criterion was, to some extent, guaranteed by the fact that these products had been on the market for some time and were covered in the light of current knowledge. Efficacy was not touched upon.

We knew at the time that this was to be a short-lived paradise and that a review would put an end to it. Review has now descended on us.

Obviously, there are many people who object to this. There has been ample time, they say, to give a practical demonstration of the safety, quality and efficacy of these old products; the system of adverse effect reporting should have eliminated the toxic ones. But this is not necessarily so. Doctors, with little time to spare, are not very interested in reporting observations of adverse effects from old drugs.

Paradoxical Situation

You also have the paradoxical situation of the CSM refusing to grant a license for a new product, while a product which is not very dissimilar to the new product and which has a product license of right can continue to be marketed.

In addition, we have the Common Market Directive 65/65 which requires application of its rules, within five years, to products already on the market under previous national legal provisions.

To effect the review, the government is, under the Medicines Act, setting up the following structure.

Slide 4: This structure parallels that of the existing licensing setup and will even borrow some of its people. Note the liaison group, in which representatives of several interested parties are included.

The starting gun has been fired and it was not loaded with a blank charge. Only a few weeks ago, manufacturers were asked to have ready, by July 31, a mass of information relating to quality and safety including quantitative and qualitative formulae in full, methods of manufacture in detail and quality control in equal detail for every one of the products on licenses of right. This has created quite an uproar and many firms have stated that they cannot possibly supply this data by the given date. I am happy to state that Abbott is not among them.

Requests for Information

Later this year will come the requests for information relating to other aspects of safety and efficacy. Fortunately, these requests will not apply to all products at once, but will be limited to certain therapeutical categories only, since the Committee on Review of Medicines is going to give its attention to only a few categories at a time. The exact nature of this attention will be specific to each category. Hence my opening quotation. The first categories will be analgesics, anti-inflammatories and psychotropics, each of which contains several hundred products. Simultaneously, some small groups will be reviewed. The first will be anabolic steroids, antibiotics for use in the ear or nose, appetite suppressants and slimming aids.

Slide 5: Each of the different levels of the review structure will examine the information and make recommendations to the next higher level.

What information? Well, we are not sure but, logically, it has to be similar to that requested at the present time with an application for a product license for a new product.

Slide 6: The general particulars which were the only course of a product license of right application are, here, merely the hors d'oeuvres to a four-course banquet. And if this information is requested, it will bring several problems. One of these is that some of the information will just not be available. Will it be possible to generate it? This can

only be answered by the manufacturer for his own products, each on its own merits. It will also be of lengthy digestion. Because each of the levels of the review system can ask for further information and because the supply of this, followed by its integration, takes time and because the review of a therapeutic category includes several products manufactured by several firms, the speed can only be that of the slowest. Considerable delays must be anticipated before the final determination of recommendations on a category. The government's present estimate of a finish in 1983 consequently appears to be optimistic.

Progress in Technology

We cannot, at this stage, fully anticipate what information will be required. This is because in categories which will be reviewed in, for example, 1980, there will have been progress in technology, toxicology, pharmacology and clinical studies which might very well change the outlook on that category.

Is the review likely to lead to many licenses being revoked? Certainly it appears that the government would not be adverse to paring away some of the 36,000 products now licensed. It is also likely that some firms will voluntarily relinquish some of their licenses or withdraw their products when requested for information which they do not have, or have incompletely, or which would be too costly, in relation to likely future returns, to generate. Those products for which efficacy is in serious doubt are likely to be recommended for removal since, under present economic conditions, our government cannot go on paying for drugs of no therapeutic value. Where the efficacy/safety result is adverse, the recommendation may well be a pruning of some of the indications or a reduction in dosage or in duration of treatment. These measures might make the product uneconomically viable to the manufacturer.

Time will tell whether the wife or the husband was right in the following exchange from Sir Walter Scott's "Guy Mannering," in which Mrs. Bertram says, "That sounds like nonsense, my dear," to which Mr. Bertram replies, "Maybe so, my dear, but it may be very good law, for all that." **[The End]**

SLIDE 1

MEDICINES ACT OF 1968

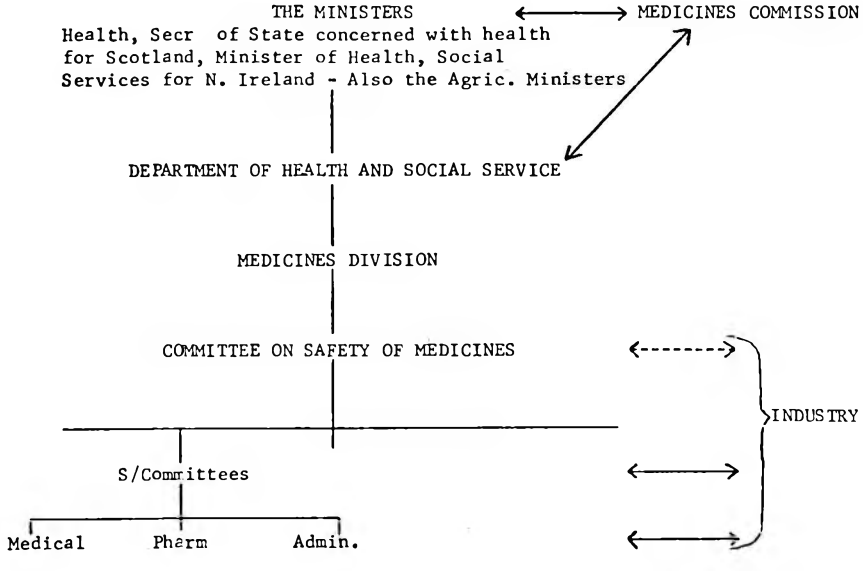
Established — Medicines Commission Licensing Authority

Enabled — the establishment of committees (CSM, CRM)
— the establishment of B. P. Commission
— other measures in future

Regulated — entitlement to licenses of right
— procedures for application, granting, revoking of licenses
— sale, supply, labeling, promotion of medicinal products
— pharmacies

SLIDE 2

SCHEMATIC STRUCTURE OF LICENSING AUTHORITY



SLIDE 3

REQUIREMENTS FOR APPLICATION

FOR

PRODUCT LICENSE OF RIGHT

GENERAL PARTICULARS

Pharmaceutical form

Name of active ingredient

Physical characteristics

Clinical use

Place of manufacture and assembly

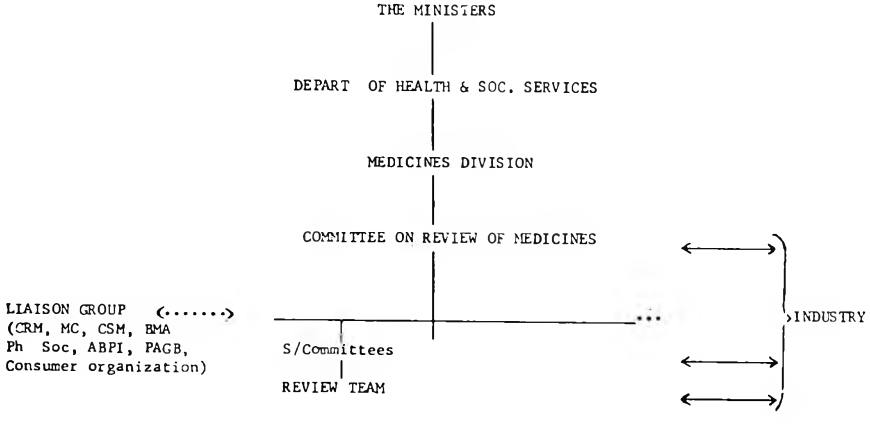
Quality control

Containers

Labeling

Method of sale and supply

SLIDE 4



SLIDE 5

THERAPEUTIC CLASSIFICATION OF DRUGS

AOO	Preparations acting on the alimentary system 14 divisions
BOO	Preparations acting on the cardiovascular system and diuretics 9 divisions
COO	Preparations acting on the respiratory system 5 divisions
DOO	Preparations acting on the nervous system 10 divisions
EOO	Preparations acting on the genito-urinary system 4 divisions
FOO	Preparations acting systemically on infections 9 divisions
GOO	Preparations affecting nutrition and blood 6 divisions
HOO	Hormones and preparations affecting metabolism 9 divisions
JOO	Contraceptive agents 4 divisions
KOO	Preparations acting on the musculo-skeletal system 3 divisions
LOO	Immunity-affecting drugs—Anti-Allergics 13 divisions
NOO	Preparations acting on the ear, nose and oropharynx 4 divisions
POO	Preparations acting on the eye 4 divisions
QOO	Dermatological and body cavity preparations (locally applied) 10 divisions
ROO	Other drugs and preparations 7 divisions
SOO	Preparations having no therapeutic claim 4 divisions

SLIDE 6

REQUIREMENTS FOR APPLICATION FOR PRODUCT LICENSE

GENERAL PARTICULARS
CHEMISTRY AND PHARMACY

Active Ingredient:
- Nomenclature and description
- Method of manufacture/in-process controls
- Impurities
- Development chemistry
- Specification; batch analyses
- Stability

Finished Product:
- Formulation
- Quality control
- Development pharmaceutics
- Biological availability
- Metabolism studies
- Stability/shelf-life
- Containers

EXPERIMENTAL AND BIOLOGICAL STUDIES

- Pharmacology
- Drug kinetics
- Toxicology: acute and chronic toxicology
  - carcinogenicity
  - reproduction
  - other studies

CLINICAL TRIALS AND STUDIES

The FDA's Regulatory Proposals for the Management of Advisory Committees

By THOMAS SCARLETT

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

ADVISORY COMMITTEES are now a way of regulatory life at the Food and Drug Administration (FDA). They are the best means the Agency has found for acquiring expertise on a systematic and continuing basis from specialists whose services would otherwise be unavailable. As important, the advisory committee mechanism involves a creative tension that assures a mature and balanced basis for regulatory action by requiring highly independent professionals of diverse training and experience to resolve complex scientific and medical issues to the satisfaction of the committee as a whole.

A committee's advice is no better than the quality of its members and of the information they have to work with. The FDA strives to obtain the best experts for service on its committees. Much of the information they need comes from their own background, and more is provided by the FDA through its administrative support. But most of the data relating to, for instance, the effectiveness of an over-the-counter (OTC) drug ingredient or the tests needed to establish the safety of a proposed new human prescription drug must come from the outside. As valuable as the contributions of the public at large, and especially of public interest groups, can be, it is in the nature of things that the pivotal role in getting the factual raw material to the committee is played by the members of the industry specifically responsible for the ingredient or the new drug under consideration.

The new FDA procedural regulations on advisory committees are intended to encourage the acquisition of the maximum amount of information on regulatory issues pending before advisory committees consistent with the statutory policy of openness in the conduct of those committee activities. At the same time, the Agency wants to assure expert consideration of regulatory issues in a manner that will yield the best possible advice. Whether the regulations will, in fact, achieve this result remains to be seen. My purpose is simply to explain the regulations.

The procedural regulations will be published in about two to three weeks.[1] Those dealing with advisory committees are set forth in Subpart D, which is entitled "Public Hearing Before a Public Advisory Committee."[2] As you might infer, two of the unifying themes in the regulations are:

(1) advisory committees act as hearing bodies to resolve pending issues in a manner somewhat analogous to that of an administrative law judge; and

(2) there is a presumption in favor of openness in the conduct of advisory committee activities.

The notion of the advisory committee as a hearing body is not a new one. It is especially familiar to those who have been involved in the OTC drug review, in which an OTC drug review panel receives all relevant data, conducts hearings at which the public and the industry appear and holds deliberative sessions to formulate the panel's advice. It then incorporates the advice in a report and recommended monograph, which are transmitted to the Commissioner for further public proceedings.

Open Public Hearing

This approach, which, increasingly, has been followed for other advisory committees in addition to the OTC Panels, is formalized in the new procedural regulations. Thus, every FDA advisory committee meeting must include an "open public hearing," that is:

"...an open portion which shall constitute a public hearing during which any interested person may present data, information, or views . . . relevant to the advisory committee's agenda or other work." (Section 2.304(a).)

Public participation will be promoted through advance notice (usually in the *Federal Register*) of the date, time and place of the

[1] The regulations were published in the *Federal Register* on May 27, 1975.

[2] See 40 *F. R.* 23012.

meeting. Also included in the notice is the general function of the committee, an agenda of the meeting and the time set aside for oral statements and other forms of public participation. (Section 2.305(b).)

The public hearing portion of the meeting will last a minimum of one hour, unless no one wishes to participate. (Section 2.312(a).) Anyone who wants to participate must notify the executive secretary of the committee, and furnish the relevant written material to the committee in advance. (Section 2.312(b).) The committee members may question the participant. Other participants may not. (Section 2.312(f).) A participant may question a committee member only with the member's consent. (Section 2.312(g).) The hearing is informal; the rules of evidence do not apply, and other procedural devices, such as motions and objections, are not available. (Section 2.312(h).)

The other portions of an advisory committee meeting are the following:

"*The open committee discussion.*... an advisory committee shall conduct its discussion of pending matters in an open portion. No public participation is permissible during this portion.... (Section 2.304(b).)

"*The closed presentation of data.* Data and information which are prohibited from public disclosure . . . shall be presented to the advisory committee in a closed portion of its meeting.... (Section 2.304(c).)

"*The closed committee deliberations.* Deliberations with respect to matters pending before an advisory committee may be made in a closed portion of its meeting...." (Section 2.304(d).)

As with any administrative hearing body, the specific advice or recommendations of an advisory committee will be supported by an administrative record. Briefly, the record will consist of all of the written data and information considered by the committee, the minutes issued by the committee, transcripts (if any) of open portions of the committee meeting and the relevant reports of the advisory committee. (Section 2.315(a).)

Administrative Hearing Body

So far, the discussion has concerned those aspects of the regulations that make advisory committee procedures like those of an administrative hearing body. The "open public hearing" is analogous to the trial part of a hearing and the closed committee deliberation compares to the consideration of a record by an administrative law judge in arriving at and writing his decision. Also, the administrative record is comparable to the evidence introduced at a hearing.

Some of the procedures referred to, however, do not have a specific counterpart in the Administrative Procedure Act hearing model. These introduce the other principal area of interest in the new regulations, that is, the extent to which advisory committee activities will be open to public scrutiny.

For example, the open committee discussion that is one of the portions of an advisory committee meeting is difficult to compare to any well-recognized procedure in the traditional adjudicatory setting. Thus, court of appeals' judges do not conduct public discussions of pending appellate matters. This is probably because a court of appeals is intended to speak with one institutional voice, and the discussion among individual judges is regarded as essentially irrelevant to the final decision of the court as a whole, as reflected in its opinion. However, a specific federal statute requires that advisory committee meetings be open to the public, subject to the exemptions of the Freedom of Information (FOI) Act. Accordingly, the FDA regulations provide that advisory committee discussions be public unless one of those exemptions permits them to be closed and public policy requires that the exemption be invoked.

Therefore, an advisory committee meeting will ordinarily be closed (and this includes members of the industry) if it involves review, discussion and evaluation of a specific investigational or marketed drug if such action is intended to result in a recommendation for regulatory action. A meeting will ordinarily be open for review, discussion and evaluation of general testing protocols for a class of drugs.

Closed Presentation of Data

Also, the regulations provide for the closed presentation of data which is prohibited from public disclosure. This procedure, too, finds little application in the traditional adjudicatory context where, if evidence is submitted, it is submitted for the public record. Of course, the kind of data subject to this procedure is generally trade secret data.

The closing of advisory committee discussions on a discretionary basis pursuant to the FOI exemptions will generally be done only when open discussion would unduly intrude into private matters; for example, where grant applications are considered. Meetings will also be closed when open discussion would compromise matters in investigatory files or would disrupt the operations of the FDA or of

a committee by interfering with the free exchange of views among committee members or by causing the premature disclosure of regulatory intentions.

The committee deliberation is essentially a subcategory of committee discussion. It will be closed because whenever a decision-making body reaches the stage of resolving specific issues and hammering out a final determination, it must be able to engage in uncompromising internal debate. Without such debate, the value of the advisory committee is largely nullified. It is felt that vigorous debate is unlikely to occur if the committee members must consider the possible impact of preliminary views or isolated statements of individual members, if communicated to outsiders. Advisory committee deliberations are thus closed pursuant to exemption (5) of the FOI Act, as incorporated in the Federal Advisory Committee Act. This provision protects from public disclosure the internal decision-making processes of the government. Although the industry is principally concerned with the trade secrets exemption of the FOI Act, it is the exemption (5) that will find the greatest application in the conduct of FDA advisory committee activities.

Trade Secrets Exemption

The trade secrets exemption, by contrast, will be invoked only in circumstances where other provisions of the laws governing the FDA's affairs proscribe the disclosure of trade secret information. For this reason, advisory committee meetings will not be closed for presentation of information by the industry unless the presentation involves data which, as presented, consist of trade secret data, rather than simply being a summary or discussion of something that is a trade secret in its raw form. The practical effect of this approach is that closed presentations by the industry will ordinarily be limited to those involving manufacturing processes, commercial information, safety and effectiveness data and information in investigational new drugs and new drug applications, the existence of which has not been made publicly known, and other similar categories.

The FDA's position on the handling of information which the industry regards as a trade secret or otherwise confidential has already inspired uneasiness among those who have encountered it. In fact, it has provoked a lawsuit. For further elaboration of the issues involved, I must, therefore, refer you to the briefs in the *Pharmaceutical Manufacturers Association* case. I should say, however, that the

FDA does not intend that trade secrets be disclosed routinely in advisory committee proceedings. It does intend that information *about* trade secrets often will be. The Agency believes that this is a necessary (and, needless to say, legally supportable) resolution of the competing needs for meaningful public participation in advisory committee activities and protection of the trade secret information itself.

Important Provisions

Other important provisions of the new regulations that deal with public disclosure of information about advisory committee activities are:

(1) Advisory committee members are allowed to discuss closed committee deliberations at any time after they occur, except that they may not attribute views to particular individuals or reveal numerical votes, and they may not discuss data or information prohibited from disclosure (for example, trade secret information) or matters specifically directed to be maintained as confidential (for example, a matter involving an incomplete or sensitive regulatory decision that would be prejudiced by premature disclosure). (Section 2.307(i).)

(2) Minutes will be prepared for each meeting. (Section 2.313.) Minutes relating to closed sessions will be made available after they are approved by the advisory committee and certified by the committee chairman. (Section 2.316(a)(6).) Those minutes will not refer to committee members by name, nor to data or information prohibited from public disclosure. (Section 2.313(b)(4).)

(3) Transcripts are not required. If made, transcripts of open sessions will be publicly available; transcripts of closed sessions will be neither publicly available nor a part of the administrative record of the committee's activities. (Section 2.314.)

That sums up the salient features of the FDA advisory committee process under the new rules. The only question remaining is what you can do about it. As far as concerns specific decisions with respect to specific committee procedures, the regulations provide an administrative remedy in the form of a petition to the Commissioner, which may be an oral petition if imminent action is objected to. (Section 2.319.) As far as the regulations themselves are concerned, the public is invited to submit comments, and then, of course, to institute suit, a procedure already well-known to those here today.

[The End]

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