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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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The FDA's OTC Drug Review: The Development and an Analysis of Some Aspects of the Procedure

By DAN R. HARLOW, Ph.D.

Dr. Harlow Is with the National Institute of Health.

Introduction

IN 1972, the Food and Drug Administration (FDA) proposed a review of over-the-counter (OTC) drugs in light of a previous Congressional requirement that drugs be "effective"; that is, have the therapeutic effect for which they are advertised and sold. The problems posed by this review were substantial and required the FDA to be quite innovative in the area of administrative law. The following is an analysis of some of the Agency's interesting innovations, the challenges to their validity, and their present status.

Historical Perspective

In the mid-1800's, legislation was passed to classify teas and to exclude certain kinds from entry into the United States. From this measure sprang food and drug law in the U. S. Between 1879 and 1906, 190 different measures were presented to Congress to control the quality of food and drugs; in 1906, the Food and Drugs Act was passed.[1] Of the 190 separate measures, 141 were never acted upon

[1] Regier, "The Struggle for Federal Food and Drugs Legislation," 1 *Law & Contemp. Prob.* 3 (1933).

and only 8 became law.[2] The reason for the failure of so many of the measures was opposition in Congress[3] which arose both from special interest conflicts (for example, an attempt to control oleomargarine made from cottonseed oil was opposed by southern Congressmen and favored by nonsoutherners) and from a general attitude that food and drug legislation was the work of cranks and reformers.

Opponents to food and drug legislation largely occupied three categories:

(1) Those who opposed on constitutional grounds (police power of federal government should not extend into states).

(2) Those who did not recognize the serious need for legislation to assure the purity and quality of food and drugs.

(3) Those who had special interest which would be adversely affected by food and drug legislation.[4]

Those in categories (1) and (2) eventually realized the inappropriateness of their opposition and finally supported such legislation while those in category (3) were the diehards and held out to the very end.[5]

Several pressures mounted to finally push enactment of the Food and Drugs Act of 1906.[6] One source of pressure was farmers who became so incensed at the adulteration of food that they pressured the establishment of state departments of agriculture with laboratories to test purity of foods. This system had obvious limitations so far as interstate commerce was involved, hence a federal law became necessary. At the same time, the muckrakers began an exposé of patent medicine frauds; the "Beef Trust" system of kick-backs between meat packers and the railroads was publicized; and Upton Sinclair wrote *The Jungle*. *The Jungle*, intended by the author to be socialist propaganda, was set in the Chicago stockyards where Sinclair had spent time, and described such revolting filth, and such unethical practices among the meat packers that the result was an outcry against the meat industry as a whole. The author himself stated that he had intended to strike the readers in their hearts but instead struck them in their stomachs.[7]

These pressures and more mounted such a force that President Theodore Roosevelt, in a message on December 5, 1905, forcefully called for legislation to control purity and prevent adulteration of

[2] *Id.* at 4.
[3] Bailey, "Congressional Opposition to Pure Food Legislation," 36 *Am. J. Soc.* 52 (1930).
[4] Regier, *supra* at 4, 5.
[5] *Id.* at 5.
[6] 34 Stat. 768 (1906).
[7] *Id.* at 9.

food and drugs. Final efforts to delay the bill persisted until June 30, 1906, when the bill was signed into law.[8]

Similar pressures, especially the "Elixir of Sulfanilamide" tragedy which resulted in more than 100 deaths from a newly marketed drug, led to the final passage of the 1938 Federal Food, Drug, and Cosmetic Act[9] which had, until the pressure was applied, languished in Congress for several years with infighting among the special interest groups (Category (3) of opponents to the 1906 Act). The opponents of Categories (1) and (2) appeared to be missing. The 1938 Act was significant in that it required drugs to be "safe" (possibly a reaction to the elixir of sulfanilamide tragedy) but did not require drugs to be effective. The latter requirement was added in the Drug Amendments of 1962.[10] These Amendments, sometimes called the Kefauver Amendments, resulted from extensive Congressional investigations led by Senator Kefauver (Democrat of Tennessee) into the drug industry. Senator Kefauver had attached himself to the investigation of drug manufacturers as a major thrust of his political image. Thus, as of the passage of the 1962 Amendments, drugs must be both safe and effective to be marketed in the United States.

With this thumbnail sketch of the historical development of legislation preceding the OTC drug reviews, it can be seen that the attempts to regulate nonprescription drugs arose early, before 1900. However, it was probably the muckraking of the early 1900's which uncovered the patent medicine frauds which eventually led to passage of the 1906 Act prohibiting adulterated or misbranded drugs. The safe and effective requirements for all drugs were added in 1938[11] and 1962[12] respectively.

The "effectiveness" requirement of the Drug Amendments of 1962 created a new dimension of drug regulation. Since 1938, drugs had to be proved safe through a formalized procedure known as a New Drug Application (NDA).[13] Thus, between 1938 and 1962, there were marketed under valid NDAs a number of OTC as well as prescription drugs. After the passage of the 1962 Amendments, the FDA was required to determine the effectiveness of all of these drugs. The FDA turned to the Division of Medical Sciences of the

[8] *Id.* at 15.
[9] 52 Stat. 1040 (1938), hereinafter cited in the text as the "1938 Act."
[10] 76 Stat. 780 (1962), hereinafter cited in the text as the "1962 Amendments."
[11] 52 Stat. 1040 (1938).
[12] 76 Stat. 780 (1962).
[13] Sec. 505, 52 Stat. 1040 (1938).

National Academy of Sciences-National Research Council (NAS-NRC) for help since, with both OTC and prescription drugs, about 4000 different drug formulations (involving about 300 different chemicals) were actually marketed and 3000 were covered by NDAs but not actively marketed. The NAS-NRC organized to carry out this job under the "Drug Efficacy Study" and submitted a report to the FDA;[14] the FDA implemented the NAS-NRC Study under its program (Drug Efficacy Study Implementation, or DESI).

The Development of the OTC Review

This quick look at past food and drug legislation, especially those aspects which arose from the need to regulate nonprescription drugs such as patent medicines, gives a historical perspective for the desire to regulate OTC drugs. Thus, the proposed rulemaking for OTC drugs published in 1972[15] was not an unheralded foray of government regulation into an unsuspecting segment of the marketplace. The proposed rulemaking explained that the NAS-NRC Study had covered 420 OTC drugs and reported that only 25 percent of them were "effective,"[16] the remaining three-fourths of them ranged from "ineffective" to "probably effective." The 420 OTC drugs examined by the NAS-NRC Study were only a small sample since it was estimated that the total number of OTC drugs marketed was between 100,000 and 500,000. One initial problem in setting up the OTC review was the desire and need to deal with *all* OTC drugs on an equal basis. For those OTC drugs which were marketed under valid NDAs, there was no problem since the 1962 Amendments would allow withdrawal of the NDA under Section 505(e) "on the basis of new information . . . there is lack of substantial evidence that the drug will have the effect it purports or is represented to have . . . ."[17] However, the 1938 Act "grandfathered" a number of drugs from requiring an NDA, including many OTC compounds, on the basis that they were covered by the 1906 Act (which did not contain the safety and effective requirements).[18] Similarly, the 1962 Amendments "grandfathered" many OTC drugs from the "effective" requirement.[19] How could the FDA reach these OTC drugs on the basis of their being not effective when they ostensibly were immune to the "effective" requirement? The FDA chose to attack the prob-

[14] *Drug Efficacy Study, a Report to the Commissioner on Food and Drugs*, National Academy of Sciences, 1969, hereinafter cited in the text as the "NAS-NRC Study."

[15] 37 *F. R.* 85 (1972).

[16] *Id.* at 85.

[17] Sec. 102(e), 76 Stat. 780 (1962).

[18] Sec. 201(p)(1), 52 Stat. 1040 (1938).

[19] Sec. 107(c), 76 Stat. 780 (1962).

lem with another weapon in the powers given it in the 1938 Act. If the OTC failed to have the effect it claimed, it would be "misbranded" under Section 502(a): "A drug . . . shall be deemed to be misbranded—(a) if its labeling is false or misleading in any particular."[20] Since the introduction into interstate commerce of a misbranded drug is prohibited under Section 301(a) and receiving of a "misbranded" drug is prohibited under Section 301(c), clearly the not "effective" OTC could be reached in this manner.[21] Criminal sanctions are available against perpetrators of prohibited acts in Section 303 of the 1938 Act.[22] Thus, the problem of reaching all OTC drugs had been overcome.

Now, however, the major hurdle was approached. How does a small regulatory agency such as the FDA handle the removal of up to 500,000 drugs? On a case-by-case basis, the withdrawal of NDAs and the determination of misbranding would be an Herculean effort likely to be altogether unreasonable. The envisioned results would be endless hearings and the intent of Congress in the 1962 Amendments would be thwarted. An alternative route was proposed: since the half million OTC drugs were composed of about 200 active ingredients, the problem could be approached on a "therapeutic class" approach with the active ingredients being examined for effectiveness.[23] The basis for the decision of effectiveness for active ingredients of each class would be "monographs" on each therapeutic class: those OTCs which met the standards of the monographs would be generally recognized as safe and effective (GRASE) and not misbranded while those *not* meeting the monograph standards would not be so designated and could be moved against via NDA withdrawal or misbranding.[24] The all-crucial aspect now arose over who would write the monographs. The rulemaking proposal suggested: "The commissioner shall appoint review panels of qualified experts to evaluate the safety and effectiveness of OTC drugs . . . ."[25] All OTC manufacturers would be requested to submit data on the safety and effectiveness of their products once the panels were selected. After listing the type of data acceptable, definitions of "safe" and "effective" as applicable to the monographs were proposed.[26] Of particular interest and of focus later in this paper is the "legal characterization" of the monographs:

[20] Sec. 502(a), 52 Stat. 1040 (1938).
[21] Secs. 301(a), 301(c), 52 Stat. 1040 (1938).
[22] Sec. 303, 52 Stat. 1040 (1938).
[23] 37 *F. R.* 85, 86 (1972).
[24] Subpart D(a)(11)(b)(2) and (3), 37 *F. R.* 85, 88 (1972).
[25] 37 *F. R.* 85, 87 (1972).
[26] 37 *F. R.* 85, 87 (1972).

"After its effective date, . . . a monograph . . . which is not the subject of a timely court appeal or which is the subject of a timely appeal and is affirmed by a court constitutes binding substantive rule . . . ."[27]

The proposed rulemaking ended with a list of the various categories of OTCs for which monographs would be prepared.

Finally the proposal moved on the remaining great logistical problem confronting the OTC review—how to avoid a separate protracted hearing for those drugs not meeting the monograph conditions or not covered by a valid NDA. The FDA approach here was as follows:

"Any such drug which fails to meet one or the other of these two conditions [meet monograph conditions or is covered by valid NDA] shall be in violation of the act and shall be subject to summary court procedure for determination of illegality."[28]

The proposed rulemaking invited comments to be sent to the FDA. Many such comments were sent. Perhaps the most often cited adverse comment (and the most vigorously expressed as well) concerned the legal status of the monographs (as substantive and not interpretive rules).[29] Following it as often cited adverse comments were: (1) the selection of members of the monograph review panels; (2) the status of drugs grandfathered both by the 1938 Act and the 1962 Amendments; (3) the validity of the summary judgment; and (4) the appropriateness of the therapeutic class approach. Further comments covered a wide variety of subjects. Each of the above specifically enumerated comments will be discussed in detail below.

Commentary on Special Problems in the Development of the OTC Review

(I) *The Monographs: Interpretive v. Substantive*

This question is of basic importance since it may effect the "weight" monographs will carry if challenged in court. According to Davis:

"Rules an agency makes pursuant to a grant of power to make law through rules are legislative [substantive] rules and have the same force as a statute if they are valid. The three tests of validity involve constitutionality, statutory authority, and proper procedure. A court may no more substitute its judgment as to the content of a legislative rule than it may substitute its judgment as to the content of a statute. Rules issued in absence of a grant of power to make law through rules are interpretative. Courts are free to substitute judgment as to content of interpretative rules, but they often give weight or great weight to the views of

[27] Subpart D(a)(11)(b)(1), 37 *F. R.* 85, 88 (1972).

[28] 37 *F. R.* 85, 89 (1972).

[29] Materials in Hearing Clerk's Office, FDA, Parklawn Building, 5000 Fishers Lane, Rockville, Maryland.

the agency, sometimes even to the extent of giving force of law to the rules. The four main factors that increase the authoritative effect of interpretative rules are special expertise of the agency, statutory reenactment, contemporaneous construction, and longstanding interpretations."[30]

The decision as to interpretive v. substantive also carries with it different standards of judicial review.[31] For substantive rules, review is under the "arbitrary and capricious" standard of 5 U.S.C. Section 706(2)(A)[32] while for interpretive rules, the standard is "substantial evidence." Clearly, there are advantages accruing to either the FDA or the industry challenger depending on which characterization the rules receive. For the advantage of the FDA, rules (in this case the monographs) would be substantive—thus review would be the arbitrary and capricious standard. It is very unlikely that an appellate court would find a technical report of a highly scientific agency such as the FDA "arbitrary and capricious." Indeed, since the FDA is relying almost entirely on outside scientific experts for producing the monographs, it is hard to conceive that any court would be able to find a monograph arbitrary or capricious.[33] In general, courts have deferred, especially in the case of the FDA, to the expertise of the agency in such highly technical matters. Thus, there is little doubt that a substantive characterization of the monographs would benefit the FDA and would burden any challengers.

On the other side, the "substantial evidence" standard as applied to interpretive rules would afford challengers more of an opportunity to successfully challenge the monographs on appeal. Also, interpretive rules can be attacked in collateral enforcement proceedings while substantive rules are binding and must be attacked by court appeal.

The position of the FDA is that it can proceed by either pathway, substantive or interpretive at its own choice.[34] The Agency's choice as set out in the proposed rulemaking was by substantive rulemaking.[35]

Returning to the analysis of the Davis text, it is not at all clear that characterization of rules as "substantive" or "interpretive" is of dispositive significance. For example:

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[30] Sec. 5.06, K. Davis, Administrative Law Text (3rd ed. 1972), hereinafter cited in the text as "Davis."

[31] Both of the terms, "interpretive" and "interpretative" are found in the literature. I will use "interpretive" since it is shorter and conveys the same meaning.

[32] Bass, Milton A., "Is the Substantive-Interpretive Issue Really Dead?," 30 FOOD DRUG COSMETIC LAW JOURNAL 448, 451 (August, 1975).

[33] *Id.* at 452.

[34] Comment 85 of Preamble, 37 *F. R.* 9464, 9471 (1972).

[35] 37 *F. R.* 85, 88 (1972).

"Courts are free to substitute judgment as to content of interpretative rules but they often give weight or great weight to the views of the agency, sometimes even to the extent of giving force of law to the rules."[36]

This matter-of-fact statement is of great significance and often reflects the attitude of courts toward the FDA. In an area of such complicated and specialized technology, the courts often will rely heavily on agency expertise, feeling themselves to be unqualified to enter into the "mysterious" and esoteric realm of scientific laboratories. In fact, Davis states:

"The four main factors that increase the authoritative effect of interpretative rules are *special expertise of the agency,* statutory reenactment, contemporaneous construction, and longstanding interpretations."[37] (Emphasis supplied.)

Thus, even though the challengers may feel that a major victory would be won by having the monographs labeled "interpretive," it is not at all clear that the result would be that the courts would find themselves willing (or able) to review the monographs on a substantial evidence standard. It is quite possible that even with the interpretive label, the rules could be given force of law status on the basis of the expertise of the agency, especially considering the use of outside experts to produce the monographs.

Thus, there is question as to the basic effect and importance of the distinction. Whereas the effect may be relatively unimportant in terms of the final weight accorded the rules, proponents for industry challengers have argued that cross-examination afforded in the interpretive model would afford them the ability to build a usable record for appellate review which is absent under the substantive model.[38] This seems to be a somewhat "anemic" approach to the significance of the interpretive v. substantive dichotomy. It would appear that the distinction must mean more than this in legal significance; if this is the totality of its significance perhaps its usefulness, at least in this area of law, has vanished.

The FDA, in its position concerning the substantive nature of the monographs, has relied on Section 701(a) to promulgate substantive rules: "The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section is hereby vested in the Secretary."[39]

This type of "broad powers" grant of rulemaking authority has been supported by the Supreme Court as power to issue substan-

[36] Davis, *supra* at 137.
[37] *Id.* at 137.
[38] Bass, *supra* at 456.
[39] Sec. 701(a), 52 Stat. 1040 (1938).

tive rules in several agencies, that is: "The Secretary may prescribe regulations to carry out his functions, powers, and duties under this title."[40]

The above grant of power to the Secretary of the Army was interpreted by the Supreme Court to make rules issued under it "have the force of law."[41] The rules of the FDA promulgated under Section 701(a) have similarly been found to: "have the status of law and violation of these carry heavy criminal and civil sanction."[42] In a more recent case, *National Nutritional Foods Association (NNFA) v. Weinberger,*[43] the Second Circuit Court of Appeals stated that FDA rules promulgated under Section 701(a) were "substantive" and binding upon the public. The Court further stated that the judicial standard of review is the arbitrary and capricious standard of 5 U.S.C. Section 706(2)(A). Barring Supreme Court review of *NNFA,* the law appears to be settled as to this question of interpretive versus substantive rules under Section 701(a). Industry challengers will be facing an "uphill grind" to change the characterization of the monographs.

It is of interest to speculate as to the willingness (if not eagerness) of the judiciary to characterize the FDA rules as substantive. Clearly such a labeling gives the rules more "clout" should the industry affected wish to challenge the action. Two threads appear to run through judicial thinking on this subject: (1) public interest considerations; and (2) judicial deference to agency expertise. A quote from *United States v. Storer Broadcasting Co.*[44] may be instructive in regard to public interest considerations:

"This Commission, like other agencies, deals with public interest . . . Its authority covers new and rapidly developing fields. Congress sought to create regulation for public protection with careful provision to assure fair opportunity for open competition in the use of broadcasting facilities. Accordingly, we cannot interpret § 309(b) as barring rules that declare a present intent to limit the number of stations consistent with a permissible "concentration of control." It is but a rule that announces the Commission's attitude on public protection against such concentration. The Communications Act must be read as a whole and with appreciation of the responsibilities of the body charged with its fair and efficient operation. The growing complexity of our economy induced the Congress to place regulation of businesses like communication in specialized agencies with broad powers. Courts are slow to interfere with their conclusions when reconcilable with statutory directions."[45]

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[40] 10 USCA Sec. 3012(g).

[41] *Public Utilities Commission of California v. United States,* 355 U. S. 534, 542 (1958).

[42] *Abbott Laboratories v. Gardner,* 387 U. S. 136, 151-152 (1967).

[43] 512 F. 2d 688 (CA-2 1975), hereinafter cited in the text as *"NNFA."*

[44] 351 U. S. 192 (1955).

[45] *U. S. v. Storer Broadcasting Co.,* 351 U. S. 192, 203 (1955).

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The flavor of this judicial attitude is clear and forceful; there is no doubt in the Supreme Court's assessment of their function *vis-a-vis* the "specialized agencies with broad powers." The specific question involved here was whether the Federal Communications Commission (FCC) could promulgate rules without a hearing under a general grant of power. The Court agreed with the FCC argument: "... that rules may validly give concreteness to a standard of public interest ...."[46] Likewise, in *Federal Power Commission v. Texaco,*[47] the Court expresses its concern with protection of the public interest by a government agency:

"The rulemaking authority here as in *Storer*, is ample to provide the conditions for applications under § 4 or § 7. Section 16 of the Natural Gas Act gives the Commission power to prescribe such regulations "as it may find necessary or appropriate to carry out the provisions of this Act." We deal here with a procedural aspect of a rate question and with a certificate question that is important in effectuating the aim of the Act to protect the consumer interest."[48]

Thus, the Supreme Court is quite mindful of Congressional intent in statutes which were specifically intended to protect the public. Certainly the Federal Food, Drug, and Cosmetic Act is such a statute, perhaps one of the best examples of "pure" public interest legislation.

The other "thread" running through judicial thinking that often surfaces is the judiciary's deference to a specialized agency's expertise. This was alluded to in *Storer.*[49] Strong enunciation of this judicial attitude is found in *NNFA,* where the Second Circuit stated that Congress intended the FDA to promulgate rules to facilitate the 1938 Act "rather than leave the decisions to the courts, which lack the medical and scientific knowledge essential to such decisions."[50]

It has been stated that *NNFA* "... is strong authority for the proposition that the OTC monographs, if promulgated by proper procedure, are also valid and binding in judicial proceedings."[51] Strong indications for judicial acceptance of the authoritative nature of the monographs is seen in *Weinberger, Secretary of Health, Education, and Welfare v. Bentex Pharmaceuticals, Inc.,*[52] where the monograph approach to OTC review is described. Although in the form of *dictum,* the description gives a strong feeling of judicial approval of the monograph procedure.

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[46] *U.S. v. Storer Broadcasting Co., supra* at 201.

[47] 377 U. S. 33 (1963).

[48] *Federal Power Commission v. Texaco,* 377 U. S. 33, 41 (1963).

[49] See note 45, *supra.*

[50] 512 F. 2d at 699.

[51] Ames and McCracken, "Framing Regulatory Standards to Avoid Formal Adjudication: The FDA as a Case Study," 64 *Calif. L. Rev.* 14, 57 (1976).

[52] 412 U. S. 645, 650 (1973).

Although confident assertions are heard from industry challengers that Congress did not intend Section 701(a) to give force of law to rules (in this case monographs) promulgated under it,[53] it appears that there is little judicial precedent upon which to base these assertions in the food and drug law area. Other commentators are just as adamant in asserting that Section 701(a) regulations do have the force and effect of law:

"Section 701(a) is the sole authority for issuing interpretive and advisory regulation. Authority for issuance of substantive regulations which implement the statute is derived from the express authorizations contained in the respective sections *as well as from Section 701(a).*"[54] (Emphasis supplied.)

In light of the public interest aspect and the judicial deference to the FDA's expertise, it is to be expected that the monographs promulgated under Section 701(a) will carry the force and effect of law.

Since the monographs are promulgated as substantive and not interpretive, the Administrative Procedure Act (APA) requirements for such rulemaking must be followed; primarily this requires adequate notice to interested parties, hearings before adopting the rules, and opportunity to participate through submission of written data.[55] There appear to be no allegations from industry that the requirements of the APA have not been met.

Assuming the substantive nature of the properly promulgated monographs, where does this leave the industry challenger? The substantive characterization of the monographs closes many *legal* options due to higher standards of review:

"If the agency [FDA] 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."[56]

With this *legal* maneuver foreclosed, industry must rely at this point on *scientific* options. Industry challengers are invited to present their data to the monograph panel who will be examining all scientific data available on a given compound or drug. The participation by industry at this point could be crucial if their scientific backup is substantial and weighty enough to persuade the panel. If the challenger's data on his compound or drug prove effectiveness, the monograph will so reflect and the compound or drug then meets the

[53] Whyte, Warren E., "The FDA's OTC Drug Review," 28 FOOD DRUG COSMETIC LAW JOURNAL 381, 384—388 (June, 1973).

[54] Markel, *The Impact of the Federal Administrative Procedure Act on the Federal Food, Drug, and Cosmetic Act*, in Federal Administrative Procedure Act and the Administrative Agencies 389 (G. Warren ed. 1947).

[55] 5 U. S. C. Sec. 553 (1975).

[56] Whyte, *supra* at 452.

requirements of the monograph. No further action is required by the manufacturer—his product meets the requirements of the monograph and is thus free to be marketed. Thus the arena of confrontation is moved from the legal to the scientific.

It is this writer's opinion that the resulting shift from legal to scientific is desirable and perhaps envisioned by the judiciary. The desirability arises from the fact that the monographs determine highly specialized complex, technical matters whereas courts are arenas for more generalized problems. Although the practice of law is now feeling pressures to specialize, it is still often characterized as the last hold-out of the generalist. Thus, the generalized court has stated often that it did not feel qualified to rule on highly complex technical matters for which Congress has seen fit to create the specialized, technical agencies to handle. By finding the monographs substantive, the courts have prevented conflicts from arriving in court to be reviewed on the "substantial evidence" basis which would require the court to make a scientific determination. The arbitrary and capricious rule is such an extreme standard as to be virtually foreclosed by the agency's use of recognized outside experts.[57] Courts appear to be saying that highly complex, technical scientific matters must be left to the scientists, not the courts.

The logical question now is the method for selecting the panel and does the panel represent a broad spectrum of biases or can the selection be manipulated to result in a narrow range of views preferred by the FDA? This very question often was presented in the comments submitted to the proposed rulemaking[58] and leads to the next major point of discussion.

(II) *The Selection of Members for the Monograph Advisory Review Panels*

It is obvious in light of the substantive nature given the monographs by the courts that selection of members for the monograph review panels is of major significance. For those working in science, the myth of the objective, non-biased scientist is often heard but such a paragon of rational, logical nature is rarely, if ever, seen. This situation is also known to some people outside of science, particularly lawyers, who deal with scientists: "Since it is well known that medical experts can easily be obtained for almost any side of any controversial proposition . . . ."[59]

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[57] Whyte, *supra* at 452.
[58] See note 29, *supra*.
[59] Whyte, *supra* at 452.

If the FDA were to appoint only panel experts who represented views favorable to itself, the resulting monographs would likely also represent such a viewpoint. In the proposed rulemaking, the FDA opened the door to participation in the selection of panelists without specifying the exact procedure:

"The members of a panel shall be qualified experts (appointed by the commissioner) and may include persons from lists submitted by organizations representing professional, consumer, and industry interests."[60]

The statement in the final rules was the same.[61] Since the make-up of the panel may itself raise due process questions, it has been suggested that the willingness of the FDA to allow industry to propose names to be considered for panel members is to prevent such a challenge.[62] It should be noted that industry or consumer groups did not have the opportunity to propose names for the NAS-NRC Study which were held valid by the courts. It appears that the FDA may be giving more than perhaps it needs to in order to assure due process in the monograph procedures. A spokesman for the FDA has said as much:

"We must assure, and this is of critical importance, the fundamental fairness in the procedures that we have been devising. In the OTC drug review we have, if anything, gone overboard in making certain that everybody has an opportunity to participate."[63]

In 1973, the procedure in selecting panelists included suggested names submitted to the FDA by interested parties (for example, industry and consumer groups). There were also two non-voting liaison members; one nominated by the Consumer Federation of America (consumers), the other nominated by the Proprietary Association (industry).[64] The procedure appears to be the same now, although somewhat more formalized in general character due to Federal Advisory Committee Act (FACA)[65] requirements.[66]

Since the FDA is promulgating the rules under "notice and comment" procedures,[67] why the due process worry with involving those to be regulated in the selection of panelists? It would seem that if only the "notice and comment" requirement were met, the

[60] 37 *F. R.* 85, 87 (1972).
[61] 37 *F. R.* 9464, 9473 (1972).
[62] Whyte, *supra* at 390.
[63] Hutt, Peter Barton, "Views on Supreme Court/FDA Decisions," 28 FOOD DRUG COSMETIC LAW JOURNAL 662 (November, 1973).
[64] Yingling, Gary L., "The OTC Drug Review," 28 FOOD DRUG COSMETIC LAW JOURNAL 273, 274 (April, 1973).
[65] 86 Stat. 770 (1972).
[66] Pinco, Robert G., "The FDA's OTC Review—The Light at the End of the Tunnel," 31 FOOD DRUG COSMETIC LAW JOURNAL 141, 142 (March, 1976).
[67] 5 U. S. C. Sec. 553 (1970).

FDA would have fulfilled its procedural requirements. Indeed, Congressional overseers have often viewed such an "unnecessary accommodation" by the FDA as suspect, perhaps even "chumminess" between the regulator and those to be regulated. This type of charge is regularly hurled at the FDA. [68, 69, 70] Why then would the FDA risk another such charge by giving industry powers not demanded by Section 553 of the APA "notice and comment" procedures?

Section 553(c), APA, gives interested persons: "An opportunity to participate in the rule making through submission of written data, views, or arguments with or without the opportunity for oral presentation."[71]

The participation required to be allowed here is through "written data, views, or arguments," and oral presentation may or may not be allowed. There is no indication of a need to allow interested persons to participate in the selection of agency panelists or advisory committees. The answer to FDA's decision to do so is, I think, twofold.

First, as mentioned above, the OTC monograph approach to handling the OTC effectiveness reviews is a new and somewhat novel approach. It is to be expected then that courts may be more critical in their review of the procedure—therefore, the FDA's desire to assure all reasonable due process protection considerations to the point of "going overboard."

Second, some courts recently have expressed dissatisfaction with simple "notice and comment" procedure under Section 553(c), APA, especially when the matters at hand are highly complex and the decision has sizeable consequences.[72] These courts have put extra requirements on Section 553(c), requirements resulting in "hybrid" or "notice and comment-plus" rulemaking. In *Walter Holm & Co. v. Hardin*,[73] the Court of Appeals for the District of Columbia held that plaintiffs were entitled to hearings on issues of "crucial" importance with a limited right of cross-examination. The regulation was rulemaking under notice and comment requirements and involved highly technical agricultural matters (whether tomatoes of one-fourth inch greater diameter could be graded as "vine ripes" versus the one-fourth

[68] Brown, Stephen A., "The Food and Drug Administration and the Impossible Dream," 28 FOOD DRUG COSMETIC LAW JOURNAL 391 (June, 1973).

[69] M. Mintz, *By Prescription Only* (1967).

[70] J. Turner, *The Chemical Feast* (1970).

[71] 5 U. S. C. Sec. 553(c) (1970).

[72] Williams, "'Hybrid Rulemaking' Under the Administrative Procedure Act: A Legal and Empirical Analysis," 42 *U. Chi. L. Rev.* 401 (1975).

[73] 449 F. 2d 1009 (CA DofC 1971).

inch smaller "mature greens"). The results of the ruling had suggestions of maneuvering against the plaintiff economically. The Court fashioned a "half-way house" between the notice and comment requirements of Section 553 and the "on-the-record" of Section 556 and Section 557, APA.

In *Mobil Oil Corporation v. FPC*,[74] the Court of Appeals for the District of Columbia held the plaintiff to be due cross-examination or some other substitute such as submitted questions to be either orally answered or answered in writing. Here, the Federal Power Commission (FPC) had issued a rule under "notice and comment" procedures setting minimum rates without having given the plaintiffs the particulars of the procedures by which they reached their decision.

In *International Harvester Corporation v. Ruckelshaus*,[75] the Environmental Protection Agency (EPA) had denied automobile manufacturers a one-year deferral on automobile emission standards. The Court remanded with an opportunity for the automobile manufacturers to have a limited right of cross-examination and a right to comment on certain materials put before them by EPA upon which they had not been given an opportunity to comment.

Thus, the FDA's grant of participation in the panel makeup, grant of nonvoting liaison members may be provided to preclude or at least reduce the risk of a court remand for a "hybrid" or "notice and comment-plus" rulemaking. The EPA has developed several means of its own to supplement the "notice and comment" requirements to insure the participation of its regulated manufacturers: "(1) an advance written statement of methodology; (2) an inquiry conference, on or off the record; and (3) written agency answers to interrogatories."[76]

It appears at this point that there is a reasonable amount of flexibility in such additional procedures; the main point being that some courts are unsatisfied with a "bare-bones" Section 553, APA, approach, especially in areas of technologically and scientific complexity in conjunction with severe results to the regulated industries. In such cases, the courts did not go so far as to require the formality of on-the-record hearings following Section 556 and Section 557, APA, because the enabling statute did not so require. But it is clear that minimal Section 553 requirements did not suffice.

[74] 483 F. 2d 1283 (CA DofC 1973).
[75] 478 F. 2d 615 (CA DofC 1973).
[76] Williams, *supra* at 448.

Thus, the FDA's design of participation by manufacturers in the selection of panelists may also be a mechanism to insure sufficient participation in the rulemaking process to satisfy the possible need a court may find for "hybrid" rulemaking as well as the wish to satisfy general due process or "fair play" requirements.

(III) *The Monograph Approach to OTC Drug Review*

Previously it was noted that in this country there are marketed between 100,000 and 500,000 different OTC products which must be reviewed as to the effective standard of the 1962 Amendments. The NAS-NRC Study looked at a small sample of these OTC products and found only 25 percent of them to be effective. The FDA then was faced with the enormous task of reviewing the effectiveness of an enormous number of products; so many as to be logistically impractical, if not impossible, if attempted on a drug-by-drug basis. The demand to remove ineffective drugs stated in the 1962 Amendments certainly would be thwarted in a time sense even if the drug-by-drug approach were feasible in terms of the FDA's resources at hand to accomplish the review. The obvious option available to the Agency would be to group drugs according to some logical procedure. It was determined that the entire OTC market was composed of about 200 chemicals in various combinations and formulations and that certain subgroups of the 200 were offered to have a specific therapeutic effect. Hence, there was a decision to list the 26 categories according to therapeutic effect (for example, antacids, laxatives, anti-perspirants, bronchodilators and antihistamines, etc.).

Comments offering the opinion that such an approach is not valid were numerous.[77] The rationale given by the FDA in the proposed rulemaking involved the logistical impossibility of the FDA carrying out the review on a drug-by-drug basis. Several comments stated that such considerations were not proper since more manpower and funds could be obtained for the purposes of the review. The FDA's position was: (1) the funds for such an unwieldy exercise were not available; and (2) even if funding were available, the results of such an enormous undertaking would be "confusing" and "cumbersome."[78] One probable unacceptable result would be the case where one OTC drug would be removed from the market while a similar one could remain on the market for an extended period of time.[79] This occurrence would be unfair among the manufacturers as well as fail in protecting the consumer, which is the intent of the

[77] See note 29, *supra.*
[78] 37 *F. R.* 9464, 9465 (1972).
[79] *Id.* at 9465.

1962 Amendments. For lack of a better alternative, the therapeutic class approach would be followed.

The main complaint of the manufacturers arises from the fact that the manufacturers are used to being dealt with by the FDA on a drug-by-drug basis in the NDA withdrawals. Even though there is a logical need to handle the situation through therapeutic classes, industry may still question the validity of the approach. However, in the *Permian Basin Area Rate* cases,[80] the Supreme Court upheld the FPC class-approach to rate determination by class proceedings. In a drug manufacturer's case, *Hoffman-La Roche v. Kleindienst*,[81] the Court of Appeals for the Third Circuit approved a class approach: "Here the final order will apply across the board to all producers, wholesalers, and distributors of Librium and Valium as well as to pharmacies and physicians."[82] The reasoning the Court used to arrive at this approach was: "quick action to protect the public, and the need to treat similarly situated drug products similarly."[83] These are quite similar reasons in the same segment of the economy as the FDA proposes to support its therapeutic class approach.

In an important recent drug case, *Hynson*, the Supreme Court held that:

"The comprehensive, rather than individual treatment may indeed be necessary for quick effective relief . . . to require separate judicial proceedings to be brought against each, as if each were the owner of Black Acre being condemned, would be to create delay where in the interests of public health there should be prompt action. A single administrative proceeding in which each manufacturer may be heard is constitutionally permissible measured by the requirements of procedural due process."[84]

Here the question was whether the FDA could move on all the manufacturers of a drug manufactured as a result of one NDA held by the original manufacturer. The court approved the FDA's moving on the "pioneer drug" and the "me-toos" in one proceeding in another case.[85]

Thus, the logical and open expression by the FDA of reasons for the therapeutic class approach and judicial attitudes which approve such reasons would suggest that FDA's approach will be found valid. Finally, in *Bentex*, the Supreme Court appears to have expressed its approval of the therapeutic class approach, although in *dictum:*

[80] 390 U. S. 747, 784 (1968).
[81] 478 F. 2d 1 (CA-3 1973).
[82] *Id.* at 13.
[83] Ames and McCracken, *supra* at 67.
[84] Hynson, *supra* at 624-625.
[85] *USV Pharmaceutical Corp. v. Weinberger, Secretary of Health, Education, and Welfare*, 412 U. S. 655 (1973).

"FDA has also realized that it is impossible to apply the 1962 amendments to over-the-counter (OTC) drugs on a case-by-case basis. There are between 100,000 and 500,000 of these products, few of which were previously approved by FDA. In May, 1972 FDA adopted a procedure for determining whether OTC products not covered by NDA's are safe products, not ineffective, and not misbranded. 37 *Fed. Reg.* 9464."[86]

In light of administrative exigency and the voices of the courts, the question of the validity of the therapeutic class approach is probably no longer in doubt; the approach can be expected to be upheld if ever challenged in court.

(IV) *The Grandfather Clauses of the 1938 Act and the 1962 Amendments*

In the proposed rulemaking, it was noted that very few of the 100,000 to 500,000 OTC drugs were covered by NDAs under Section 505 of the 1938 Act. The mechanism of withdrawal of an NDA would not reach these drugs. The proposal was to reach the OTC drugs not under NDAs as not GRASE under Section 201(p)(1) definition. Obviously, if the OTC drugs were found by the monograph panels to be ineffective, they could not meet the GRASE requirements of Section 201(p)(1) and, therefore, be, by definition, a "new drug" requiring the filing of an NDA. The NDA would, of course, be denied if the drug were ineffective.

The problem of the "grandfathered" drugs came as a result of the last portion of Section 201(p)(1) of the 1938 Act:

". . . except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use . . . ."[87]

This grandfather clause would exempt those pre-1938 drugs which had been subject to the 1906 Act from the "safe" requirements of the 1938 Act. There being no "safe" requirement, these drugs were then not liable to action under Section 505 since they are not "new" drugs.

Similarly, the 1962 Amendments had a grandfather clause:

"In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic act as then in force, and (C) was not covered by an effective application under Section 505 of that act, the amendments to Section 201(p) made by this act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."[88]

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[86] Bentex, *supra*, at 650.

[87] Sec. 201(p)(1), 52 Stat. 1040 (1938).

[88] Sec. 107(c)(4), 76 Stat. 780 (1962).

It is obvious that the Congress intended to exempt from the new "effective" requirement of the 1962 Amendments those drugs which were "generally recognized as safe"—not "new" under the 1938 Act, and those drugs not covered by NDAs (Section 505 of the 1938 Act).

The OTC drugs under NDAs could be reached for withdrawal by the monographs under Section 505(e)(3):

". . . or (3) on the basis of new information before him [Secretary, DHEW] with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; . . . ."[89]

The data accumulated by the monograph panels could thus be used for the withdrawal of an NDA and, therefore, the "not effective" OTC drug. However, those drugs which were grandfathered in the 1938 Act and the 1962 Amendments could not be handled in this manner. The Congressional intent being clear as to the "effective" requirement, the FDA had to look elsewhere in the 1938 Act for power to remove those OTC drugs which were grandfathered and found "not effective" by the monographs. Section 301 provided a route of reaching such drugs through the misbranding approach:

"The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."[90]

If an OTC drug is not effective, is it also misbranded? Section 502 of the Act states: "A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular."[91]

Is lack of effectiveness "misleading in any particular"? It would logically seem so.

The industry challengers may argue that the FDA should not be able to circumvent the intent of Congress to grandfather these drugs by the use of another provision of the 1938 Act. However, Section 502 was a part of the Act as passed in 1938; the grandfather clause applied only to the definition of "new drug" (Section 201(p)(1)) of the 1938 Act. Therefore, Congress was interested in exempting existing drugs from the new "safe" requirement in the new drug definition, but no mention was made of exempting the pre-1938 drugs from the misbranding provision (Section 502). What is seen here are

[89] Sec. 505(e)(3), 52 Stat. 1040 (1938).
[90] Secs. 301, 301(a), 52 Stat. 1040 (1938).
[91] Secs. 502, 502(a), 52 Stat. 1040 (1938).

two entirely independent sections of the Act. There is no reason to assume (since there is no evidence for the basis of the assumption) that Congress intended to grandfather drugs from the misbranding provision. It is even more unlikely that Congress would have such an intention since the misbranding provision was in the 1906 Act as well as in the 1938 Act, and the 1962 Amendments left the provision intact. The Act taken as a whole has the flavor of a strong consumer protection statute in a highly technological and complex sector of the economy. In the face of the explicit language of Section 502, an argument that Congress intended free-marketing of drugs found to be "not effective" for the purposes for which they are labeled and sold is tenuous. If the grandfather status is attacked in court, it would be hard to predict the outcome. The technical nature of the area and a possible appearance of "maneuvering" on the part of the FDA may make the decision in court a difficult and complex one.

It should be pointed out here that manufacture of misbranded drugs is a prohibited act under Section 301 which can bring *criminal* penalties on executives of the drug companies under Section 303. The misbranding approach ends in quite different results, more severe than those which result under the withdrawal of an NDA. The criminal penalties are undoubtedly one reason industry may vigorously oppose this alternative approach by the FDA.

(V) *The Use of Summary Adjudication by the FDA*

In the proposed rulemaking, the FDA presented its procedure for removal of OTC drugs which do not meet the conditions as set forth in the monograph:

"Once a monograph becomes a binding substantive rule pursuant to subparagraph (1) of this paragraph, an OTC drug falling within the category of drugs covered by that monograph shall, prior to its marketing either comply with all of the conditions established in that monograph or be the subject of an approved new-drug-application. Any such drug which fails to meet one or other of these two conditions shall be in violation of the act and shall be subject to *summary court procedure* for a determination of illegality."[92] (Emphasis supplied.)

The summary court procedure referred to was of a type which had already been used in withdrawing prescription drug NDAs on the basis of the NAS-NRC Study. It is quite interesting to note that the final regulations did not state the summary court procedure would be used: "(12) *Regulatory action.* Any product which fails to conform to an applicable monograph after its effective date is liable to regulatory action."[93]

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[92] 37 *F. R.* 85, 88 (1972).

[93] 37 *F. R.* 9464, 9475 (1972).

A possible reason for removing the specification for summary judgment may be that although the procedure had been used with the NAS-NRC Study, it was being challenged in court. If the FDA tied itself down to the summary judgment procedure which might later be found invalid in court review, the regulations would have to be modified, again with the lengthy notice-and-comment procedure. By stating the regulatory action in such broad terms, the FDA has avoided such an undesirable future event.

The summary judgment procedure has been challenged in an interesting series of cases. The decision on whether summary judgment is appropriate is one which requires almost as much scientific judgment as legal judgment. Since the question of whether the plaintiff requires a hearing or instead can be moved against through summary judgment is one which has such dire legal consequences, the courts have not been able to back off as they did with the monographs (declaring the monographs substantive and subject only to arbitrary and capricious standard of review). In the summary judgment situation, the courts find themselves inextricably drawn into a highly significant legal question whose answer depends to a great extent on scientific judgments. The results of such an incongruous situation are, as might be expected, very uneven.

The basic scenario for calling on the summary judgment procedure for the NAS-NRC Study on prescription drugs is as follows. The 1962 Amendments direct disapproval of new NDAs for drugs which are not effective and withdrawal of old NDAs whose drugs were later found to be not effective, if: ". . . there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed . . . ."[94]

The all crucial words "substantial evidence" mean

". . . evidence consisting of adequate and well controlled investigations, including clinical investigations by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed . . . ."[95]

Using the statutory language above, the FDA formulated regulations which would particularize the types of data which would qualify for "substantial evidence" characterization. Basically the regulations require:

(1) a statement of the objectives of the experiments;

(2) description of the methods used to select various test and control groups and procedures which would reduce any biases present;

[94] Sec. 102(c)(5), 76 Stat. 780 (1962). [95] Sec. 102(c), 76 Stat. 780 (1962).

(3) description of methods to be used in recording data; selection of methods best suited to minimize bias;

(4) description of control groups and why the control is valid; and

(5) a summary of results obtained including any suitable statistical analyses.[96]

With the characterization of "substantial evidence" now particularized, the FDA can go to Section 102(c)(5) of the 1962 Amendments and can withdraw NDAs on the basis of lack of "substantial evidence" of effectiveness. However, under the NDA withdrawal procedure: "The secretary shall, after due notice *and opportunity for hearing* to the applicant, withdraw approval."[97] (Emphasis supplied.)

Thus, the FDA is directed by the statute to give the applicant a hearing prior to withdrawal. The FDA has conceded that the hearing envisaged here is the formal, on-the-record type of Sections 556 and 557, APA.[98] The FDA had only two hearing examiners[99] and had suffered through some seemingly endless hearings on vitamin-mineral supplements and on peanut butter.[100] The practical problem arose from the fact that there were nearly 4,000 prescription drugs on the market with effective NDAs that had to be examined by the NAS-NRC Study. A sizeable number could be expected to require withdrawal actions (70 percent of the claims were found unwarranted)[101] which would logistically be impossible resulting in thwarting the 1962 Amendments to the Act.

The option of a summary judgment procedure akin to that found in Rule 56(c) of the Federal Rules of Civil Procedure (FRCP) was considered.[102] The requirement for the use of such procedure would be, as in the FRCP, that there is "no genuine issue as to any material fact." At such an NDA hearing, it would be expected that the embattled manufacturer would submit any data that would give any support to the possibility of "effectiveness" of its drug. In the past, such "data" as testimonial letters of practitioners and even patients had been received by the FDA, but the Agency had promulgated regulations stating the requirements for substantial evidence.[103] If

[96] 35 *F. R.* 7251 (1970).
[97] Sec. 505(a), 52 Stat. 1040 (1938).
[98] Ames and McCracken, *supra* at 19.
[99] *Id.* at 20.
[100] Marcus, Daniel, "The New FDA Hearing Regulations—An Analysis," 29 Food Drug Cosmetic Law Journal 336, 337 (June, 1974).
[101] Ames and McCracken, *supra* at 18.
[102] *Id.* at 17.
[103] See note 96, *supra*.

no data could meet these standards, then there would be "no genuine issue as to any material fact" and the FDA could move by summary judgment to withdraw the NDAs for prescription drugs found not effective by the NAS-NRC Study. The FDA proceeded in this direction, withdrew NDAs, which led to an interesting series of cases.

In *Upjohn Co. v. Finch*[104] and in *Pharmaceutical Manufacturers' Association v. Richardson,*[105] the manufacturers attacked the NAS-NRC Study and demanded a hearing to cross-examine the NAS-NRC panel. The manufacturers had submitted various types of data which the FDA had stated did not meet the substantial evidence test as demanded in its regulations.[106] There being no "substantial evidence" of effectiveness, the FDA had moved via summary judgment to withdraw the NDAs.

Both courts relied on *Storer* and *FPC v. Texaco* in finding the summary judgment procedure valid. In *Storer,* the Court had stated:

"We agree with the contention of the Commission that a full hearing, such as is required by § 309(b), n. 5, *supra,* would not be necessary on all such applications . . . We do not think Congress intended the Commission to waste time on applications that do not state a valid basis for a hearing."[107]

The question was whether the FCC could refuse an application for a television station license without a hearing when the applicable rules stated that the applicants must have a hearing before denial of an application.

In *FPC v. Texaco,* the Court stated:

"...the statutory requirement for a hearing under § 7 does not preclude the Commission from particularizing statutory standards through the rule making process and barring at the threshold those who neither measure up to them nor show reasons why in the public interest the rule should be waived."[108]

Both cases seem on point as far as the procedures used by the FDA are concerned. The FDA had, by rulemaking, particularized the statutory standard[109] and had barred at the threshold those who did not measure up to this standard.

One unstated consequence of the summary judgment procedure is that the manufacturer must bear the burden of showing that there is a "genuine issue as to any material fact." His failure to do so triggers and validates the summary judgment procedure.

In *Hynson,* the Court specifically validated the FDA summary judgment procedure:

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[104] 422 F. 2d 944 (CA-6 1970).
[105] 318 F. Supp. 301 (DC Del. 1970).
[106] See note 96, *supra.*
[107] *Storer, supra,* at 205.
[108] *FPC v. Texaco, supra,* at 39.
[109] See note 96, *supra.*

"What the agency [FDA] has said then, is that it will not provide a formal hearing where it is apparent at the threshold that the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the regulations.

"The propriety of such a procedure was decided in *United States v. Storer Broadcasting Co.* . . . There can be no question that to prevail at a hearing an applicant must furnish evidence stemming from "adequate and well-controlled investigations." We cannot impute to Congress the design of requiring, nor does due process demand, a hearing when it appears conclusively from the applicant's "pleadings" that the application cannot succeed."[110]

Thus, the FDA's summary judgment procedure seemed to be well established. However, in *Hynson,* Hynson had argued that its submission was sufficient to warrant a hearing. The Commissioner obviously did not agree. However, the Court agreed with Hynson. The decision as to the sufficiency of scientific data to meet the substantial evidence requirement is scientific, not legal, in character. Thus, the court doffed its judicial robes and donned the white laboratory coats to read the regulations which establish "substantial evidence," from whence they made the scientific judgment. Although the Supreme Court has not stated openly its reticence in making scientific decisions, other courts have done so,[111] and the Supreme Court has on other occasions deferred to specific technical agency expertise. The difficulty appears to be that a legal decision (summary judgment) lies upon a scientific decision (whether there is a genuine issue as to any scientific fact). The scientific decision-making in *Hynson* led to a predictable result in the next case to challenge the summary procedure, *E. R. Squibb & Sons, Inc. v. Weinberger.*[112] In *Squibb,* the Court of Appeals for the Third Circuit donned their white laboratory coats and adjudged the scientific data submitted by Squibb to be substantial evidence of the effectiveness of the drug in question and vacated the FDA's summary judgment.

In the next challenge, *Cooper Laboratories, Inc. v. Commissioner, FDA,*[113] the Court of Appeals for the District of Columbia Circuit was faced with the same type of question. However, wishing to avoid delving into the specific scientific facts as the *Hynson* and *Squibb* courts had done, the *Cooper* Court searched *Hynson* for general rules more amenable to court decisions than specific scientific facts. In attempting to do so, the Court stated that the reviewing court must ascertain:

". . . whether the Commissioner's findings accurately reflect the study in question and if they do, whether the deficiencies he finds conclusively render the study inadequate or uncontrolled in light of the pertinent regulations."[114]

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[110] *Hynson, supra* at 620-621.
[111] See note 50, *supra.*
[112] 483 F. 2d 1382 (CA-3 1973).
[113] 501 F. 2d 772 (CA DofC 1974).
[114] *Id.* at 777, n. 14.

Having made this valiant effort to abstain from technical and scientific matters, the Court proceeded to determine whether or not two clinical studies were only "partly-controlled" instead of "well-controlled." To do so effectively would require examining Cooper's submissions in light of the regulations[115] which requires such scientific decisions as proper patient selection, assignment of subjects to minimize bias, etc. A majority of the Court found the studies deficient, and the FDA's summary judgment was affirmed. However, the majority warned the Agency that its criticism of Cooper's data was insufficient due to lack of explicitness. Judge Leventhal filed a dissent also criticizing the FDA for poor quality of work in finding Cooper's data lacking substantial evidence.

The cases since *Hynson* have disturbed several commentators as well as the parties involved. The discomfort, I think, arises from the obvious uneasiness and lack of confidence shown by the courts when they enter the scientific decision-making arena. If the courts rely completely on the FDA to make the scientific decision, then the courts' decisions on summary judgment, in effect, are made by the FDA. This is not a desirable result for obvious reasons. If the courts rely on themselves to make the scientific decisions, the results are as in *Squibb* and *Cooper,* which show a lack of confidence and scientific understanding.

Perhaps a solution to this problem may be found in a mechanism similar to the FDA's monograph approach; that is, the selection of panel by the court composed of non-FDA scientists who can, by training and experience, make scientific judgments. They then can report back to the court concerning the scientific adequacy of the submitted data in light of the FDA's technical regulation requirements.

Challenges to the FDA's summary judgment procedures have been made on other grounds. In *Hess & Clark, Division of Rhodia, Inc. v. FDA,*[116] the manufacturer argued that the FDA had used a "new" test procedure (radioactive labeling of the drug in question and examining tissue for its presence by sophisticated instrumentation) and had not notified Hess & Clark so that it could present data against the "new" procedure. Hess & Clark argued that it had not been given adequate notice of the methodology and therefore not a fair opportunity to raise issues of fact. The court agreed with Hess & Clark. This decision appears to be a straightforward legal decision with few problems in the purely scientific realm.

[115] See note 50, *supra.*

[116] 495 F. 2d 975 (CA DofC 1974).

As far as the summary judgment procedure is concerned, there are obvious problems presented to courts in terms specific, scientific facts to be determined. An acceptable procedure needs to be designed to accomplish this. However, the FDA's use of the summary judgment procedure itself has, clearly been judicially approved.

(VI) *The Impact of the Supreme Court Decisions of 1973*

It would be inconceivable to discuss the OTC review procedures and the summary judgment procedures without mentioning the impact of four Supreme Court cases that came down on the same day, June 18, 1973, and which had a profound effect on many aspects of food and drug law, especially those aspects relating to drugs. The four cases are *Hynson, Bentex, Ciba Corp. v. Weinberger, Secretary of Health, Education and Welfare*[117] and *USV Pharmaceutical Corp. v. Weinberger, Secretary of Health, Education and Welfare.*[118] References to effects of *Bentex* on specific aspects of the OTC review were discussed previously.

Several consequences of the decisions have indirect, if not direct, effects on the OTC review.

First, in *Hynson, Bentex* and *Ciba,* the Court stated that the FDA has primary jurisdiction to determine whether or not a drug is "new" (requiring an NDA)or "not new" (GRASE). Consequential to this is that the FDA has "administrative finality" and court review will be based on the "arbitrary and capricious" standard. Thus FDA rules (and the OTC monographs) have substantive effect.

Second, in *Ciba,* the Court stated that plaintiffs could litigate this issue only through the FDA, *then* the courts. If the manufacturer did not enter into administrative litigation with the FDA over the "new drug" issue, it would be foreclosed from doing so in any court.

Third, in *Hynson,*[119] the FDA's summary judgment procedure with its "substantial evidence" standard particularized by regulations was found "appropriate" by the Court. The Court even published the regulations particularizing "substantial evidence" as an "Appendix to Opinion of the Court." Thus, the FDA's requirements for data which can be considered in determining "substantial evidence" has been published in a Supreme Court opinion. This deletes much "data" previously used, especially testimonial letters of physicians, etc.

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[117] 412 U.S. 640 (1973).
[118] 412 U.S. 655 (1973).
[119] *Hynson, supra.*

Fourth, the grandfather clauses were restricted to apply only to drugs which had never been subject to an NDA in *Hynson* and *USV*. In *Bentex,* the FDA was stated to have primary jurisdiction over determining grandfather status of a drug. This removes a number of OTC drugs from possible "grandfather" status.

Fifth, in *USV,* the Court stated that when an NDA was withdrawn, all similar drugs or "me-too's" would also be withdrawn with it. Thus, the FDA can move against one drug manufactured by several companies in one action.

Sixth, in *Bentex,* the OTC procedure was approvingly described in *dictum.*

In general, the most consistent theme of these decisions is the giving of more direct decision-making authority to the FDA in the technical, scientific arena; hence, the Court's statement that primary jurisdiction, summary judgment and administrative finality reside in the FDA. The Court's reasoning here appeared to be that courts and judges do not have the expertise in difficult chemical issues while the FDA does.

The grandfather clause limitation expresses the Court's apparent reading of the Act as having a strong consumer protection purpose.

The "me-too" drug decision and the approving description of the OTC procedures appear to take into account the intent of Congress to have meaningful standards of safety and effectiveness for drugs and the FDA's limited resources to perform this function.

The four cases in balance are very supportive of FDA's procedures for achieving the tasks set out for it by Congress.

Conclusion

The FDA, faced with the task of reviewing up to 500,000 OTC drugs for effectiveness and removal from the market of those which are "not effective," has, through innovation in administrative law, developed a procedure to accomplish this task using limited resources. The courts, recognizing the intent of Congress in establishing expert administrative agencies, have accorded the FDA substantial authority in scientific and technical aspects of this OTC review but retained to themselves legal authority. Although some issues have not yet received final court decisions, the basic procedures have received court approvals reaching, in some cases, to the Supreme Court. **[The End]**

Public Participation in Toxicology Decisions

By PETER BARTON HUTT

Mr. Hutt Is a Partner in the Law Firm of Covington & Burling.

IN A PAPER on "Safety Regulation in the Real World," delivered in 1973 at the First Academy Forum sponsored by the National Academy of Sciences, I identified the following five obstacles to reasoned scientific decision-making on safety issues:

(1) The scientific data base is seldom adequate to make a definitive safety judgment on any substance.

(2) Even when substantial safety data are available on a particular substance, there is seldom scientific agreement on the meaning or significance of that information.

(3) Even assuming that an adequate base of scientific data were available, together with scientific agreement on the meaning and significance of the data, there appears to be no public or scientific consensus today on the risk or on the uncertainty acceptable to justify the marketing of any substance for public use.

(4) There is enormous and continuing public pressure for governmental agencies to resolve whatever may be the latest current safety issue promptly and decisively.

(5) Regardless of the outcome of the decision, those who disagree with it will continue to pursue the matter through all available channels, while those who agree with it will inevitably remain silent, preparing themselves for the next issue.

I predicted, in that paper, that these obstacles would not change dramatically in the near future. Certainly, the events of the intervening four years have sustained that prediction.

I also identified three procedural mechanisms as the only realistic ways to surmount these obstacles:

(1) Governmental agencies must be opened up to assure public access to and participation in all decisions, including safety decisions.

(2) Advisory committees of outside independent experts must be used by governmental agencies to broaden the base of their decisions on safety issues.

(3) Governmental agencies must provide full and careful articulation of the background and reasons for their safety decisions.

The United States Food and Drug Administration (FDA) has made considerable progress in this direction, but much still remains to be done.

In this paper, I shall begin where I left off in that 1973 paper. In particular, I shall focus on the future implementation of the three procedural mechanisms I identified as essential to assure that toxicological evaluation and decision-making proceeds on a rational scientific basis.

My thesis is that both the procedural structure and the substantive principles that govern the toxicological evaluation of any substance that is subject to regulatory control by a government agency must be spelled out in written rules, subjected to the intense scrutiny of public comment, exposed to rigorous review in the courts, and then followed by the government in the same way that it must adhere to any other written rule. Indeed, it is my belief that the failure of government agencies to pursue this approach has been responsible in large part for the continuing public controversy about the safety of many substances that are widely used today, and for the lack of public acceptance of many recent toxicology decisions.

This thesis has been uniformly unpopular with scientists, both inside and outside the government, whenever I have advanced it in the past. There appears to be a mystic belief that the science of toxicology is really a black art, known only to those who practice it, and that mere written words are incapable of reflecting its obscure subtleties and permutations. Skeptics, on the other hand, question whether this professed distaste for rules reflects a lack of true scientific rigor in this field or, even worse, a simple parochial desire to fence out an increasingly inquisitive public.

I shall not attempt to resolve that debate in this paper, because it is not central to the thesis I am advancing. Suffice it to say that, regardless of the limitations of what we now know about the science of toxicology, or the motives of those who would restrain public participation in toxicology decisions, the force of current events is carrying all of us inexorably toward a degree of openness in government,

and public intervention in toxicology, that has not previously been imagined. It is that process with which I shall deal in the remainder of this paper.

I

Many scientists believe that the increasing concern about toxicology by legislators, government agencies, and, indeed, the public at large, can be traced to the fears generated by a few maverick malcontents who are intent on destroying public confidence in the safety of our modern technology and in the competence of toxicologists to protect us from serious hazards. I see little or no evidence to support that belief.

Instead, it is the very enormity and complexity of our modern technology itself that has allowed these concerns to develop and multiply. Our genius for discovery and invention—indeed, the very success of our scientific enterprise—has brought upon itself the public concerns and demands that we see reflected in daily proposals for still more stringent and effective regulation to prevent consumer hazards. And although it is no comfort to you, it is a very simple matter to predict that these public concerns will continue to increase in the future in direct proportion to the continued success of science and technology. The current public intervention in basic research on recombinant DNA molecules—the first governmental control over basic research of any kind—merely foreshadows far greater future regulation of other biohazards in the laboratory.

Investigative reporters and consumer advocates do not invent these concerns and problems. They may capitalize on them, and they often may serve as a catalyst in focusing public attention on them. But if the problems themselves were not real and did not exist, they could not be uncovered and exploited.

I therefore urge that we not waste time berating consumer champions, or asking who elected them to represent the public. These simply are inadequate responses to a public that is truly fearful of toxic substances in the environment, in the workplace, and even in consumer products. We must, instead, realize that these problems raise real issues, not imagined or false issues, and deal with them on their scientific merits.

Mack Schmidt, the former Commissioner of Food and Drugs, was fond of saying that there is no such thing as a dumb question, but there are lots of dumb answers. If the field of toxicology had a sound answer for every safety question raised, those questions would soon

disappear. But the real problem, as we all know, is that toxicology does not presently provide sound answers to many of the safety questions that are now being asked.

Nor will it help, when adequate answers are unavailable, to ignore the issues and hope they will go away. We must begin to cope even with those safety issues that seem the most insoluble.

Too few people realize that, in a government regulatory agency, every conclusion to delay action is, in reality, a very decisive act itself, resulting in very important consequences. A conclusion by a toxicologist to require additional testing before a product may be marketed, or before a product will be removed from the market, is in fact a decision that the product will not be made available to the public, or will continue to be made available to the public, in the interim. Even a failure to confront an issue at all, or a conclusion that a decision should be postponed indefinitely for further deliberation, is a very conscious and deliberate act having predictable conseqences both for the regulated industry and for the public. There is no such thing as a regulatory vacuum. Therefore, it is not surprising that the public is beginning to be aware of, and to take far greater interest in, the technical decisions that have heretofore been the private province of toxicologists and other scientists.

II

As this public concern is translated into action by both legislatures and government agencies to assure the safety of the substances and products made available to the public, it is increasingly important that the resulting toxicology decisions be made on the basis of clearly enunciated rules, rather than *ad hoc* judgment. These rules must, I submit, encompass both the procedures by which toxicology decisions are made, and the substantive principles that will determine the decision itself.

It is important to distinguish clearly between the two types of rules involved.

The first are procedural rules to structure the decision-making process on toxicology issues. These types of rules tell you what kinds of applications to file and where, how the government agency will process them, how the various segments of the public—including industry, consumers, professional groups, and others—can participate, and other details about the process that will be followed in arriving at toxicology decisions.

Rules of the second type are substantive principles to guide the toxicology decision within that structure. These rules tell you what kind of animal tests to run, specify the protocols, and in general relate the important toxicology principles that will be used by the government agency in determining whether a substance or product is or is not safe.

In both of these two areas—procedural and substantive—government agencies are presently going about their business daily, sometimes on a systematic but more often on an *ad hoc* basis. Toxicology decisions must be made, after all, regardless of the lack of guiding principles. Indeed, procedural and substantive requirements are constantly evolving in every government agency, even though they are seldom written down, much less codified in published guidelines or regulations.

In the future, we have only two choices. We may allow these requirements to continue to evolve as a government agency concludes appropriate in its sole discretion, with perhaps an occasional court challenge of an isolated decision in the context of a particular substance; or we can demand that these requirements be written down and followed. There is, I submit, no third alternative. And between these two alternatives, I believe that we have only one realistic choice.

III

The best examples of the need for written procedural rules governing toxicology decisions stem from the four major safety review programs undertaken by the FDA in the past ten years:

(1) The review of the effectiveness of all drugs marketed pursuant to a new drug application between 1938 and 1962, which began in 1966 (the Drug Efficacy Study Implementation, or DESI, Review).

(2) The review of the safety of all food ingredients included on the list published by the FDA in the late 1950's of food ingredients that are generally recognized as safe (GRAS), which began in 1969 (the GRAS List Review).

(3) The review of the safety and effectiveness of all marketed nonprescription drugs, which began in 1972 (the OTC Drug Review).

(4) The review of the safety and effectiveness of all biological drugs licensed by the Public Health Service for marketing between 1902 and 1972, which began in 1972 (the Biologics Review).

Lest anyone misinterpret the remarks that follow, I must remind you that I served as legal counsel for the Agency for four years during 1971 through 1975, and thus I am at least as responsible as, and indeed perhaps more responsible than, anyone else for the deficiencies that I will discuss.

The first portion of the DESI Review was undertaken by the National Academy of Sciences under contract with the FDA. No written procedural rules whatever were established for the Academy portion of this review, largely because there was no provision whatever for industry, consumer, professional society, or even governmental, participation in the process.

When the Academy reports were delivered to the FDA in 1968, there was no written procedure for their implementation by the Agency. As a result, enormous controversy and litigation ensued. The only procedural requirements governing the review were incorporated in a court order that resulted from one piece of litigation and in the four Supreme Court decisions that settled many of the legal issues involved. To this day, the only truly comprehensive description of the entire DESI Review exists in the briefs filed by the Solicitor General in those Supreme Court cases.

The GRAS List Review has proceeded on a somewhat similar basis. No procedural regulation was promulgated when it was first announced, and thus the procedure actually utilized for its implementation has been slowly evolving as the Review itself has progressed. Major changes have occurred well after the program began, such as the release of tentative safety evaluation reports and the use of public hearings. Some aspects of this evolving procedure have been the subject of published notices but, to this day, there is no comprehensive procedural regulation governing this program and indeed no coherent statement anywhere of its entire scope, purpose, and process.

In contrast, the FDA did issue comprehensive proposed procedural regulations before undertaking both the OTC Drug Review and the Biologics Review, carefully considered all of the comments received from the public, and then promulgated final regulations governing all procedural aspects of these Reviews. Although some slight modifications of these procedures have been promulgated in the intervening years, these changes have been relatively insignificant and the reviews have proceeded in accordance with the original regulations without any major controversy about the type of procedure employed. This remarkable achievement has largely been due to the fact that,

because published procedures were utilized, all of the issues about the purpose, scope, and mechanism of the review had to be carefully thought through at the beginning, rather than allowed to evolve at a later date as the review progressed. Although the advance planning forced by consideration of these procedural regulations did not, and could not, avoid all controversy about these ambitious Review programs, they clearly avoided many of the pitfalls encountered in the earlier DESI and GRAS List Reviews, and assured that all interested members of the public would understand how and when they would be permitted to participate.

The FDA has just announced a new cyclic review of the safety of food additives that have previously been approved for marketing subsequent to the enactment of the Food Additives Amendment of 1958. Although the precise mechanism for this review has not yet been announced, the Commissioner of Food and Drugs has publicly stated that a comprehensive procedural regulation will be promulgated to govern the Agency's conduct of this review. I believe this will substantially enhance the success of this very difficult program.

Of course, the specific provisions of the procedures governing these reviews are also of major importance in determining their success. The major innovation of the DESI Review was the strong reliance upon outside independent advisory committees. This innovation, which was quite successful in obtaining public acceptance of the results, has been followed in each of the subsequent reviews. I hope it will also be incorporated in the new cyclic review of food additives. I have pointed out on numerous prior occasions my belief that use of independent experts from outside the government is perhaps the most effective and efficient step that can be taken by a government agency to enhance the scientific capability of the agency and increase the credibility of the ultimate decisions in all segments of the public.

Access and participation by the lay public is, however, equally important. In the OTC Drug and Biologics Reviews, a consumer liaison representative and an industry liaison representative were included in the advisory committee process for the first time. Their thoughtful participation has not only added new dimensions to the decisions, but the mere fact of their direct participation in the entire decision-making process has added greatly to the integrity of these programs. Even the recent requirement to open up virtually all advisory committee discussions to public view has not dampened the free and open discussion of the important issues that these committees

are considering. In a very real way, it has been shown, in committee after committee, that the democratic process can readily be made to work in the area of toxicology decision-making.

IV

Published procedures for public participation in toxicology decisions is, however, only the first step. There is an equally pressing need for written substantive rules governing the toxicological evaluation of substances and products. I suspect that many scientists who would be strong advocates for written procedural rules will nonetheless be very reluctant to embrace written substantive rules that will, if they are effective, directly impinge upon the freedom and flexibility of a toxicologist in evaluating the safety of any particular substance or product.

It is important to understand, at the outset, that there are two quite different ways of adopting substantive rules of this type, and that each has a quite different legal effect.

Substantive rules governing toxicology decisions could be adopted by the government in the form of regulations, which have the force and effect of law. The United States regulations in the *Federal Register* can be either very rigid or very flexible, depending on how they are written. Many regulations are stated only in general terms, or include exceptions, or allow variances for good reason. Thus, if regulations were adopted to govern toxicology decisions, there is no reason why they could not, where appropriate, be written to permit whatever flexibility is justified for the particular scientific decision involved. In short, there is nothing inherent in the nature of a regulation which precludes the exercise of whatever scientific judgment is justified by a particular situation.

Substantive rules governing toxicology decisions could also be adopted by the government in the form of guidelines, rather than regulations. A guideline states recommendations but not requirements. Those recommendations constitute an acceptable way of doing something, but not the only way. Under the new procedural regulations recently promulgated by the FDA, all guidelines are required to be filed with the Hearing Clerk and may be changed only with public notice, but they are not promulgated in the same formal way as a regulation. Until changed, they bind the Agency and, therefore, one can rely upon them with confidence.

Many scientists do not realize that, in the past, the FDA has issued some regulations, and a far greater number of guidelines, specifically adopting substantive rules with respect to toxicology decisions. A regulation promulgated many years ago adopted 100:1 as the usual safety factor in setting a tolerance for a food additive on the basis of animal toxicity data. A recent regulation has established in minute detail the type of testing to be required for determining approval of a new animal drug which is shown to be a carcinogen in test animals. The proposed good laboratory practice regulations will similarly determine the acceptability of animal toxicity studies.

Existing FDA guidelines on toxicology are too numerous to mention. The Agency has issued acceptable protocols for everything from animal toxicity testing, to animal field trials, to human clinical trials.

I do not underestimate the difficulty of codifying the rules by which toxicological evaluation is to be undertaken. But the very difficulty of codifying these rules underscores how essential it is that this task be undertaken.

Toxicologists in every government agency are, every day of the year, making toxicology decisions that they believe reflect the scientific policy of their branch, division, agency, department, and government. If they are in fact applying consistent rules, then those rules obviously can be put in writing. And if they are not applying consistent rules, that situation must be exposed and remedied. The alternative is to risk quite different rules by each individual toxicologist or government agency, a lack of any knowledge by the regulated industry of the toxicology requirements to be imposed, and a resulting distrust and loss of confidence by the public, legislatures, and the courts.

The importance of clear and consistent rules is nowhere more important than in the very emotional area of animal testing for carcinogenicity. In the United States there are at least five regulatory agencies with specific legislative mandates that require frequent toxicology decisions as to whether a specific substance or product is a carcinogen—the FDA, the Environmental Protection Agency, the Occupational Safety and Health Administration, the United States Department of Agriculture, and the Consumer Product Safety Commission. We simply cannot have five different animal carcinogenicity testing policies, one for each of these agencies, any more than we could tolerate different policies within different bureaus or divisions or branches of those individual agencies. Either benign tumors must

be counted the same as malignant tumors, or not. Either invasion or metastasis is required for a tumor to be classified as malignant, or not. Sound public policy cannot tolerate inconsistent rules on these important toxicology issues.

The importance of clear and consistent rules on toxicology decision-making will be brought into even sharper focus as the new *in vitro* short-term carcinogenicity predictive tests mature, are validated, and come into widespread acceptance and use. The regulatory issues that these tests pose are of enormous importance. If a marketed substance is negative in a battery of these tests, will it still be necessary to conduct a traditional animal carcinogenicity study on it? If a marketed substance turns up positive in this battery of tests, must it immediately be removed from the market, or may it stay on the market pending a traditional animal carcinogenicity study? Indeed, what type of traditional animal carcinogenicity study, using how many test animals, will be required to overcome a positive result from a battery of *in vitro* tests? If a not-yet marketed substance turns up positive in a battery of *in vitro* tests, is there any type of animal or other testing that could ever be done to overcome the presumption of carcinogenicity and permit its subsequent marketing? The answers to these representative questions, and many more, are wholly uncertain at this time. But it is obvious that they must be faced in the relatively near future and that clear government-wide rules must be established to govern these situations.

Of course, some judgment—and often a great deal of judgment—will in many instances be involved in any final toxicology decision. No set of rules, however detailed, could be devised to cover every situation. All that should be required is that the judgmental factors in the decision be identified, and the rationale for the judgment explained in a written statement documenting the decision. That is surely not too much to expect. Our vocabulary is sufficiently flexible to permit these judgmental matters to be fully articulated. Having gone through a clearly defined evaluation procedure, and after applying written toxicology rules, this should not be a difficult job.

I have always found it unusual that most regulatory statutes do not require the government agency to summarize or explain any toxicology decision unless it is subsequently challenged through legal proceedings. Food additives, color additives, new drugs, and medical devices may all be approved as safe in the United States without one word of explanation. Indeed, it is a paradox that the Freedom of

Information regulations promulgated by the FDA now require a written summary of the basis for safety decisions for new drugs only where the raw safety data cannot be released. Since the raw safety data can be released on food additives and color additives, no summary of the basis for a safety decision is ever required for approval of these substances. Needless to say, few people, if any, have ever sat down to read the raw safety data underlying approval of a food additive or a color additive.

If the public is to be expected to accept toxicology decisions by governmental agencies, those decisions must be explained in written decisions, in terminology that can be understood by a non-scientist. In this respect, the GRAS List Review, the OTC Drug Review, and the Biologics Review have all represented a major step forward in communicating the rationale for toxicology decisions to the public through detailed written statements.

V

The approaches advocated in this paper will not guarantee that all toxicology decisions will be correct, or noncontroversial, or accepted by those who have advocated a result different from the one that emerges. But I firmly believe they represent a substantial improvement in the development of public policy and afford the best available hope, at this time, of enhancing both the substance of these decisions and their credibility to the public at large. We will never have a perfect process, but we should never fail to pursue any improvement that will bring us nearer that objective. **[The End]**

The OTC Review and the Standardization of Symptom Nomenclature in Labeling

By FRANK P. DI PRIMA

Mr. DiPrima Is Staff Vice President of the Schering-Plough Corporation.

AT ANY STAGE in the developing and marketing of a nonprescription drug, the most important question to the manufacturer is: What conditions can I claim my product relieves? In the over-the-counter (OTC) field, for many years, the regulatory process has largely revolved around this question. And it should.

The OTC Review must necessarily address this question for every category it reviews. It has begun to do so, however, in a way that was anticipated only vaguely, if at all, in the Review's early stages. I refer to the apparent effort by the Food and Drug Administration (FDA) and the OTC Review Panels to prescribe the exact words that may be used to describe a product's conditions of use. Let me try first to review the history of this effort, then suggest why I think it is counterproductive, and finally propose some better ways to accomplish the desired result.

History of Labeling Regulations

First some history. The final regulation on general conditions for marketing all OTCs, published in the *Federal Register* of November 12, 1973,[1] indicates that the "statement of identity" shall be the term or phrase used in the applicable monograph. Let's trace the process through the first few series of monographs that have been issued to date in some

[1] Codified at 21 CFR 330.1 (c).

phase. All three antacid monographs ("Proposed," "Tentative Final" and "Final") required that the labeling "represents or suggests" the product as an "antacid" to alleviate the symptoms of "heartburn," "sour stomach" or "acid indigestion."[2]

The two accompanying antiflatulent monographs used similar language—"represents or suggests" the product as an "antiflatulent" to "alleviate or relieve the symptoms of gas." So far so good—"represents or suggests" appeared to permit synonyms or other phrases of reasonably similar import. But an early hint of what was to come was Paragraph 79 of the Preamble to the final antacid and antiflatulent monographs published in the *Federal Register* of June 4, 1974. Paragraph 79 referred to a comment submitted in response to the earlier publications, to the effect that the monograph appeared to permit use of commonly existing descriptive terms, and stated: "The monograph allows only the use of the word 'antiflatulent' or the statement 'to alleviate the symptoms of gas'. Those are the only terms that can be properly used for OTC antiflatulent drugs." New words were being prescribed, *to the exclusion of all other words.* Paragraph 79 appeared to extend beyond statements of identity, to encompass all labeling. Then, in the *Federal Register* of March 13, 1975, the FDA amended the monographs for antacids and antiflatulents by striking the words "represents or suggests" and substituting the word "identity." The publication stated: "The Commissioner concluded... that allowing each manufacturer to select words to be used would result in continued consumer confusion and deception."

Thus, with "represents or suggests" out, the label now had to identify the product by the exact words.

The Antimicrobial I Proposed Monograph, published in the *Federal Register* of September 13, 1974, also prescribed exact quoted phrases, though it allowed a wider choice within each of several subcategories.

The Laxative Proposed Monograph, published on March 21, 1975, was the most word conscious of all. Certain commonly used and easily understood terms, such as "irregularity," were specifically found offensive and were proposed to be outlawed. Section 334.50 specified that "the labeling shall identify the product as a 'laxative' for 'short-term relief of constipation'." Thus, the language of the Antacid amendment of the previous week ("shall identify") was picked up. The Section

[2] See *Federal Registers* of April 5, 1973, November 12, 1973, and June 4, 1974.

went further and specified that the Panel's definitions of laxative subcategories must also appear—such terms as "hyperosmotic laxative," "lubricant laxative" and "laxative stool softener."

The Proposed Monographs on Sedative/Sleep Aid Products[3] and Cold/Cough Products[4] take much the same approach, and future monographs can be expected to follow the same pattern.

Effect of FDA Legislation

Where does all this lead? There are many unanswered questions. Is the purpose of the language in the antacid and laxative monographs to limit symptom nomenclature only on the statement of identity or does it extend to other places and uses on the label? To what extent would the attempt by the FDA to legislate words and ban synonymous phrases on labeling apply to advertising as well?

Federal Trade Commission (FTC) staff is currently engaged in a curious "me too" effort to apply the same *per se* rule to language used in advertising. A proposed Trade Regulation Rule (TRR),[5] and the staff's interpretation thereof,[6] is the subject of a vigorous contest at hearings which continue as this is written. It may be three years before the appellate processes produce a final result. The issues peculiar to the TRR proceeding have been thoroughly briefed on the public record, and I have made no attempts to discuss them here. What is pertinent here is that the FTC staff's interpretation is bottomed on the premise that the FDA's attempt to prescribe words in labeling is largely valid and a good idea. The FDA's move toward standardizing language describing symptoms and claims would thus be extended to all communications about nonprescription drugs.

Why is all this such a bad idea?

First, it would outlaw legitimate and needed efforts by manufacturers to explain the uses of their products in ways that will be understood by consumers. Both labeling and advertising play a significant role in this regard. If these communications media contain only boilerplate language, no one will pay much attention.

Second, the Panels are not experts in mass communications. Perfectly proper textbook words, such as "hyperosmotic," mean nothing to laymen. Industry is better equipped to communicate product uses,

[3] 40 *F. R.* 57292 (Dec. 8, 1975).
[4] 41 *F. R.* 38312 (Sept. 9, 1976).
[5] 40 *F. R.* 52631 (Nov. 11, 1975).
[6] Herzog, Richard B., "The FTC's Proposed Rule on OTC Drug Advertising," speech given at Food and Drug Law Institute's Human Drug Workshop, December 3, 1975, published at 31 Food Drug Cosmetic Law Journal 147 (March 1976).

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and the FDA has its remedies and should exercise them if the company makes misleading or unsupported claims.

Third, the effect on the English language will be appalling. Edwin Newman, the most popular living critic of English usage, made the following statement, recorded in the published proceedings of the Proprietary Association's 1975 Annual Meeting:

"Somebody told me last night that one thing your business is up against is that you may not be able to call cough syrup or cough medicine 'cough syrup' or 'cough medicine' anymore. You may be required to call it an 'antitussive agent.' Well that's the kind of thing that is happening and it seems to me that the consequences of not referring to a cough as a cough are very, very serious. It is like calling . . . . murder and assault 'escalated interpersonal altercation.' It doesn't advance matters. It leads to retrogression in my opinion."

I am not sure that the Proposed Cold/Cough Monograph, as subsequently issued, would require the word "antitussive" and ban the word "cough,"[7] but is it any better to ban the word "antigas" and require "antiflatulent"?

Fourth, this is a highly significant restraint, and in a free society any governmentally imposed restraint should be made cautiously, and only when there is countervailing social value. What social value is there in banning "constipation remedy" but permitting "short-term relief of constipation"?

Fifth, the calls for data to the Panels did not include requests for lists of specific phrases, nor *support* for them, and consequently little or none were provided. Although the Panels had labeling samples before them, anyone asserting that the Panels combed the labeling for specific words would be engaging in a psychedelic fantasy. If the calls for data had asked for such phrases, prudent manufacturers with an eye to the future would have had to send in every combination of words their people and computers could possibly think of.

Sixth, this is a wasteful way to use scientific talent.

Seventh, the effort to legislate wording of claims lacks legal validity. Let's examine the conceivable legal underpinnings for a moment.

Legal Qualifications of Labeling Regulations

The Fair Packaging and Labeling Act, at 15 USCA 1453 (a), requires that the item bear a label specifying the identity of the commodity. Section 502 (e) of the Federal Food, Drug, and Cosmetic Act

[7] 41 *F. R.* 38312—38424, at 38421 (Sec. 341.50 (a) [1]) and 38419 (Sec. 341.3) (Sept. 9, 1976).

requires that the label bear the established name, and if there is none, the common or usual name. As applied to nonprescription drugs, these requirements are codified at 21 CFR 201.61, and the regulation requires a "statement of identity" on the principal display panel and cites both acts as its authority. Section 508 authorizes the Secretary to establish official names for drug substances.

But none of this authorizes codification of the exact words used to describe modes of action and symptoms to be relieved.

To the contrary, there is Section 502 (c) of the Federal Food, Drug, and Cosmetic Act, which requires that any information be in such terms as to render it likely to be read and understood under ordinary conditions of purchase and use. Hyperosmotic? Stool Softener? Antiflatulent?

Nothing in any of these sections evidences any Congressional intent to grant the FDA the authority to legislate the exact wording of OTC claims. The statutory admonition to use terms easily understood by consumers evidences the contrary, and, if manufacturers used some of the prescribed terms, they may well be in violation of Section 502(c).

If the intent as expressed in Paragraph 79 and in the preamble to the March 13, 1975 antacid amendment is to limit all labeling, not just statements of identity, to specific words expressing symptom nomenclature, then the action is beyond any color of legal authority. The only conceivable enabling section is Section 502 (a), which renders a drug misbranded if its labeling is false and misleading in any particular, and, even more remotely, Section 502 (f), requiring adequate directions for use. Would any court hold that a product is falsely and misleadingly labeled if it says "provides temporary constipation relief," but is fine if labeled "for short-term relief of constipation"? We must assume that Congress meant what it said when it said "false and misleading." This is clearly outside the intent of the Act, and therefore has no legal validity.

Nor does it help to cite cases vesting the FDA with authority to issue binding legislative regulations under Section 701 (a). Legislative regulations are subject to precisely the same judicial review as is a statute, and besides they are only valid if within the scope of authority the Congress has delegated. Legislative regulations are subject to attack, just as a statute would be, as arbitrary, capricious and unreasonable under both the Administrative Procedure Act, at 5 USCA 706 (2) (A), and Fifth Amendment substantive due process.

They are subject to review on other Constitutional grounds as well, including First Amendment free speech. Let's apply this.

As I have argued, the regulations requiring specific words and banning all other truthful synonymous phrases is beyond the scope of the enabling statute, and any substantive rulemaking authority cannot cure this.

If it is not "arbitrary and capricious" to permit "short-term relief of constipation" and to ban "constipation remedy," I'd like to know what is.

Now that First Amendment guarantees have been extended to commercial speech,[8] the FDA is on tenuous Constitutional ground if it tries prospectively to ban truthful, undeceptive claims. Of special importance is *Virginia State Board of Pharmacy v. Virginia Citizens Council,*[9] in which the U. S. Supreme Court voided a state statute prohibiting pharmacists from advertising retail prices of prescription drugs. The Court made one clear limitation—its oft-discussed Footnote 24, which indicates deceptive commercial speech is not protected.

In *Beneficial Corporation v. Federal Trade Commission,*[10] the Third Circuit applied *Virginia State Board* to reverse and remand a Commission cease and desist order. The Court held that the FTC could not ban Beneficial from all future use of the challenged phrase "Instant Tax Refund", even though the Court found the phrase misleading in the context of Beneficial's past advertising. The Commission was directed to issue a cease and desist order that "goes no further than is necessary for the elimination of the restraint". As this is written, the Commission's petition for *certiorari* is pending.

The test is and should be deceptiveness. An attempt to ban all truthful phrases which are the substantial equivalents of approved claims is the most sweeping conceivable case of prior censorship in the commercial sphere.[11]

Conclusion

The FDA and the Panels nonetheless have a legitimate concern in wanting to prevent the use of certain terms they regard as mis-

[8] *Bigelow v. Virginia,* 95 S. Ct. 2222 (1975).

[9] 96 S. Ct. 1817 (1976).

[10] 1976-2 Trade Cases.

[11] See my comments on these cases in DiPrima, Frank P., "Advertising of OTC Drugs and the Proposed TRR on Warnings," 32 Food Drug Cosmetic Law Journal 96 (March 1977).

leading. Let me suugest the following approach as an alternative to saying "these words may be used to the exclusion of all others."

The process should be turned around. Specific terms the panel finds offensive may be proposed to be banned. This should be a continuing process, and if any offensive term not contemplated when the monographs were written is later used, the FDA can either prosecute or initiate rulemaking.

Also, any regulation of words should be limited to the statement of identity. This should be clearly expressed. This would permit truthful communication of approved claims elsewhere in labeling, and in advertising as well. Attempts to standardize Section 502 (a) ("false and misleading") should be abandoned.

In my opinion, this approach could serve the basic purpose behind the attempt to standardize symptom nomenclature, but at the same time would permit clear, understandable communication of the uses of nonprescription medicines. **[The End]**

Hearing to Be Held on GRAS Status Findings

A public hearing will be held on the tentative status determinations for acetic acid, sodium acetate, sodium diacetate, papain, pectin, pectinates, and amidated pectin as generally recognized as safe (GRAS) or as subject to prior sanction. The purpose of the hearing, to be held by the Select Committee on GRAS Substances of the Life Sciences Research Office, Federation of American Societies for Experimental Biology, is to receive data, information, and views not previously available to the Committee. The Select Committee's tentative reports on the substances in question are available for review at the Office of the Hearing Clerk of the Food and Drug Administration.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,934

A Consumer Advocate's View of the FDA's Procedures and Practices

By MARCIA D. GREENBERGER

Marcia D. Greenberger Is the Head of the Women's Rights Project, Center for Law and Social Policy.

AS AN ATTORNEY with the Center for Law and Social Policy, a public interest law firm located in Washington, D. C., I have represented a variety of women's rights organizations, consumer groups and poverty groups before the Food and Drug Administration (FDA). Therefore, I am particularly pleased to have the opportunity to discuss the procedures used by the FDA in its administration of the Federal Food, Drug, and Cosmetic Act. My discussion today will reflect my experiences in representing consumer interests before the FDA.

The bulk of my practice has concerned the FDA's regulation of drugs or cosmetics which have a particular impact on women. In this practice, I have been struck consistently with the scarcity of public interest representation before the Agency. In meetings, we have often been the only consumer representatives present, let alone participating. Also, the number of comments on proposed FDA actions filed by consumer groups is usually far outweighed by those of industry. The FDA has indicated that very few consumer groups file Freedom of Information Act requests as opposed to industry representatives.

However, I also think that the trend is shifting, at least to some degree. Consumer groups are becoming increasingly vocal and sophisticated in the technique they use to press their positions. Attorneys, scientists and others with specialized expertise are turning their attention to consumer issues. And, it is my impression that the FDA has been and will continue to be affected by this increase in consumer advocacy.

As a result, I have reviewed the FDA regulations not only from the perspective of their impact on consumer interests as they have been, but what we might expect because of the developing consumer movement. In this regard, I believe that in many respects consumers, as well as industry, will find themselves similarly affected by FDA procedures.

FDA Conception of Its Regulatory Role

The FDA seems to see its regulatory role as arbitrator between industry and the public. This regulatory attitude is reflected in the structure of its advisory committees, public boards of inquiry, and other aspects of the procedural regulations which have recently been promulgated by the FDA.[1] The regulations recognize, for example, that increasingly consumers are more active in urging their view of proper or necessary Agency action. There is a section which formalizes citizen petitions, and sets forth guidelines on contents, time frames, etc. Consumers have long argued, and FDA staff have acknowledged, that consumer petitions have been ignored far more often than those filed by industry. These regulations set forth time frames for FDA response to citizen petitions, which, albeit longer than I would have liked, are still a great advance. Citizen petitions have been elevated and given an importance more comparable to those filed by industry.

Moreover, perhaps as a result of increased sensitivity to procedural "even-handedness," the regulations also reflect a significant increase in technical requirements, deadlines, filings and formal actions which all groups must be prepared to meet—both industry and consumer—if they are to present their views effectively to the FDA. This increase in formalism means an increase in predictability and openness, but also an increase in the cost of dealing with the Agency.

There are numerous examples of rigid timeframes and requirements that all sides must meet. The Hearing Clerk may reject submissions if they do not adhere exactly to formal submission requirements.[2] There is no right of appeal or resubmission if a submission is rejected. Petitions for reconsideration must be filed within 30 days of the action to be reconsidered, with no provision for extension for good cause.[3] Lengthy requirements are set forth as the FDA's view

[1] See 40 *F. R.* 22950 (May 27, 1975); 40 *F. R.* 40682 (Sept. 3, 1975); 41 *F. R.* 26636 (June 28, 1976); 41 *F. R.* 48258 (Nov. 2, 1976); 41 *F. R.* 51706 (Nov. 23, 1976); 41 *F. R.* 52148 (Nov. 26, 1976); 42 *F. R.* 4680 (Jan. 25, 1977).

[2] On Tuesday, March 22, 1977, the FDA recodified the procedural regulations (42 *F. R.* 15553). The textual citations are outdated and the new section numbers are provided. 21 CFR Sec. 2.5(c)(6) (now Sec. 10.20(c)(6)).

[3] 21 CFR Sec. 2.8(b) (now Sec. 10.33).

of what is necessary to exhaust administrative remedies before a party may seek review in court.[4]

In short, all private parties must be fully conversant with these regulations in order that opportunities not be missed and rights not be waived. The expense of complying with the procedural rules can be formidable for all parties. However, it is especially burdensome for consumers.

Advisory Committees

An examination of the FDA's use of advisory committees is particularly instructive in understanding the Agency's approach to regulation and the complementary position in which consumers and industry are placed. Advisory committees, each comprised of experts in a variety of areas, have been established to aid the FDA in its regulatory responsibilities. Moreover, under Subpart D[5] of the new procedural regulations, advisory committees may hold public hearings in place of formal evidentiary hearings.[6] These "unbiased" experts are supplemented by nonvoting members who represent industry and consumer interests.[7]

The FDA has virtually conceded that outside representatives are needed to present consumer positions, although it stopped short of requiring such representatives on all advisory committees. Under the Medical Device Amendments Act of 1976, consumer representatives are required. Consumers, therefore, have reviewed the practical workings of the advisory committee system as it now exists to determine whether consumer positions are being adequately presented.

Experience has shown that the consumer representatives have simply lacked the resources to present their views adequately and to press vigorously for adoption of their positions. At least from the consumer perspective, the industry representatives have had far greater resources behind them, which can be used for effective advocacy of industry interests.

It is rare, for example, that the consumer representatives have the resources to commission a study of relevant literature on a particular topic, consult with experts, or in any other way generate information to present to the advisory committee in support of the consumer's position. In fact, the lack of information makes it difficult for the consumer representatives even to recognize problems which

[4] 21 CFR Sec. 21.11 (now Sec. 10.45).
[5] Now Part 14.
[6] 41 *F. R.* 52153, 21 CFR Sec. 2.300 and following (now Sec. 14.1).
[7] 41 *F. R.* 52161, 21 CFR Sec. 2.332 (now Sec. 14.84).

they should address. Industry representatives, on the other hand, often are able to marshall information which they can then present to the voting members of the committees. They have access to the resources of the industry whose products are at issue, and know full well the positions which will best serve their constituency.

Consumer groups are becoming increasingly aware of the importance of these consumer representatives. Greater care is being taken in the selection of such representatives to assure that they are strong, knowledgeable advocates for consumers. But, in addition, there is greater awareness of the need for financial support for these consumer representatives so that they can generate and distribute information to assure that all sides are presented. It has been urged that the FDA has a responsibility to assure that consumer representatives have adequate backup and resources available in order that they fulfill the function assigned them by the FDA.

A further problem for consumers, and potentially for industry as well, is caused by the restrictive attitude of the FDA as to what constitutes an advisory committee under the Federal Advisory Committee Act. That Act provides a series of safeguards on the manner in which advisory committees may operate, including a requirement, with only narrow exceptions, of open meetings. The FDA takes the position that only meetings with outside groups where the Agency is seeking advice are advisory committee meetings. However, in the practical application of this position, the FDA has tended to view meetings with industry groups as *not* for the purpose of the FDA seeking their advice—even when the appearance to those of us who are excluded would seem otherwise. This particular issue is now before the Court of Appeals in the District of Columbia in *Consumers Union of the United States v. HEW*.[8] In that case, an industry-sponsored group conducted a cosmetic ingredient safety review program, at the express suggestion of an FDA official, with FDA guidance and following FDA criteria. The review group held a series of meetings with FDA staff in the performance of its function. However, consumer representatives who asked to attend were refused.

Such an approach denies consumers access to critical information, and seriously hampers their ability to develop and represent consumer viewpoints before the FDA. But, in addition, as consumers become more aggressive, and volunteer to undertake similar tasks for the

[8] C. A. No. 75-1250 (DC DofC, March 12, 1976), appeal pending No. 76-1385 (CA DofC).

Agency, industry might well find itself similarly displeased at being excluded from participation in such meetings.

Public Boards of Inquiry

The new procedural regulations also provide for a public board of inquiry to hold hearings concerning "any matter, or class of matters, of importance pending before the Food and Drug Administration."[9] The Board may act as an administrative law tribunal, and replace a formal evidentiary public hearing.

The Board consists of three members, chosen by the Commissioner from lists of five names each. The first member is selected from lists submitted by the FDA bureau director, or nonparties, involved in the issue, the second from lists submitted by parties, and the third from any source the Commissioner chooses. The regulations also provide that a private party may veto any FDA employee as a member of the Board.

In short, the concept of the FDA as arbitrator between competing groups is applied again. In this circumstance, I believe, however, the actual decision-makers are representatives of these competing groups.

In contrast, the FDA contends that this mechanism will not permit parties or interested persons to designate members of the Board to represent their viewpoint. The FDA asserts that since five persons have to be nominated, from which one will be selected, the Agency has sufficient latitude to avoid persons who will represent one party's viewpoint.

I would argue, however, that the FDA is ignoring reality in advancing this position. Certainly, it can be expected that any individual chosen would exercise his or her independent judgment, and would not feel bound in a formal sense to "represent" the interests of the nominating party. However, nominating parties will certainly be aware of the approaches taken by individuals. It often would not be difficult to find five people whose approach, although arrived at independently, would be completely compatible with the nominating party. The whole notion of nominations from different sources obviously implies an expectation of different viewpoints.

It is important, therefore, to review the groups or individuals likely to be parties, and therefore likely to have their views reflected

[9] 40 *F. R.* 26636 (June 28, 1976), 21 CFR Sec. 2.200 and following (now Sec. 13.1).

in the composition of the Board. Depending on the issue, one could expect consumer groups or industry to be nominating candidates for Board membership. In such a situation, there would be a member of the Board chosen, for example, by industry, one by the FDA bureau, and one by the Commissioner. Where will the consumer view be reflected? And similarly, if a consumer group is the party, where will positions sympathetic to industry be found? The FDA responds that the Agency itself will represent the interests of the nonparty. However, even if FDA and the nonparties agree on a general approach to be taken, they often will not agree on the justification for the approach, the evidence which is relevant, the specific regulatory action which should be taken, and the like. Courts have often recognized that even if "on the same side," the position of the government and private parties can be different.[10] In the design of the Board of Public Inquiry, the FDA has ignored this basic fact of life.

FDA Compensation for Costs of Formal Participation

In the new procedural regulations, the FDA sets out elaborate mechanisms for Agency review and alternatives of full evidentiary hearings, public hearings before a public board of inquiry, advisory committees or the Commissioner. Moreover, because of the essential information which is often classified as trade secrets, and the possible availability of such information only to parties or their counsel, formal and full participation in these hearings can be critical if a group wishes to have meaningful input on a regulatory decision. In the case of these hearings, heavy burdens are placed on any group which wishes to participate in these proceedings to prepare lengthy and complex papers, and in all cases, strict time limits are set.

The FDA recognizes the expense attendant to participation in such proceedings, and the regulations provide for *"in forma pauperis"* participation. Parties who show indigency and/or a public interest in their participation may avoid the costs of service of all papers they file to all participants. However, the costs of reproducing papers is only a minor expense involved in effective participation.

Expert witness fees, travel costs, attorneys' fees, costs of transcripts and the like all must be borne by serious participants in many of these proceedings. And it is the consumer groups who are least able to bear the expense of such participation. Congress has recog-

[10] *Trbovich v. United Mine Workers,* *Mining,* 56 F. R. D. 408 (DC Minn. 404 U. S. 528 (1972); *U. S. v. Reserve* 1972).

nized the importance of institutionalizing public participation before the Federal Trade Commission, and recently provided for the recovery of costs and attorneys' fees under circumstances which could be applied appropriately to the FDA, as well as other agencies.[11]

Using the citizen's petition provision, Consumers Union has filed a petition with the FDA requesting the adoption of a provision which would allow the Commissioner to provide reasonable attorneys' fees, expert witness fees and other costs of participation to persons whose perspective is important for a fair balance of views and who could not afford to pay such costs or whose economic interest is small in comparison to the costs of participation. Consumer groups view this petition as raising an issue of critical importance. These procedural regulations reflect an expectation on the part of the FDA that consumer groups will complement, or be a counter-force to industry. Both interests are subject, on the whole, to the same requirements and opportunities. Consumer groups are developing the expertise to use these opportunities and meet the requirements. However, at least for the foreseeable future, unless provision is made for financial remuneration for services rendered by consumer advocates, as was suggested in the Consumers' Union petition, the proper functioning of consumer groups before the FDA will remain unrealized.

Conclusion

In sum, the FDA's decision-making processes are structured in such a way that, perhaps inevitably, industry and consumers must balance each other. As a result, the procedural requirements for participation in the FDA's regulatory processes affect both groups in similar ways. However, the financial disadvantages under which consumers now operate are serious. Steps should be taken to redress the imbalance, and provide consumer groups with the resources to advance their interests as they are expected and required to do by the FDA.

[The End]

[11] See Magnuson—Moss Warranty—FTC Improvement Act, PL 93-637, 93rd Congress, 2nd Session.

COURT ALLOWS LAETRILE SUIT AS CLASS ACTION

A federal district court has extended its order enjoining the Food and Drug Administration (FDA) from interfering with a terminally ill patient's importation and interstate transportation of laetrile for his own use to include all terminally ill cancer patients. The court determined that terminally ill cancer patients satisfied the criteria for a class action and that the class was sufficiently identifiable so that it could be administratively determined whether a particular person was a member. The court said that requiring lawsuits on an individual basis would deny many patients the opportunity to have their claims heard and that allowing a class action would save the FDA the time and expense of defending a multiplicity of suits.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 38,108

IODINE COMPOUNDS: GRAS STATUS AFFIRMATION PROPOSED

The addition of potassium iodide, potassium iodate, and calcium iodate to the list of generally recognized as safe (GRAS) direct food substances has been proposed by the Food and Drug Administration (FDA). Although potassium and calcium iodates were not included in the initial GRAS determination, the need to affirm their safety came about in part by a revision in the standard of identity for bakery products to permit the use of safe and suitable ingredients that do not alter the basic identity of the food or affect its nutritional characteristics. Prior to the revision, the recipe requirements for bread specifically listed the substances as optional ingredients. In addition to fulfilling the safe and suitable provision, GRAS affirmation of the substances would satisfy a recent regulation that requires a reexamination, according to current scientific information and safety evaluation procedures, of substances (except for food additives) that have in the past been considered to be safe.

The FDA, which concluded from its own evaluation and from studies of the Select Committee on GRAS Substances that use of the three compounds at current levels does not pose a health hazard, proposed that GRAS affirmation for potassium iodide be limited to use of the compound in table salt at a level of 0.01 percent based on the weight of the table salt and that affirmation for potassium and calcium iodates be limited to their use in the manufacture of bread at levels not to exceed 0.0075 percent based on the amount of flour used.

Comments on the proposal are due by August 9, 1977.

CCH FOOD DRUG COSMETIC LAW REPORTER, No. 754

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