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# Food Drug Cosmetic Law JOURNAL

Papers Presented at the 1969 Annual Meeting of the New York State Bar Association Section on Food, Drug and Cosmetic Law

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

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# FOOD DRUG COSMETIC LAW JOURNAL

## Table of Contents . . . . . March, 1969




VOLUME 24 NUMBER 3

# FOOD DRUG COSMETIC LAW JOURNAL

## Editorial Advisory Board



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# REPORTS

## TO THE READER

**Twenty-Fourth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association.**—The introduction and succeeding papers in this issue of the JOURNAL were presented at this meeting, which took place at the New York Hilton Hotel on January 28, 1969. Additional papers read at the meeting will be published in a later issue.

The "Introductory Statement" on page 117 is by *Franklin M. Depew,* President of the Food and Drug Law Institute and Chairman of the Meeting. Mr. Depew includes comments on the FDA's consolidation into the Department of Health, Education and Welfare's Consumer Protection and Environmental Health Services. He also discusses the Committee on Hearing and Rule-Making Procedures.

*William P. Woods,* Counsel for American Home Products Corporation, in "The Murky Crystal Ball—Future Drug Legislation," beginning on page 119, discusses past FDA legislation and proposed legislation, such as drug economics, patents and trademarks, and generically identified drugs. In comparing past and proposed legislation, he concludes that many of the new proposals go far beyond the original issues of safety and deception and are directed at the basic structural elements of the system of manufacturing and distributing drugs.

*Murray D. Saver,* an attorney for General Foods Corporation, explores in "Synthetic Foods and the Law," an article which begins on page 128, the various factors which are affecting the development of synthetic or "fabricated" food. He points out that although there are pressures exerted by certain groups who are antagonistic to the development of synthetic foods, the search for new sources of food supplies will continue despite these impeding factors.

*Bernard L. Oser* in "Regulatory Requirements for Misleading Labeling" discusses the inconsistencies in labeling requirements. Unwarranted apprehension can be aroused in the typical consumer through the listing of chemical ingredients already declared safe by the FDA. Functional labeling may be achieved through the listing of individual food components and the use of descriptive phrases. The author, whose article begins on page 141, is the scientific editor of the JOURNAL and the President of the Food Drug Laboratories, Inc.

The FDA's hearing activities treat only one symptom of the disease of sick regulations, say *David A. Seligman* and *John R. Stafford,* who diagnose the disease as FDA regulations that are unacceptable to industry, causing tension and conflict between the two. A great deal of the help required to cure the illness must come from within the agency, supplemented by suggestions from industry. The authors of "The Other Man's Shoes," beginning on page 146, are attorneys with Hoffman-LaRoche, Inc.

*William R. Pendergast* in his article on page 154, "The Challenge to Improve the Hearings of the Food and Drug Administration," answers many questions concerning improvements in hearing procedures. He discusses the authority of the examiner and suggests that examiners should be empowered to make initial decisions on issues of fact. Mr. Pendergast, a Washington attorney, is also the chairman of a committee investigating and proposing improvements, where necessary, in the hearing and rule-making procedures of the FDA.


Annual Meeting of the Food, Drug Cosmetic Law Section, New York Bar Association, January 28, 1969, New York Hilton Hotel. Left to right: (Sitting) William J. Condon, J. Henry Neale, Franklin M. Depew, William R. Pendergast, John R. Stafford, Dr. Bernard L. Oser; (Standing) M. W. Jensen, Hon. Everette MacIntyre, William P. Woods, Dr. Julius G. Zimmerman, George G. Coughlin, Murray D. Sayer.

Vol. 24, No. 3 March, 1969

Food·Drug·Cosmetic Law
Journal

# Introductory Statement

By FRANKLIN M. DEPEW

This Statement Introduces a Series of Articles Presented at the Twenty-fourth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, at the New York Hilton Hotel on January 28, 1969. Mr. Depew, the Chairman of this Section, Is the President of the Food and Drug Law Institute.

DURING THE PAST YEAR there occurred an event of great interest and importance to all of you as practitioners in the field of food, drug and cosmetic law. Your clients, too, have looked upon it as an event of major interest. As you know, the Food and Drug Administration (FDA) has been consolidated within the Department of Health, Education, and Welfare's (HEW's) Consumer Protection and Environmental Health Service (CPEHS) as a major arm of that recently formed agency. The changes were said to be made to consolidate some scattered functions and to arrange other activities to assure more effective protection against controllable health hazards in the environment.

I am sure I speak for all of us when I say that FDA is the finest consumer protection agency which our system of government and law has ever produced. In saying this, I recall to your minds the enviable tradition of this agency since its inception under Harvey Wiley, Walter Campbell and their distinguished successors. This is a tradition of high purpose, dedication and integrity which members of industry and the Bar are concerned to see preserved. We, therefore, hope that administrative problems in the complicated parent agency will not impair or dilute its great functions.

Another matter of concern during the past year has been the time consumed by the hearings to revise the Regulations for Foods for Special Dietary Uses and to Establish Standards of Identity for

Certain Vitamin and Mineral Fortified Foods. The Hearing Examiner, David H. Harris, Esq., called for a conference to begin last week to reconsider the use of written direct testimony as a means of shortening the lengthy public hearings. Government attorneys stated that upon reflection they are now of the opinion that written direct testimony is in the best interest of all participants. At the conclusion of the conference Examiner Harris ordered that future direct testimony be written.

The proposal for regulations for Good Manufacturing Practices (GMPs) has also been a matter of concern. This proposal has been characterized as a temporary climax to the assumption of power by federal agencies by way of a new interpretation of an already existing statute. One of the significant features in the development of these GMP regulations has been the registration of objections to the FDA proposal on the ground that they would have the force and effect of law, rather than to serve as guidelines or interpretations. Members of the Bar are, therefore, gratified to observe that the revised proposal better accommodates the interpretive character in the regulatory process. It appears that the new proposal will be more generally acceptable to industry and to members of the Bar.

In the light of these developments in administrative law, I have, in my capacity as Chairman of the American Bar Association's Division of Food, Drug and Cosmetic Law, appointed a "Special Committee on Hearing and Rule-Making Procedures of the Food and Drug Administration" to review and evaluate:

1. The adequacy, effectiveness and fairness of the present hearing and rule-making procedures of that agency;

2. The adequacy of the enabling legislation providing for administrative procedures in the hearing and rule-making area relative to food and drugs; and

3. The adequacy of the Administrative Procedures Act as it is applied to the hearing and rule-making procedures of the agency.

Charles W. Whitmore, Esq., Chairman of the Food and Drug Committee of the Administrative Law Section of the American Bar Association, has also appointed a Special Committee with similar responsibilities. The two Committees plan to meet together in joint session to consider what action should be taken. The Chairman of the Joint Committee is William R. Pendergast, Esq., who will report to us on deliberations to date. It is my hope that the Committee will suggest improvements which will be adopted as recommendations of the American Bar Association. **[The End]**

# The Murky Crystal Ball—Future Drug Legislation

By WILLIAM P. WOODS

Mr. Woods Is Counsel for American Home Products Corporation.

THE ROLE OF A PROPHET, as the experience of Jonah demonstrates,[1] can be unrewarding. And now, after the tumultuous span of time that was 1968 and in the opening days of a new national administration, that enterprise is fraught with more hazards than usual. Nevertheless, it might be worthwhile to unpack the old, battered crystal ball in an effort to peer into the future, in an effort to obtain some insight into what we can expect from the new Congress in the way of legislation affecting drugs and drug products.

Since no historical event is unrelated to those which preceded it, perhaps, before we endeavor to see where we are going, we should recall where we have been. We might wish to re-examine the purposes of those who drafted and enacted the great charter of food and drug law, the Federal Food, Drug and Cosmetic Act of 1938[2] and to ascertain how these purposes have been effectuated by subsequent amendments to the Act. Our look into the future may then take on a new perspective.

## Birth of a Charter

The legislative gestation period of the Food, Drug and Cosmetic Act was five years. Senator Copeland introduced S. 1944, which had been prepared in the Department of Agriculture, in the first Session of the 73rd Congress on June 12, 1933. Incidentally, the good Senator later admitted on the floor of the Senate that he had introduced the so-called Tugwell bill without having read it.[3] The statute, the result of many legislative mutations, was signed into law on June 26, 1938.

[1] Book of Jonah, Ch. I, v. 15-17; see also Matt., Ch. XIII, v. 57.

[2] 52 Stat. 1040 (1938), 21 U. S. C. 301 and following.

[3] Dunn, *Federal Food, Drug and Cosmetic Act—A Statement of the Legislative Record*, 155 (1938).

As the legislation, in the form of a successive series of bills, had been approaching the end of the Congressional maze, the reaction in Congress to the sulfanilamide tragedy resulted in the formulation of further controls over "new" drugs. As recorded in a Special Report to the Congress[4] by the Secretary of Agriculture, in September and October of 1937, 93 people had died after ingesting an elixir of sulfanilamide in which ethylene glycol had been used as the solvent. The manufacturer had made no toxicity studies prior to introducing the product into the market. The report pointed out that, under the 1906 law, the only charge that could be brought against the drug was that of misbranding and this was possible only because, although the product had been identified as an elixir, it contained no alcohol. In response to the recommendation of the Secretary of Agriculture, the House Committee on Interstate and Foreign Commerce inserted into the bill before it the provisions relating to new drugs which were to become § 505 of the 1938 Act. It is interesting, particularly in the light of some current suggestions, to read the Committee's comment:

> This provision will not put the Federal Government into the business of developing new drugs, nor will it require the Government to duplicate laboratory and clinical tests made by responsible manufacturers. The provision merely sets up a method for authoritative review of the manufacturer's tests and will not unreasonably delay the introduction of new drugs in the market. (H. R. Rep. 2139, 75th Cong., 3d Sess., 9, (1938).)

The statute, as enacted, fulfilled most of the hopes of its sponsors. True, control over advertising of drugs, as well as of foods and cosmetics, had been assigned to the Federal Trade Commission (FTC);[5] true, the provisions for issuing permits to certain manufacturers of foods, drugs and cosmetics[6] had been deleted. However, the essential aims of the supporters of the legislation, as had been outlined in 1933 by the Food and Drug Administration (FDA),[7] had been accomplished. Factory inspection had been authorized; far greater disclosure in labeling had been mandated; medical devices had been subjected to the law; proof of fraudulent representation was no longer needed to establish misbranding; the penalties for violation had been made substantially more severe. The Congress had committed the government to a far more active role in protecting the public from unsafe and impure foods, drugs and cosmetics and from deception practiced in connection with the marketing of those goods.

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[4] Report of the Secretary of Agriculture, Sen. Doc. 124, 75th Cong., 2d Sess. (1937).

[5] Wheeler Lea Act, 52 Stat. Ill. (1938).

[6] S. 1944, 73rd Cong., 1st Sess., Sec. 12 (1933).

[7] Report of the Food and Drug Administration for the Fiscal Year Ending June 30, 1933.

## A Change in Objectives

Safety again was the Congressional objective in the enactment, in 1941, just prior to the expiration of patent protection for insulin, of Section 506 of the Act, which requires the batch certification of that important therapeutic agent.[8] With the development of antibiotics during the Second World War, the law was amended to provide, first for certification of penicillin,[9] and, subsequently, to require certification of streptomycin,[10] chlortetracycline, chloramphenicol and bacitracin.[11] Again safety was the goal.

In 1951, the Humphrey-Durham Amendment[12] was adopted. As noted in the Report of the Senate Labor Committee,[13] the legislation was intended: "(1) to protect the public from abuses in the sale of potent prescription drugs, and (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician."[14]

The Amendment defined prescription drugs in general terms and specified simplified labeling for such drugs when dispensed to the consumer. Prior to dispensing, such drugs were required to bear the legend "Caution: Federal law prohibits dispensing without prescription." Here was an effort to maintain safety while eliminating troublesome and needless paper work.

Mention must be made, although out of chronological order, of the Drug Abuse Control Act of 1965.[15] The Congress found that the use of depressant and stimulant drugs "often endangers safety on the highways . . . and otherwise has become a threat to the public health and safety." The statute set up stringent regulations for stimulant and depressant drugs. It also sowed seeds of controversy regarding findings by the Secretary of Health, Education and Welfare that a given substance is habit-forming because of its stimulant effect or that a given drug contains a substance which has "a potential for abuse because of its depressant or stimulant effect on the central nervous system." The regulatory structure mandated by that statute has relevance, as I shall indicate later, to contemplated legislation.

The Congressional hearings which began on December 7, 1959 may have represented a watershed in the history of federal drug legislation. The laws to which I have referred were aimed at prevent-

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[8] 55 Stat. 851 (1941); 21 U. S. C. § 356.

[9] 59 Stat. 463 (1945).

[10] 61 Stat. 12 (1947).

[11] 63 Stat. 409 (1949).

[12] 65 Stat. 648 (1951).

[13] S. Rep. 946, 82nd Congress, 1st Sess., (1951).

[14] 1951 *U. S. Code Cong. and Ad. News* 2454.

[15] Pub. Law 89-74, 79 Stat. 227 (1965).

ing the manufacture and distribution of unsafe or impure drugs, as well as of the other goods subject to the laws, and at the use of deception in marketing such products. However, the hearings conducted by the Senate Subcommittee on Antitrust and Monopoly under the not too genial chairmanship of Estes Kefauver went much further. When the Senator from Tennessee introduced his "Drug Industry Antitrust Act"[16] on April 12, 1961, he asserted: "Our hearings have revealed a direct connection between these high costs of drugs and the manner in which drugs are advertised and sold."[17]

## The Substance of the Kefauver Bill

Here was the economic theme which, as the years went by, was to be heard more and more clearly as the motif of legislative proposals affecting drugs. Kefauver's bill encompassed amendments to the Sherman Act[18] which would have outlawed certain agreements relating to patents covering drugs, amendments to the Patent Act[19] which would have compelled licensing of drug patents and which would have required a ruling on efficacy from the Secretary of Health, Education and Welfare as a condition for the issuance of a patent on a "molecular modification or other modification of any patented or unpatented drug or for a combination of two or more drugs" and a series of amendments to the Food, Drug and Cosmetic Act. The three principal objectives of the Kefauver bill were described by its sponsor in the following terms:

1. To bring about reductions in the present high prices of drugs.

2. To provide physicians with better and more adequate information about drugs and correlatively to reduce the dissemination of information which is false and misleading.

3. To insure that all drugs are of adequate and acceptable quality.[20]

A modified version of the Kefauver bill, its way somewhat eased by the furor surrounding the thalidomide incident, was signed into law[21] a year and a half after its introduction, and less than three months after being reported out by the Senate Judiciary Committee. The antitrust amendments had been stricken as well as the compulsory patent licensing provisions, but the amendments to the Food, Drug

[16] S. 1552, 87th Cong., 1st Sess. (1961).

[17] *Congressional Record*, Senate, April 12, 1961, p. 5638.

[18] 26 Stat. 209 and following (1890); 15 U. S. C. § 1 and following.

[19] 66 Stat. 797 and following (1952); 35 U. S. C. § 100 and following.

[20] Individual views of Senator Kefauver and others, S. Rep. 1744, 87th Cong. 2d Sess. 33 (1962).

[21] P. L. 87-781; 76 Stat. 781 and following (1962).

and Cosmetic Act did place much tighter controls over the drug industry and particularly over new drugs and prescription drugs. Among other things, the new law:

1. Required the certification of all antibiotics;

2. Required the registration of all establishments in which drugs are manufactured or processed;

3. Required proof of efficacy as part of a new drug application;

4. Provided for affirmative approval of new drug applications by the FDA;

5. Bestowed upon the FDA authority over prescription drug advertising; and

6. Provided a mechanism for the establishment of official generic names.

## Current Proposals

Where does all this leave us today? It seems to me that, with respect to safety of drugs and consumer deception, there are very few areas where governmental supervision can be increased without completely subjecting the industry to administrative fiat. An example of a proposal which would do just that was adverted to by the Task Force on Prescription Drugs in its Second Interim Report. The Task Force recommended, among other things, that the Secretary of Health, Education and Welfare call one or more conferences to consider "Development of a registration and licensing system under which no drug product would be permitted in interstate commerce unless produced under quality control standards set by the Secretary of Health, Education and Welfare."[22]

Since conferences are proposed, immediate legislative action in this direction is unlikely. Another proposal which, to me, would unnecessarily restrict the development of new drugs was recently made by a witness[23] before Senator Nelson's Monoply Sub-Committee. The witness suggested the founding of a federally sponsored institute which would supervise new drug clinical investigations and would set and enforce standards for such investigations. This is quite a contrast to the views of the House Committee, quoted above, which approved the "new drug" provisions of the 1938 Act.

Certainly we can expect reintroduction of Congressman Staggers' bill[24] to require premarket testing of devices prior to their

[22] Task Force on Prescription Drugs, Report and Recommendations, Sub-Committee on Monopoly, Senate Select Small Business Committee, 90th Cong., 2d Sess. 19-20 (1968).

[23] Dr. Paul Lowinger.

[24] H. R. 10726, 90th Cong. 1st Sess. (1967).

introduction but the courts may have already accomplished that at which the legislation is aimed.[25] A bill properly distinguishing between devices used in or on the body of man from those with other uses might well receive favorable legislative attention. A new version of Congressman Bell's bill[26] on "child-proof" closures will probably appear in the Congressional hopper, but its fate is uncertain at this time. Senator Nelson has already introduced a bill[27] authorizing the creation of a National Commission on Public Health "to investigate the potentially harmful effects of certain drugs, cosmetics, food additives and other chemicals." One can only hope that action on this proposal will be delayed until the existing National Commission on Product Safety makes its report.

Former Secretary Cohen, in testifying at the FTC's hearings on consumer protection last November advocated that producers of over-the-counter drugs be required to submit records and reports of product performance to the Department of Health, Education and Welfare. He also supported requirements that drugs in tablet or capsule form bear numbers identifying the drug and its manufacturer and that the label of a prescription drug bear the generic name of the drug and the name of the manufacturer. Although Mr. Cohen has not quite the influence he possessed a few months ago, the introduction of legislation to effectuate his suggestions is a possibility. Whether the FTC or the new Secretary of Health, Education and Welfare will support the proposal is in doubt. Mr. Cohen's proposal, in regard to prescription drug labels, went a bit further than the Task Force on Prescription Drugs which had recommended that:

> The Congress should enact legislation requiring that the containers of all dispensed prescription drugs be labeled with the identity, strength and quantity of the product, except where this is waived upon specific orders of the prescriber.

Senator Nelson, in the last session of Congress, introduced a bill to this effect.[28] In commenting on the Task Force Report, the Pharmaceutical Manufacturers Association endorsed this proposal and suggested it be broadened to require the label of dispensed prescription drugs to bear not only the name by which the drug was prescribed, but also the name of the manufacturer or distributor and lot and con-

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[25] *AMP, Inc. v. Gardner*, CCH Food Drug Cosmetic Law Reports ¶ 80,192, 389 F. 2d 825 (CA-2 1968), cert. denied, under name of *AMP, Inc. v. Cohen*, U. S. Sup. Ct. 1968, — U. S. —, 21 L. Ed. 95; compare *U. S. v. An Article of Drug*, CCH Food Drug Cosmetic Law Reports ¶ 80,194, 392 F. 2d 21 (CA-6 1968), cert. granted U. S. Sup. Ct. 1968, — U. S. —, 21 L. Ed. 197.

[26] H. R. 17355, 90th Cong., 2d Sess. (1968).

[27] S. 365, 91st Cong., 1st Sess. (1969).

[28] S. 3290, 90th Cong., 2d Sess. (1968).

trol numbers.[29] The argument in favor of identifying a prescription drug on the label which reaches the consumer is one based on safety: a user of prescription drugs, should he require medical treatment from a physician other than the prescriber, should be able to inform him, without delay, of the nature of the medication he is taking.

The Department of Justice is in the process of developing an omnibus Dangerous Substances Bill whose purpose would be to impose rigid control over the manufacture and distribution of hallucinogens, narcotics, stimulants and depressants. A draft bill which has been informally circulated for comments combines certain features of the Narcotics Manufacturing Act[30] and the Drug Abuse Control Law[31] including the imposition of quotas for hallucinogenic and narcotic drugs. The draft bill would also give the Attorney General authority, pursuant to procedures outlined in the Administrative Procedure Act,[32] to alter the statutory classification of drugs subject to regulation. A parallel and related development is the proposal for international control of psychotropic drugs now under consideration by the United Nations Commission on Narcotic Drugs. Adherence to any United Nations agreement would be by treaty, requiring presidential approval and consent of two-thirds of the Senate. Detailed analysis of the Justice Department draft or of the United Nations' proposals is beyond the scope of this paper. However, it would seem desirable, if both the nation and the world body take action to control psychotropic drugs, that the controls imposed by each be consistent with one another.

## Cost-Oriented Legislation

It is in the area of drug economics, however, where we can expect most of the legislative fireworks in the present session of Congress. As I noted before, Senator Kefauver, almost 10 years ago, sounded the tocsin calling for an assault on what he called the high price of drugs. Today, the political appeal of attacking so-called high prices paid by consumers for drugs is enhanced by the ever-increasing involvement of government, at all levels, in progressively more expensive medical programs. A measure of that involvement is the contrast, as set forth in President Johnson's last budget message to the Congress, between the $5.1 billion of federal expenditure for health in 1964 and the $18.3 billion requested for fiscal 1970.

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[29] Critique of the Report and Recommendations of the Task Force on Prescription Drugs, 57.

[30] Pub. Law 86-429; 74 Stat. 55 and following (1960); 21 U. S. C. Sec. 501 and following.

[31] See footnote 15 above.

[32] Pub. Law 89-554; 80 Stat. 381 and following (1966); 5 U. S. C. Sec. 551 and following.

Drug patents and trademarks were the target of several witnesses before Senator Nelson's Monopoly Sub-Committee last year,[33] their argument being that the restriction or even elimination of these industrial properties would encourage price competition. No legislation in this area is likely until completion of the joint study, by various federal departments and agencies, called for by the Task Force on Prescription Drugs. Whether the study will include presentations by non-governmental organizations is not clear. However, I find it ominous that the Task Force recommended conferences with representatives of the drug industry, pharmacy, clinical medicine and consumer groups to consider the proposal of federally mandated quality control standards but called only for a study by federal agencies of the revision of patent and trademark law.

In the First Session of the 90th Congress, a Senate House conference deleted from the Social Security amendment bill[34] a Senate-approved proposal of Senator Long[35] which would have established a United States Formulary of generically identified drugs together with price ranges for such drugs for use in making federal payments for drugs dispensed under Medicare and State Medicaid programs. The Conference did adopt a substitute[36] calling for a study by the Secretary of Health, Education and Welfare of the quality and cost standards for drugs for which payments are made under the Social Security Act with a report to the Congress due on or before January 1, 1969. Not long before that action of the Conference, a proposal[37] to add prescription drugs to the benefits available under the voluntary coverage provisions of Medicare Plan B had been defeated in Committee. That bill also contained provisions for a drug formulary with price information. Senator Nelson, still embroiled in his hearings, introduced a bill[38] to amend the Food, Drug and Cosmetic Act to provide for a Federal drug compendium of prescription drugs by their generic names, which compendium would include price information.

On January 14, Secretary Cohen released a further report of the Task Force on Prescription Drugs, presumably in response to the Congressional mandate calling for a report by January 1, analyzing

[33] For example, Testimony of Dr. Leonard G. Scheflin, Hearings before the Sub-Committee on Monopoly, Senate Select Committee on Small Business 90th Cong., 1st and 2nd Sess., Part 5, p. 1863 and following; Testimony of Dr. Henry Steele in reference above at 1901 and following.

[34] H. R. 12080, 90th Cong., 1st Sess. (1967).

[35] Senate Amendment 295, 90th Cong., 1st Sess. (1967).

[36] Senate Amendment 142, 90th Cong., 1st Sess. (1967).

[37] S. 17, 90th Cong., 1st Sess. (1967).

[38] S. 2944, 90th Cong., 2d Sess. (1968). The Senator has reintroduced this legislation, S. 950, 91st Cong., 1st Sess. (1969).

the generic formulary proposal of Senator Long, characterizing it as "feasible and medically acceptable." The report recommended the use of generically identified drugs, where available, when federal funds were used, thereby accepting as accurate the thesis that the use of branded drugs is inordinately expensive. The Senator hailed the report as a vindication of his position and announced his intention to reintroduce, in the new Congress, the legislation rejected by the Senate-House Conference in the First Session of the 90th Congress. The legislative struggle over any such bill of Senator Long and over the expected renewal by Senator Montoya of his proposal, coupled with a provision for a drug formulary, that outpatient prescriptions be covered under the voluntary provisions of Plan B of Medicare, will be the central drama, with respect to drugs, of the present session of the Congress.

## A Proper Balance

It seems to me that our gaze into the crystal ball, in the light reflected from the mirror of the past, clearly demonstrates the contrast between the thrust of anticipated legislative proposals and those of the years gone by. Despite differences in approach to details, there was no essential conflict among government, the drug industry, and the medical and pharmaceutical professions about the desirability of providing the American public safe and effective drugs under informative and truthful labeling. I believe that it is a credit to all concerned that this goal has been, to the extent human fallibility permits, achieved. However, as I have endeavored to point out in this paper, many current proposals go far beyond the issues of safety and deception and are directed at trade practices of long standing and, indeed, at basic elements of the structure of the American system of manufacturing and distributing drugs. Perhaps an examination of that system is in order, for the massive use of public funds either to purchase or to pay for drugs has unquestionably introduced a new factor into the marketplace. But I maintain the hope, despite the political heat (which sheds little light) that surrounds many of the legislative proposals with which the Congress must deal, that the national legislature will strike a proper balance between the desire to reduce the cost of drugs and the need to provide incentive for the invention and development of new drugs, as it has between the desire for safe drugs and the need for efficacious drugs. And it will fall to members of our profession, representing government, consumer organizations, pharmaceutical manufacturers and the medical and pharmaceutical professions to assist in the fact-finding process on which Congressional action will be based. **[The End]**

# Synthetic Foods and the Law

By MURRAY D. SAYER

Mr. Sayer Is an Attorney for the General Foods Corporation, White Plains, New York.

THE SUBJECT OF THIS PAPER is "Synthetic Foods and the Law." As lawyers are inclined to do, I thought I would start off by defining these terms.

But before I do that, I would point out that the term "synthetic foods" is probably a misnomer. The term synthetic carries the connotation that the food is turned out of a test tube in some way. Actually these foods rely for their ingredients on substances of nature. But like the victims of Proteus, they are changed and altered into new forms. It is true that some ingredients are synthesized chemically, but more often than not, these synthesized ingredients are exact duplicates of what exists in nature. So "synthetic foods" is not an apropos term. These products are called by various names, such as technologically developed foods, constructed foods, facsimile foods, etc. My own preference is for the term "fabricated foods" and so I shall refer to them as such throughout this discussion.

As I understand it, a fabricated food is one which is constructed by the scientists or food technologists to achieve predetermined attributes of taste, texture, flavor, color and form. This definition, obviously, is insufficient since many foods not within the ambit under discussion, such as a cake or a beef stew, could fall within that definition. What has to be added to this definition is the fact that the ingredients, or at least the critical ones, used in fabricated foods are not common food ingredients but are themselves specially designed to achieve a particular function in the product which common food ingredients could not. These may include things such as specially constructed fat components, starches, fibers, and flavors which are available today only because of significant technological advances.

The law referred to in this paper is not merely the current statutes, but also general principles enunciated by the courts and regulations adopted by various administrative bodies. While techni-

cally not law, it would be appropriate to include within the ambit of discussion the pressures exerted by various groups which are antagonistic to the development of fabricated foods. As any lawyer involved in counseling is aware, these pressures frequently inject an aura of uncertainty into the development and marketing of new food products.

Before launching into a discussion of the law itself, I think it would be useful to explore the factors, both pro and con, which are affecting the development of fabricated foods. These factors which are responsible for the development of more and more fabricated foods can be roughly classified under the headings of technologic, demographic, medical, economic, convenience, and, to a certain extent, religious.

## Relevant Factors

The key which unlocks the door to new food development is, of course, technology. And with the host of technological keys available to industry today, seemingly no doors need bar the way to new foods, providing that time, money and motivation are applied. In the area of fabricated foods, good nutrition becomes important since many of these foods may begin to replace staple, natural foods in the diet. And the arsenal of nutritional technology is, perhaps, the easiest problem in the fabricated food area. Essential vitamins have been synthesized for a considerable period of time and can be easily and economically incorporated in most food products. Good quality protein is, of course, a must in many fabricated foods because they may replace protein rich staples. Today there are many sources of good quality protein, including fish flour and protein from plant sources. In addition, work is being done on producing protein from yeast or bacteria grown on petroleum and certain individual amino acids have been chemically synthetized and are commercially available.

The attributes of taste and texture are much greater stumbling blocks in the way of fabricated foods. It is axiomatic that, like the horse that can be led to water but can't be made to drink, you can make the most nutritious product in the world but the consumer won't buy it or eat it if he doesn't like it. However, these stumbling blocks are also being overcome by technological advances. A few years ago, artificial flavors were often less than satisfactory because they were made by combining ingredients which merely approximated the natural flavor. Today, by sophisticated analytical techniques, scientists are analyzing more and more the actual chemical constituents of flavors. Once these constituents are known, they are syn-

thesized and blended to provide flavors comparable to the natural flavors.

The problems of texture are also falling before the advancing technological developments. We all know there are certain foods we like to sink our teeth into. If we approach a food with such anticipation and end up, instead, with a mouthful of mush, the product will not sell. The technology of structuring various protein fibers has already gone a long way towards eliminating this problem.

So much for technology. The next factor in the development of synthetic foods is demography. We are all aware of various reports which state that between 60 and 70 percent of the world's population is suffering from malnutrition. We are also aware that we are in the midst of a population explosion which will place greater and greater demands on our world food supplies. Newer and more efficient sources of nutritious food must be developed to meet this problem. While the United States is more fortunate as far as a good food supply goes, we are not totally exempt from the problem. Therefore expanding pressure for new food supplies will force the continued search for new sources of food. For example, a major source of protein in this country is beef. It is recognized today that obtaining protein needs from beef is highly inefficient. A steer will provide for human consumption only 10% of the protein which it consumes as food. As our society expands in terms of numbers, it will probably be impossible to expand our meat resources to meet the demand. Therefore, while I am not anticipating the early demise of steak and hamburger, they and other animal sources will probably diminish gradually as sources of protein.

The medical factor arises from increasing knowledge that certain components of our natural food supply may create medical problems for some individuals. For example, some infants are allergic to milk and need to take a non-dairy substitute. There is a large body of evidence and strong medical opinion to the effect that a high ratio of saturated fats to unsaturated fats in the diet may contribute to atherosclerosis in certain groups of the population. The recommendations of the medical profession for improving this situation involve decreasing consumption of saturated fats and high cholesterol foods, primarily from animal sources, and replacing these with certain oils of vegetable origin. There is also a body of medical opinion which equates the increasing rate of heart disease with an increased consumption of sucrose. Of course, there are several million diabetics who must control their carbohydrate intake, often with the aid of

artificial sweeteners. And let us not forget the thousands of dentists around the country who incessantly urge millions of mothers to cut down on consumption of sweets by their children in order to avoid cavities. Now many of these problems, or the recommended solutions to these problems, could be accomplished by substituting certain natural foods for the potentially offending foods. Nevertheless, these forces are bound to have an impact on the formulation and development of fabricated foods.

The economic factor is so well known that it hardly needs any discussion. The cost of food today is constantly rising, along with other goods and services in our economy. While we are called the affluent society, many consumers feel the pressure on their food dollars and are quick to look for savings in their weekly food budget. If fabricated foods can offer savings over the purchase of their natural counterparts, many consumers will respond.

Convenience has long been a prime factor in the development of new foods. Foods providing quicker and easier preparation, longer shelf life, and more convenient packaging are eagerly snapped up by the consumer. To the extent that fabricated foods can contribute to convenience, assuming the presence of other desirable attributes, they will be accepted by the consumer.

The final factor listed which affects fabricated food development is religion. While this factor may be small, it has already given the fabricated food technology a big push. This technology has been primarily in the area of meat analogues made from soy protein for religious groups who are vegetarians and in kosher non-dairy replacements for dairy products.

## Obstacles to Progress

These, then, are some of the major factors working toward the development of fabricated foods. But there are also factors working against the development of these products, and it might be worthwhile to touch on them briefly. The main obstacle is the pressure which can be exerted by agricultural groups on legislatures and regulatory officials. The reasons for such pressure is obvious. Many of the fabricated foods are in substantially the same form, or can be used as replacements for, natural agricultural products. Typical products include non-dairy coffee whiteners, non-dairy whipped toppings, imitation fluid milk, and replacements for citrus fruit juices. Products such as these are currently on the market and, in varying degrees, have received favorable consumer acceptance. To the extent these products achieve acceptance in the market place, the producers of the

natural products, understandably, become concerned. Their approach, to date at least, in combating this competition, has been to seek economic or inhibitory legislation or regulations.

One phase of fabricated foods which has only scratched the surface, but which offers fascinating possibilities for the future, is the development of meat analogues, that is vegetable proteins, usually soy proteins, with the form and taste of meat. So far, these products have reached the market primarily only in condimental form or as extenders for regular meat products. However, the door is ajar and I suspect it will not be too long before some very interesting meat analogues will be appearing on the market. Of course, if these products are successful, they will begin to have an impact on the meat industry although such impact may be minor for some time to come. Unlike the dairy and citrus industries, the meat packers seem to have adopted the approach that if you can't lick them, join them. And indeed, some of the meat packers seem to be in the forefront of research on meat analogues. But they too have a view as to certain marketing limitations which should be put on these products and have made their views known to the regulatory agencies.

Consumer attitudes also affect the development of fabricated foods. Particularly in the past, consumers reacted unfavorably if a food appeared to be anything but nature's own. Overcoming these biases was at times extremely difficult. Today's generation, however, has seen and accepted the development of many synthetic articles, such as synthetic fabrics, used either alone or blended with natural fibers, plastics, synthetic leather, "fake furs", and, in the food area, synthetic vitamin pills. Far from rejecting these items, you see more and more often the adjective "miracle" applied to them. While the "now" generation is receptive to new developments, they still insist, at least in the food area, that fabricated foods bear a relationship in taste and appearance to natural foods. In the future, this attitude will probably also be overcome and food scientists may become very creative in developing new forms and tastes unrelated to natural foods.

Now that the introductory remarks are completed, we can move into a discussion of the law.

## What the Law Says

The largest segment of laws applicable to fabricated foods are not laws which were designed for such foods. They are laws of general applicability and so a discussion of these laws does not neces-

sarily involve fabricated foods within my definition. However, they are important in that they are the body of the laws which will be applicable to such products.

So, back in history we go to the first major product designed to replace, or substitute for, a natural agricultural product, namely, margarine. Margarine was invented around 1872 in response to a contest sponsored by Napoleon III to develop a butter substitute. Its use spread rapidly to the United States and Federal restrictive legislation was passed in 1886 in the form of a special tax on oleomargarine.[1] The states too, being responsive to the dairy industry, were active in promulgating restrictive legislation and this led to some cases which eventually ended up in the Supreme Court. These cases established basic guidelines as to the type of restrictions which could be imposed on substitute foods.

In the case of *Powell v. Pennsylvania*,[2] handed down by the Supreme Court in 1887, the Court upheld a conviction under a Pennsylvania Statute which prohibited the manufacture and sale of margarine. The statutory prohibition was absolute and the decision evoked a strong dissent by Mr. Justice Field. His philosophizing is as interesting as his legal analysis and I would like to quote some of his comments.

> Upon first impressions one would suppose that it would be a matter for congratulation on the part of the State, that in the progress of science a means had been discovered by which a new article of food could be produced, equally healthy and nutritious with, and less expensive than, one already existing, and for which it could be used as a substitute. Thanks and rewards would seem to be the natural return for such a discovery, and the increase of the article by the use of the means thereby encouraged. But not so, thought the Legislature of the Commonwealth of Pennsylvania. By the enactment in question it declared that no article of food to take the place of butter shall be manufactured out of any other oleaginous matter than that which is produced from pure milk or cream, or be sold within its limits or kept for sale under penalty of fine and imprisonment.

The dissenting Justice also quoted from the case of *People v. Marx*,[3] a New York case handed down in 1885, which arrived at the opposite conclusion on a similar statute.

> If the argument of the respondent in support of the absolute power of the Legislature to prohibit one branch of industry for the purpose of protecting another, with which it competes, can be sustained, why could not the oleomargarine manufacturers, should they obtain sufficient power to influence or control the legislative councils, prohibit the manufacture or sale of dairy products? Would arguments then be found wanting to demonstrate the invalidity under the Constitution of such an Act? The principle is the same in both cases. The numbers engaged upon each side of the controversy cannot influence the question here.

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[1] Oleomargarine Act of August 2, 1886.

[2] 127 U. S. 678.

[3] 99 N. Y. 377.

In 1894, margarine legislation again appeared before the Supreme Court in the case of *Plumley v. Massachusetts*.[4] This law did not prohibit absolutely the manufacture and sale of margarine, but merely margarine which was colored in imitation of yellow butter. The Court again upheld the statute. This case, however, was challenged on the basis of the Commerce Clause of the Constitution, rather than the 14th Amendment as in the Powell Case. The decision seemed to contain language that if margarine had been absolutely prohibited, it would have violated the Commerce Clause.

So in 1897, the identical statute which had been before the Court in Powell reappeared in the case of *Schollenberger v. Pennsylvania*.[5] This time the claim was that it violated the Commerce Clause of the Constitution. The Court struck down the statute and established the following guidelines:

> In the execution of its police powers we admit the right of the State to enact such legislation as it may deem proper, even in regard to articles of interstate commerce, for the purpose of preventing fraud or deception in the sale of any commodity and to the extent that it may be fairly necessary to prevent the introduction or sale of an adulterated article within the limits of the State. But in carrying out its purposes the State cannot absolutely prohibit the introduction within the State of an article of commerce like pure oleomargarine.

The first Federal Food and Drug Act was passed in 1906. While it was a milestone in food legislation, it did not contribute significantly to the discussion at hand except that it did permit imitations provided they were plainly stated as such. So the next significant development at the Federal level would appear to be the Federal Filled Milk Act of 1923.

This law is still a unique law in that it is the only Federal law which actually prohibits the sale in interstate commerce of a food product. It was aimed at a specific product which had developed a sizeable amount of sales from about 1910. The product was canned, evaporated, skimmed milk to which vegetable oil had been added to replace the butterfat. The reason stated for the prohibition was that the product "was injurious to the public health, and its sale constitutes a fraud upon the public." These reasons were reasonably documented at the hearings and in the legislative reports. The basis for the injury to health claim was that vitamins normally found in milk were substantially absent from filled milk. While the legislative record was rational on its face, the Congressional Reports also made clear that the persons most concerned with this threat to health were the dairy farmers. Consider the following excerpt from the House Report.

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[4] 155 U. S. 461. [5] 171 U. S. 1.

The farm and dairying organizations are a unit in opposing the manufacture of this compound. If the business grows, as it will without legislative interference, it will mean a decided decrease in the dairy herds of the country. Instead of vast quantities of whole milk being condensed, the butter fat will be extracted and turned into a comparative oversupply of butter. The oversupply will depress the price, and as the price of milk is regulated by the price of butter fat, the keeping of dairy herds will become less profitable. It is possible that in isolated instances farmers receive more money for their milk where the skimmed milk is manufactured into the substitute, but there can be no question that the introduction of the cheap coconut oil in competition with butter fat is an economic injury to the dairying industry as a whole.

The Supreme Court sustained the legislation in 1937 and 1944 in the *Carolene* cases.[6] In the 1937 decision, the Court based its decision primarily on the health question:

In twenty years evidence has steadily accumulated of the danger to the public health from the general consumption of foods which have been stripped of elements essential to the maintenance of health. The Filled Milk Act was adopted by Congress after committee hearings, in the course of which eminent scientists and health experts testified. An extensive investigation was made of the commerce in milk compounds in which vegetable oils have been substituted for natural milk fat, and of the effect upon the public health of the use of such compounds as a food substitute for milk.

The 1944 decision took a different tack. By 1944, the manufacturers had developed the technique for adding back the lost vitamins, so the health basis of the Act had disappeared. This time the Court put emphasis on the aspect of confusion:

While, as we have stated above, the vitamin deficiency was an efficient cause in bringing about the enactment of the Filled Milk Act, it was not the sole reason for its passage. A second reason was that the compounds lend themselves readily to substitution for or confusion with milk products. Although, so far as the record shows, filled milk compounds as enriched are equally wholesome and nutritious as milk with the same content of calories and vitamins, they are artificial or manufactured foods which are cheaper to produce than similar whole milk products. When compounded and canned, whether enriched or not, they are indistinguishable by the ordinary consumer from processed natural milk. The purchaser of these compounds does not get evaporated milk. This situation has not changed since the enactment of the act. The possibility and actuality of confusion, deception and substitution was appraised by Congress. The prevention of such practices or dangers through control of shipment in interstate commerce is within the power of Congress.

Thus the Filled Milk Act of 1923 is still with us today, an anachronism and anomaly of monumental proportions. The health reasons for such law are long gone. The remaining basis for sustaining the law, the possibility of confusion, stands in stark contrast to the provisions of the Federal Food, Drug and Cosmetic Act of 1938, and the court rulings thereunder, that any food product which is in imitation or semblance of another food may be sold if labeled as "imita-

[6] 304 U. S. 144; 323 U. S. 18.

tion." The continued presence of this law has brought many a research project to a halt and denied the consumer the benefits of new developments in this area. And, as will be seen later, it has created a new series of problems today which might have otherwise been avoided.

## FDA Litigation

With the passage of the Federal Food, Drug and Cosmetic Act of 1938, new developments began to occur. While the 1906 Act permitted the sale of products labeled as imitation, there was no litigation on this provision, presumably because manufacturers were unwilling to label their products as imitations. However, a series of cases under the new law made it perfectly clear that manufacturers would have to take the bull by his imitation horns. The initial cases arose with respect to food products for which standards of identity had been promulgated. For example, FDA had issued standards for jam which required a ratio of fruit to sugar of 45% to 55%. Two cases[7] were tried in which the manufacturers had less than the 45% fruit content and had labeled their products with coined names, such as fruit spread. Both of these cases held the products to be in violation because they purported to be the standardized food, jam, but did not conform to the standard.

The big case on this subject followed in 1951. This was the imitation jam case.[8] In this case, the manufacturer also had a product which purported to be jam but did not conform to the standard. However, in this case the manufacturer clearly labeled the product as "Imitation Jam." The problem here resulted from an interpretation by FDA. FDA's position was that once a standard of identity had been adopted, any product that purported to be the standardized product must comply with the standard, and no deviation could be made from the standard regardless of whether it was labeled imitation or not. The Court emphatically rejected this position.

According to the Federal Food, Drug and Cosmetic Act, nothing can be legally "jam" after the Administrator promulgated his regulation in 1940, 5 Fed. Reg. 3554, 21 C. F. R. § 29.0, unless it contains the specified ingredients in prescribed proportion. Hence the product in controversy is not "jam." It cannot lawfully be labeled "jam" and introduced into interstate commerce, for to do so would "represent" as a standardized food a product which does not meet the prescribed specifications.

But the product with which we are concerned is sold as "imitation jam." Imitation foods are dealt with in § 403 (c) of the Act. In that section Congress

[7] *United States v. Ninety-Nine Cases of Peach Fountain Fruit*, 89 F. Supp. 992 (1948); *United States v. Thirty Cases of Leader Brand Strawberry Fruit Spread*, 93 F. Supp. 764 (1950).

[8] *62 Cases of Jam v. United States*, 340 U. S. 593 (1951).

did not give an esoteric meaning to "imitation." It left it to the understanding of ordinary English speech. And it directed that a product should be deemed "misbranded" if it imitated another food "unless its label bears, in type of uniform size and prominence, the word imitation and, immediately thereafter, the name of the food imitated."

In ordinary speech there can be no doubt that the product which the United States here seeks to condemn is an "imitation jam." It looks and tastes like jam; it is unequivocally labeled "imitation jam." The Government does not argue that its label in any way falls short of the requirements of § 403 (c). Its distribution in interstate commerce would therefore clearly seem to be authorized by that section. We could hold it to be "misbranded" only if we held that a practice Congress authorized by § 403 (c) Congress impliedly prohibited by § 403 (g).

This decision was fortunate for industry and, in my opinion, for consumers since it permits variants from the standards (which could represent significant technological advances) to be sold at least under some form of labeling.

The imitation jam case made clear what an imitation food product was if a standard was involved. However, it did not define an imitation food where no standard existed. This definition was clearly set forth in 1953 in the *Chocolate Chill-Zert* case.[9] In that case, the product in question was held to be an imitation of chocolate ice-cream because a vegetable fat and a soy protein had been substituted for the butterfat and milk protein that ice-cream usually contains. Other than this, the Chill-Zert was exactly like ice-cream. It tasted and looked like ice-cream and was manufactured and packaged like ice-cream. In holding that the Chill-Zert was an imitation of ice-cream, the court said the following:

Resemblance alone is not enough to constitute imitation . . . It would seem that imitation is tested not by the presence or absence of any one element of similarity, but rather by the effect of a composite of all such elements. As indicated above, Chill-Zert is identical with ice-cream in its method of manufacture, packaging, and sale. It is similar in taste, appearance, color, texture, body and melting qualities. It has identical uses; . . . .

The criteria set forth in the *Chill-Zert* case completed the guidelines applicable to imitation foods, at least so long as these foods were of the conventional type. Essentially these principles were that no state could prohibit the interstate sale of a pure food product which was not deceptive. Under Federal law, imitation food products could be manufactured and sold if they were properly labeled as imitation, except for filled milk. A food was an imitation if it purported to be the standardized food but did not comply with the standard. If there was no standard, a food was an imitation if it had sufficient attributes, such as taste, smell, appearance, and use of the original product so that people might take it for the real thing.

[9] 114 F. Supp. 430.

## Technological Growth

But the new technology was already raising its protean being. It had its genesis during World War II by the successful development of a continuous method of producing so-called soy milk and cream by extracting soy protein from the soy bean. In the years following the war, a growing line of products incorporating this new technology appeared on the market. All the products growing out of this development fell in the category of replacements for dairy products. Essentially they included whipped toppings, coffee whiteners, and sour cream dressings. They came in all sorts of forms: liquid emulsions, powdered form, pressurized cans, frozen liquid, and prewhipped and frozen. While each of these products is intended as a replacement for dairy products, it is significant that they offer attributes of their own which dairy products cannot. For instance, they have very long shelf life and can therefore be distributed nationally. This shelf life is the result of the fact that these products can be distributed in frozen or powder form. This in turn offers the consumers a great convenience in that they can be purchased any time and be held without spoilage until they wish to use them. Once they are thawed or prepared, these products hold up much longer and retain their functionality long after their natural counterparts would have to be thrown out. There is no question that, as a class of foods, these products have been well received by the consumers.

In contrast to the consumers, regulatory agencies were strongly opposed to these products. Various states brought actions against these products charging them to be imitations of dairy products. Uniformly, the courts rejected the charges and held that the products were not imitations. Following is a quotation from one of those decisions.[10]

> We reach the inescapable conclusion that [the coffee whitener] is not an imitation of cream or half-and-half and that it is a new and distinct food product having characteristics unique unto itself. [The coffee whitener] is no more an imitation of cows' cream, half-and-half, or any other dairy product than nylon is an imitation of silk, saccharine an imitation of sugar, or [vegetable shortening] an imitation of lard. Those products, and [the coffee whitener], are separate, distinct, individual products developed as a result of modern scientific and technical advances and inventions. They are products *sui generis*.... Paraphrasing *Baltimore Butterine Co. v. Talmadge*, supra, the state of Kansas is not committed to the proposition that nothing new and distinct is possible. To require the product here involved to be labeled "imitation cream," or "imitation half-and-half" would thwart the development of not only [the coffee whitener] but also other distinctive new food products and would fall within the evils seen in *Balti-*

[10] *Coffee Rich, Inc. v. The Kansas State Board of Health*, CCH FOOD, DRUG, COSMETIC LAW REPORTS ¶ 40,094, 388, P. 2d. 582, (Kan. Sup. Ct. 1964).

*more Butterine Co. v. Talmadge,* supra, where it was said:

> ". . . The purpose of this law it must be remembered, is not to protect other industries, even though they be so important as the dairy industry, but is to protect the consumers from deception or injury. If this be not the correct view, the state is committed to the use of creamery butter for all time for the purposes now used, and cannot use any substitute therefor derived from other sources, even though more economical, more palatable, and more popular." (p. 909).

It should be noted that in all these products, the Federal and state filled milk laws were avoided by using no dairy ingredients. Had there been no filled milk law, many products might have utilized nonfat dry milk, thereby offering some benefit to dairy producers.

Now there is an even newer threat to the dairy producers. Although it is only a trickle so far, a substitute for liquid whole milk has appeared on the market. Again because of the filled milk laws, this product contains no milk ingredients. Since this product is not allowed to contain nonfat dry milk, at least if it moves in interstate commerce, other sources of protein are used which are not as high quality as the protein from milk. For this reason, FDA has entered the picture and proposed standards for, of all things, "imitation milk" and "imitation cream." These standards are now being thrashed out in Washington and, at this stage, it is anybody's guess as to how they will be resolved. If these standards are adopted, you will then have three categories of products,—regular milk, imitation milk, and filled milk (which can be sold intrastate in some states). My own belief is that the problem could best be resolved by repealing the filled milk laws. This would enable the imitation milks to achieve the same nutrition as regular milk and yet supply those additional desirable attributes which regular milk cannot supply. If this is not done, technology will eventually overcome the present deficiencies of imitation milk and the dairy producers will again be the losers.

## Conclusion

Dairy products are not the only ones affected by the growing technology. In 1963, a company developed a product intended to look, taste like, and provide at least equal nutrition to, frozen orange juice concentrate, but containing no orange juice. It was sold under the name "frozen concentrate for orange flavored breakfast drink." It apparently was successful enough so that the citrus industry let out a howl. FDA began to investigate the product and finally concluded that it met all the criteria for an imitation orange juice. The company was called into FDA at Washington, and, after negotiations, it was agreed to change the name of the product to "frozen

concentrate for imitation orange juice." It is still on the market and enjoying reasonable success.

The meat analogues which I mentioned earlier are a third category of products where technology and the law are locking horns. For quite a few years, there have been soy-based products in link form on the market. These were designed primarily for vegetarians. Up until now, with the exception of some state actions, the imitation question has not been involved because regulatory agencies were of the opinion that they did not meet the imitation criteria. But with the new textured protein technology, the door is open and the legal issue has been joined.

The first product on the market (that I know of) was one which looked somewhat like pieces of fried, crumbled bacon. They were called "Crispy Bits with a Bacon-Like Flavor." FDA, after due deliberation, took the position that the product should be called imitation bacon. The company countered with the proposal that a standard be adopted for this product, using the arbitrary name "Bontrae." Another company working on another method of texturing soy protein, proposed a different standard under the name "textured vegetable protein." This matter, too, is now being thrashed out in Washington.

It is interesting to note that, unlike the dairy and citrus interests, the meat industry is not opposing the development of these fabricated foods. In fact, they are doing a great deal of research in the area of meat analogues. What is of even more interest is that this industry seems opposed to the use of the word imitation on these meat analogues. I assume the reason for this opposition is the concern that the word "imitation" in conjunction with a specific meat designation, such as beef, hamburger, or bacon, may carry more of a quality image than some arbitrary name. If this is so, then it may be that the word imitation has grown in stature over the years from a term which connotes debasement to a term of quality, not necessarily of equality with the natural product, but of quality in which the imitation product may have many of the attributes of the natural product but also desirable attributes not found in the natural product.

This completes the summary of legal developments with respect to fabricated products. It is an aspect of law that is changing and full of ferment. It is also exciting and challenging to be a part of the technological developments. It is to be hoped that some of the antagonisms which have developed between competing segments of the food industry can be resolved without burdening the new technology with hamstringing laws. If not, the consumer will be the loser. **[The End]**

# Regulatory Requirements for Misleading Labeling

By BERNARD L. OSER

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AT THE RISK OF BEING CHARGED WITH BEATING A DEAD HORSE, I have chosen to discuss one aspect of food labeling which has received little or no attention lately, whereas controversy has raged over the type sizes and positioning of net content declarations. I refer to the listing of ingredients in foods, more specifically in foods composed of two or more ingredients.

The misbranding section of the Food, Drug and Cosmetic Act of 1938 (and I emphasize that date) requires that labels of foods bear "(1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient." Certain exemptions are allowed to which I shall refer later. At this point, however, I submit that the application of this section of the law has led to ingredient declarations which, though not actually deceptive, are misleading, inconsistent, confusing, and non-informative. These ingredient statements often tend to depreciate wholesome foods and to raise doubts as to their safety.

The Food and Drug Administration (FDA) has, in fact, straddled the fence in the enforcement of this provision of the Act. It has stated interpretively that "The word 'ingredients' does not refer to the chemical composition, but means the individual *food components* of a mixed food" (emphasis supplied). This concept has also been stated by Bigwood and Gerard, in Volume 1 of their treatise on *Fundamental Principles and Objectives of a Comparative Food Law* (published by S. Karger, Basel, Switzerland and New York, 1967), who point out that, in Europe, it is usually regarded as confusing and unjustified to include food additives among ingredients. Thus, because of "the limited understanding the consumer may have concern-

ing the technical significance of the information he receives . . . the consumer may be misled by the information according to the way it is worded; it may create suspicions which are inappropriate or which were not meant to be given. In other words, the information may be misleading and deceive the consumer."

## Illusion of Hazard

One can well appreciate the justification for listing the *food components* of products offered for sale under fanciful names. People should have the means of exercising dietary preferences whether for health, sensory, religious, or other reasons. But selection on the basis of safety should not be left to the consumer. This is a matter for scientific expertise for which reliance must be placed on the competency and judgment of those charged with protection of public health. Once the safe use of a chemical additive has been permitted, no useful purpose is served by fostering the illusion of hazard or inferiority, which unfamiliar chemical names inevitably engender. Nevertheless, FDA has insisted on the declaration of certain chemical components, viz. food additives, on the labels of many foods, including some for which definitions and standards of identity have been established. For the most part, standardized foods are exempt from the listing of components except when the regulations require the naming of certain optional ingredients on the ground that they are not customarily expected to be present by the consuming public. The ingredients of spices, flavoring, and coloring are not required to be listed except when sold as such.

## Inconsistency in Listing Ingredients

Thus, policies vary with regard to the listing of ingredients, some foods bearing extensive lists of items identified specifically by name, while others, that is those that are standarized, do not. However, Mrs. Consumer is generally not aware of this distinction.

It is pertinent to recall some of the major reasons advanced for the statutory requirement for listing ingredients during the hearings on S. 1944, the progenitor of the Act of 1938. Among them were (1) to prevent concealment of inferiority by the substitution of cheaper or less nutritious ingredients, (2) to permit the exercise of food preferences including the avoidance of certain foods by persons allergic to or otherwise intolerant of specific components, and (3) to aid regulatory agencies in the analytical control of food composition and quality.

What effect has ingredient listing had in achieving these objectives? With respect to revealing the presence of cheaper or inferior ingredients, very little. The "common or usual names" of food ingre-

dients are often vague and obscure even to so-called informed consumers. Your colleague and my friend, Vincent Kleinfeld, has written on this subject in the FOOD DRUG COSMETIC LAW JOURNAL back in 1961.[1]

An ingredient which is itself a standardized food may consist of a number of mandatory or optional ingredients. Technical terms like "plant protein hydrolysate" or "hydrogenated vegetable oil" are descriptive of processes rather than products and convey little information to the ordinary consumer. Is the "plant protein" one that should be avoided by reason of hypersensitivity? Is "partially hydrogenated oil" better or worse than "hydrogenated oil"? With regard to declared chemical constituents, what is the difference between sodium nitrate and sodium nitrite, and other terms which identify chemical entities, not food components in the sense that the term is commonly understood? Has the abbreviation of polyoxyethylene monooleate to polysorbate 80 made it more meaningful to the consumer? How do these "common or usual" names enable her to make intelligent choices, particularly when the identity of such components may be buried among the optional ingredients in a standard? The only effect these names can have on the ordinary consumer is to cause apprehension and uncertainty as to the safety of the food. For some substances there are no common or usual names, and acronyms or euphemisms have been coined in the expectation that they will become common, for example BHT for butylated hydroxytoluene, or cellulose gum for sodium carboxymethylcellulose. Niacin was adopted as a name for nicotinic acid, the antipellagra vitamin.

The Food Additives Amendment of 1958 effectively removed questions of safety from food standards hearings. It should also have been possible, by regulation, to avoid engendering unwarranted doubts concerning the safety of chemicals in food by requiring commonly understood language, rather than technical terminology, on food labels.

## The Value of Functional Declaration

The proposal to restrict chemical ingredient declarations to functional categories has had a mixed reception. FDA has permitted the use of the terms shortening and leavening, and the statute itself provides for the declaration of artificial flavoring or coloring without identifying their individual components. Functional phrases are sometimes appended to the names of chemical substances, for example "added as a dough conditioner," "to preserve freshness," "to protect

[1] "'Common or Usual Name'—Its Meaning, If Any," 16 FOOD DRUG COSMETIC LAW JOURNAL 513 (August, 1961).

against rancidity," or "to retard mold growth." Such descriptive phrases are more informative and reassuring than chemical names standing alone. It would seem to be just as honest and more educational to require *only* functional labeling of all chemical components when necessary to declare them at all now that their safety must be assured through regulatory channels. The impracticability of disclosure of the identity of individual components of spices, flavoring, and coloring in foods was recognized by Congress when it provided for the exemption of these functional classes of ingredients. No greater risk to health or to "honesty and fair dealing in the interest of consumers" would be incurred by extending the list of functional categories.

Protection of allergic or hypersensitive individuals can be achieved only to a limited degree by ingredient labeling. Allergies are most often induced by proteins, although reactions to non-proteinaceous foods or to chemical substances such as essential oils or food colors, also exist. However, even a standardized food may contain undeclared substances to which some individuals may react adversely.

Ingredient statements are of some value to the regulatory analyst to the extent that they clearly identify components in descending order of concentration. But they assuredly do not reveal the presence of non-permitted components. Plant inspections are more likely to facilitate the disclosure of such adulterants than analytical tests for unknown ingredients. If the administrative agency had a need to know the qualitative composition of a food, this information could be available under existing law.

In short, I do not believe that the listing of ingredients has fulfilled all the objectives it was expected to achieve.

## Who Is the "Ordinary" Consumer?

Though not a member of your learned profession, I have read enough to know that the courts have interpreted the labeling requirements of the law in relation to the capability of the ordinary consumer to understand what is stated. The ordinary consumer has been variously described, on the one hand, as the "casual, incautious, unwary or unsuspecting purchaser" and, on the other, as being "reasonably intelligent" or of "average intelligence." Arithmetically, the word "average" is meaningless in this context. If it is assumed to refer to usual or typical consumers, it should not include either the most or the least intelligent among the consuming population. This has been ably discussed by Wesley E. Forte in a recent paper entitled "The Ordinary Purchaser and the Federal Food, Drug and

Cosmetic Act" (52 *Virginia Law Review* 1467 (1966)). It would be futile and virtually impossible to describe the contents of foods in terms that would be comprehensible to what one court described as "the vast multitude which includes the ignorant, the unthinking and the credulous, and those who do not stop to analyze." However, it has been urged that sophisticated consumers also have a "right to know." My remarks can be said to represent the reaction of a sophisticated consumer reasonably well informed on matters relating to foods and their composition.

It has been argued by consumer-oriented professionals that ingriedient statements should be mandatory even for standardized foods. The "right to know" could be readily conceded if consumers generally had the capacity to understand, but when common or usual names are meaningful only to the technically knowledgeable, it is easy to realize how the ordinary consumer can be perplexed and misled, rather than informed.

There are circumstances when labeling should be informative not just to the ordinary purchaser or consumer of food but to trained personnel, such as members of the medical or paramedical professions, and to institutional purchasers. In some instances, however, administrative policy has been against label disclosures which suggest special dietary value. For instance, the characterization of fats according to their content of saturated and polyunsaturated fatty acids and the labeling of vitamin-fortified sugar, have been the subject of controversy or litigation.

The FDA has on numerous occasions taken positions based on its understanding of what the consumer expects. The question can legitimately be raised as to the validity of such judgments, and whether they represent the results of adequate consumer research or the opinions of individual consumers or consumer groups, and how qualified these opinions are. In developing policy with respect to informative labeling, it would be most enlightening to survey a statistically sufficient population of "ordinary consumers" to determine the limits of their ability to comprehend meaningful information via labeling. Such a survey could establish a really objective basis for regulatory requirements and might lead to ingredient declarations which would be both reliable and understandable. To be fair to consumers and manufacturers alike, labels should not kindle doubts and misconceptions in the minds of those who bother to read them.

**[The End]**

# The Other Man's Shoes

By DAVID A. SELIGMAN and JOHN R. STAFFORD

The Following Article Was Prepared by Mr. Seligman with Contributions and Delivery by Mr. Stafford. The Authors Are Group Attorneys at Hoffman-La Roche Inc., Nutley, New Jersey.

SEVERAL PAPERS HAVE BEEN WRITTEN RECENTLY concerning the procedures of the Food and Drug Administration (FDA) in respect to its hearing activities on the establishment of regulations. Questions have been raised concerning the legal integrity of the present hearing procedures,[1] the utility of the hearing procedures,[2] and the suitability of the hearing procedures,[3] among others.

The questions on FDA hearing activities, however, using as an analogy a remark often directed at drug products, treat only one aspect or symptom of what could be called a "disease"—namely, the "sick" regulation. For our purposes, let's consider a "sick" regulation to be any regulation proposed by the FDA which cannot be accepted by the persons who would be affected by it and which therefore leads to controversy between such persons and the FDA.

A comment made by Commissioner Ley at the 1968 Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration stated the fundamental principle of the FDA regulatory process and also stated what this process should *not* be:

> This is not an adversary contest, a kind of game in which FDA proposes all the regulations it can think of and industry defeats as many as it can. Rather, the fundamental question has to be: What rules are *necessary* to safeguard the consumer? If we keep that principle in mind, it is much easier to deal with and resolve the disagreements that do arise between FDA and industry.[4] (Emphasis provided.)

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[1] Levine, "Separation of Functions in FDA Administrative Proceedings" 23 FOOD DRUG COSMETIC LAW JOURNAL 132 (March, 1968).

[2] Goodrich, "The Food and Drug Administration's View on Procedural Rules" 23 FOOD DRUG COSMETIC LAW JOURNAL 481 (October, 1968).

[3] Pendergast, "Have the FDA Hearing Regulations Failed Us?" 23 FOOD DRUG COSMETIC LAW JOURNAL 524 (November, 1968).

[4] Ley, "FDA Today and Tomorrow" 23 FOOD DRUG COSMETIC LAW JOURNAL 620 (December, 1968).

## Origin of Conflict

Industry is not opposed *per se* to FDA activities. The continuing cooperation in the development of a National Drug Code Directory is a good example of how mutual cooperation and understanding can be beneficial to both industry and Government. The basic question which gives rise to the regulations and to the problems is: "What rules are necessary to safeguard the consumer?"

Unfortunately, FDA's regulatory efforts create the "sick" regulation which, in turn, creates what Dr. Ley, FDA, and industry do not want—an adversary contest. This comment is not intended as harsh criticism of the Agency, nor, I hope, is it interpreted that way. I believe that the people at FDA are trying to achieve a goal of what might be simply termed "better" products—meaning safe, effective, properly packaged and labeled products in the fields of foods, drugs, and cosmetics.

Some of us may not agree with certain actions of the FDA or its interpretations of what is a "safe" product, of when a drug is "effective," of what constitutes "proper" packaging, or of what is "correct" and "informative" labeling, but we all, both as producers and consumers, should agree with FDA's objective. With this thought in mind, how then may this disease of the "sick" regulation, the regulation which causes open conflict between the FDA and industry, be alleviated?

Obviously, there are no panaceas to the problems of arriving at necessary suitable and workable regulations any more than there are medical panaceas. However, there are steps which could be taken to prevent at least some of the hassles over regulations which seem to be developing with increased frequency. The matter may be approached as you would a legal problem by determining, first, the facts or background surrounding the particular situation; second, the problems involved; and third, the possible solutions.

The FDA, during the past half dozen or so years, has issued various regulations on both simple and complex issues which have been objected to by a particular company, by a number of companies, or, sometimes, by an industry fairly much as a whole. Listed below are a few examples of what could be termed, at least in part, "sick" regulations:

(1) The vitamin regulations;[5]

(2) The 1963 advertising regulations;[6]

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[5] 27 Fed. Reg. 5815; 31 Fed. Reg. 8521. [6] 28 Fed. Reg. 6376.

(3) The advertising regulations published in June of 1968;[7]

(4) The color additive regulations;[8]

(5) The "generic name every time" regulations;[9]

(6) The peanut butter regulations;[10]

(7) The record keeping and reporting regulations;[11] and

(8) The proposed regulation on "certain sulfanilamide and sulfathiazole preparations for topical use."[12]

The problems which these regulations illustrate include:

(1) Exceeding the statutory basis of authority in their requirements;

(2) The use of vague and indefinite terminology and the imposition of subjective standards, making it virtually impossible to judge with any reasonable certainty what circumstances will result in a violation of the regulations;

(3) The imposition of a requirement beyond that reasonably required to accomplish the basic purposes of the regulation; and

(4) The use of general wording, making it difficult to determine the intent and requirement of the regulation.

## Extension of Authority

The "generic name every time" case is an example of an occasion when the Agency, in order to achieve its purpose, exceeded its statutory authority without need. The primary reason for the underlying legislation was to bring to the mind of the physician the established name of the particular drug. This would enable him to prescribe generically if he so desired. According to the Agency's thinking, the obvious way to achieve this objective was to require the use of the generic name every time the trade name of the drug was used. But was this requirement necessary under the wording of the statute or to accomplish the intent of the statute?

Obviously, the Third Circuit Court of Appeals did not think so.[13] As you probably know, the decision of that Court in favor of the industry's position was appealed to the Supreme Court on the issue of "ripeness for review." The Supreme Court held that the regulations were indeed ripe, and, as a result, after long and expensive litigation, the FDA and industry arrived at a settlement of the matter.

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[7] 33 Fed. Reg. 9396.

[8] Color Additive Amendments of 1960, Act of July 12, 1960 Pub. Law 86-618, 74 Stat. 396.

[9] 28 Fed. Reg. 1448; 28 Fed. Reg. 6375; 33 Fed. Reg. 3217.

[10] 32 Fed. Reg. 17482; 33 Fed. Reg. 10506.

[11] 29 Fed. Reg. 7019.

[12] 33 Fed. Reg. 16307.

[13] *Abbott Laboratories v. John W. Gardner, HEW Secretary,* CCH Food Drug Cosmetic Law Reports ¶ 40,258 (U. S. Sup. Ct. 1967), 387 U. S. 136.

The decision of the Supreme Court in the "generic name every time" case, and the color additive regulations case, may help to encourage the FDA to consider more carefully industry's viewpoint *before* issuing regulations—not because industry won those particular cases but because the FDA now realizes that a person need not always run the risk of prosecution under the regulation before he can ask a court to look at its validity. But the overall impact of those cases must be examined at some future time when we can look back to see if they served the secondary purposes which I just proposed.

## Vague and Indefinite Terminology

The use of vague and indefinite terminology and the imposition of subjective standards is probably best illustrated by the advertising regulations. The instances of this problem in these regulations are covered in the objections and request for hearing filed by the Pharmaceutical Manufacturers Association (PMA) with the Department of Health, Education, and Welfare on July 26, 1968, and are too numerous to discuss completely in these comments.

One example, however, is a provision relating to the use of nonclinical studies in advertising.[14] The section states:

> An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:
>
> (vii) Contains favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated.

The difficulty with this is how one is to determine when such a reference will "suggest" clinical significance. The PMA's objection to this regulation is that:

> The requirement of Section 1.105(e)(6)(vii) is unreasonable, arbitrary and capricious in that it is uncertain and vague in its application. There is not sufficient evidence that this provision offers a practical and understandable standard for the guidance of persons affected by it. It is impossible to judge with reasonable certainty in what circumstances a citation or reference to data or conclusions from nonclinical studies will be considered to suggest clinical significance.

Of course, since violation of many such regulations issued by the FDA can result in criminal penalties and product seizures, industry must challenge and seek revision where regulations do not provide reasonably clear guidelines.

## Compounded Problems in Vitamin Regulations

The next example of "sick" regulations—the vitamin regulations—includes examples of many of the problems listed above. Since I

[14] Section 1.105(e)(6)(vii).

cannot cover all sections of these regulations here, I will discuss only the so-called "crepe label" statement.

The vitamin regulations issued in June 1966 required the following statement on the label of dietary supplements:

> Vitamins and minerals are supplied in abundant amounts by the foods we eat. The Food and Nutrition Board of the National Research Council recommends that dietary needs be satisfied by foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.

It is questionable whether the Agency has the statutory authority under Sections 401 or 403(j), or any other provision of the Act, to require the inclusion of this or any similar label statement on the label of foods for special dietary use. Section 401 merely authorizes the adoption of regulations requiring the declaration of optimal ingredients on the labels of foods subject to standards.

It can be well argued that under Section 403(j) of the Act, the Agency's authority to promulgate regulations with respect to label declarations of foods for special dietary use is limited to requiring statements dealing with vitamin and mineral properties of those foods. This Section does not appear to authorize the Agency to require food manufacturers to include label statements that vitamins and minerals are available in other foods, or that these supplements should not be routinely used.

The question can certainly be asked—do the requirements set forth in this particular regulation go beyond those reasonably required to accomplish the basic purpose?

Assuming that the ultimate purpose of this label statement is to prevent false and misleading labeling and advertising of dietary supplements, it would appear that the answer to this question is yes and that the Agency has used the proverbial elephant gun to kill a mouse. False and misleading advertising was prohibited prior to this regulation under other sections of the Act.

The reasonableness of this requirement is further put into question when the required label statement is examined substantively in light of current scientific knowledge—or lack thereof—with respect to the nutritional status of the population of the United States. When the Agency republished the vitamin regulations in December of 1966, the label statement was amended to read as follows:

> Vitamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.

Although the Agency has now changed to a deer gun, this label statement is also open to criticism. The statement that "vitamins

and minerals are supplied in abundant amounts by commonly available foods," though perhaps true, tends to be misleading itself and does not convey meaningful information to consumers. The abundance of these nutrients consumed by an individual depends upon the foods actually eaten by the particular consumer which in turn depends upon regional, religious, and ethnic preferences, financial status, and other conditions too numerous to mention. These facts the statement fails to recognize. Moreover, there appear to be large segments of the population who obtain substantially less than the level of nutrients established by the recommended dietary allowances.

The statement that "except for persons with special medical needs, there is no scientific basis for recommending the use of dietary supplements" is overstated and, interestingly, conflicts with other portions of the regulations. Not only do many physicians now recommend dietary supplements on a routine basis, but Section 125.2(b)(1) of the regulations clearly prohibits representations on vitamin and mineral supplements which suggest or imply that such a supplement is adequate or effective for the treatment, prevention, or mitigation of *any* disease. This is in clear contradiction to the representation that such supplements are useful only in meeting "special medical needs."

The general lack of clear, concise scientific information with respect to the nutritional status of the population of the United States should raise a flag of caution to the Agency when considering such broad, sweeping and restrictive regulations. It is questionable whether the vitamin regulations as now written are a reasonable and correct way to deal with the problems of providing adequate nutrition to all people of the United States.

## Intent and Requirement of Regulations

The fourth specific type of problem area noted—the use of general wording making it difficult to determine the intent and requirement of the regulation—is illustrated by a proposed regulation resulting from the National Academy of Sciences/National Research Council Drug Efficacy Study entitled "Certain Sulfanilamide and Sulfathiazole Preparations for Topical Use." A sentence in this regulation proposed by the FDA states:

> Accordingly, the Commissioner of Food and Drugs intends to initiate proceedings to withdraw approval of the new drug applications for the preparations listed above *as well as for any other applications which became effective for sulfonamides for topical use.* (Emphasis provided.)

This latter phrase can be interpreted in a number of ways and raises many questions. Does FDA, by this sentence, intend to act against all topical sulfa preparations; against only those containing

the same ingredients or intended for the same use as those listed in the regulation; or against only so-called "me too" type products similar to those listed in the regulation? It is hoped that in this instance any final regulation issued will clarify the matter.

## How Do Problems Arise?

Why do these problems arise from regulations drafted by the FDA? I do not believe the difficulties encountered with various regulations are the result of an intentional effort by the Agency to block a product or a practice of the industry for no valid purpose, although it may, at times, seem that way. Rather, the problems arise, I believe, from one or more of the following reasons: a failure of understanding or comprehension of the effects of a regulation beyond those intended by the author; a misconception of the reasons for the existence of the activity at which the regulation is aimed; or from a desire to achieve what appears to be a laudatory goal when, in reality, the accomplishment of that goal may cause more harm than good.

Deputy Commissioner Rankin has said: "If you consumers and you industries are satisfied with things as they are now going, then you can relax and cheer at whatever success or failure we achieve. If you are not satisfied, we need help."[15]

It appears clear from the number of disputes arising from published regulations that industry is not satisfied. I as a consumer in the lay sense—and as a "consumer" of these regulations—am not satisfied ". . . with things as they are now going . . ."

Industry, I believe, is more than willing to help, if allowed. Government and industry representatives have met in a number of instances to discuss and work on various matters such as the Drug Code Directory previously mentioned. They have met both before and after publication to discuss the wording of regulations—for example with regard to the 1963 edition of the advertising regulations and the present revisions of these regulations. There are also discussions going on concerning the now-pending revisions of the current Good Manufacturing Practice regulations for the drug industry.

At certain times these meetings have met with more success than at other occasions. All too often these sessions are held only to discuss the particular words which will be used to express a set Agency concept with no time being given to the more important question of the basic need for the regulation or the appropriate scope

[15] Rankin, "The FDA Program for 1969" 23 FOOD DRUG COSMETIC LAW JOURNAL 627 (December, 1968).

of the regulation. On the other side, industry may be seeking to protect a position which, for the purposes of safeguarding the consumer, might be better relinquished.

## Remedial Suggestions

Both the quantity and the quality of these meetings between industry and the FDA must be improved. I believe it is apparent, however, that a great deal of the "help" required to alleviate the illness of the "sick" regulation must come from inside the Agency. It is important that the Agency carefully consider the following points about a proposed regulation before it is drafted and published:

(1) The regulation must be for the accomplishment of a useful and necessary purpose.

(2) The scope of the regulation must be carefully considered to avoid either exceeding the scope of authority granted by the applicable statutes or exceeding the limits of control reasonably required to achieve the regulatory goal.

(3) The primary effects of the regulation must be carefully reviewed to determine that it will not be more harmful in one particular than beneficial in another.

(4) The collateral effects of the regulation should be determined to make certain that it does not impinge upon a practice or activity which may be related to the primary object of the regulation but which need not be interfered with to accomplish the purpose of the regulation.

(5) The use of indefinite or ambiguous phrasing or terminology should be avoided. The standards set forth should be defined on an objective rather than subjective basis, wherever possible.

(6) The intent and effect of the regulation should be clear to avoid confusion or uncertainty by those who must work with it.

Adherence by the Agency to these principles will, I believe, achieve both more effective regulations and more cooperation by the regulated industries in bringing the regulations to final form without prolonged controversies.

In any relationship such as that between the FDA and industry, the regulator and the regulated, certain instances of conflict are bound to arise. However, in many instances a careful review of the intended action by each party, a willingness of each party to make the effort to place itself in "the other man's shoes"—to listen to his side of the story and then to consider fully his point of view—will certainly reduce the number of occasions where open conflict and objections do arise.

**[The End]**

# The Challenge to Improve the Hearings of the Food and Drug Administration

By WILLIAM R. PENDERGAST

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LAST MAY THE FOOD AND DRUG ADMINISTRATION (FDA) BEGAN ITS ADMINISTRATIVE HEARING to establish standards for and to otherwise regulate dietary supplements, fortified foods, artificial sweeteners, and many other products. This hearing is continuing and the record now exceeds 14,000 pages of transcript with over 700 exhibits before the examiner for rulings of admissibility. This last August, William W. Goodrich, Assistant General Counsel of the Department of Health, Education and Welfare (HEW), in a speech before the American Bar Association (ABA),[1] criticized FDA's protracted "trial-type proceedings" which, to him, have strained the administrative process almost to the breaking point by delays and financial expense. He warns that, unless the situation improves, "entirely new methods" of handling such rule-making proceedings must be devised. He did not amplify on this point but the inferences to be drawn are not comforting. Mr. Goodrich urges, and we agree, that the Bar and the FDA have a joint responsibility for making the present system work.

These two events—the hearing in May and the speech in August —are obviously related and I am happy to report that the Bar is responding to both of these challenges.

[1] Goodrich, "The Food and Drug Administration's View on Procedural Rules," 23 FOOD DRUG COSMETIC LAW JOURNAL 481 (October, 1968).

## Formation of a Joint Investigating Committee

Last November, the Food and Drug Divisions of the Corporation Banking and Business Law Section and the Administrative Law Section of the ABA, formed a joint committee to investigate and propose improvements, where necessary, in the hearing and rule-making procedures of the FDA. The members of the Committee are H. Thomas Austern, Vincent Kleinfeld, Michael Markel, Daniel Marcus, Rodney Munsey, Alan Kaplan, Walter Byerley, Selma Levine, and myself, as chairman. Of course, Franklin Depew and Charles Whitmore, as officers of the parent section, are ex offico members.

This Joint Committee has the responsibility to investigate the current hearing and rule-making procedures of the FDA, with a view to making them more expeditious and, at the same time, fair to all parties. We hope, in the near future, to propose new regulations governing the hearing procedures under existing law while, at the same time, investigating the possibility of new legislation to remedy any defects which do not appear amenable to correction under current statutory provisions. We have already investigated many avenues of approach to both these problems, but, since we have not yet achieved complete unanimity of opinion, much of what I say today reflects my thinking and I am not yet speaking on behalf of the Committee as a whole.

## Hearings Without Guidelines

Without doubt the present administrative procedure regulations for hearings under the various laws entrusted to the FDA are cumbersome, outdated, and incomplete. It has been pointed out that there are now eight different sets of administrative regulations governing and describing the course of hearings at FDA. In addition, and this is most serious, there are statutory requirements for administrative hearings for which the agency has completely failed to publish any regulations at all. One notable example of this is Section 507(f) of the Act which deals with the promulgation of regulations governing the manufacture and sale of antibiotic drugs. This section provides that if anyone objects to a regulation proposed under that section he may request a public hearing which shall be held by the FDA after due notice. In spite of this statutory hearing requirement, not a single implementing regulation has been published by the FDA describing the means, the conduct, or the procedures by which such a hearing will be held. An examiner assigned to such a hearing has absolutely no guidelines to follow and, necessarily, counsel must face

a perilous and uncertain course. Such an administrative omission is bound to cause considerable confusion. And, if one is ever held, I predict that the hearing will be both cumbersome and protracted, in large measure because of this total failure of regulatory guidelines and controls.

## New Tools for Examiners

This demonstrates just one of the problems with which this Committee is concerned. There are many more. Be that as it may, our primary goal is to propose regulations giving the hearing examiner, in every instance, the authority to hold fair and complete hearings for the resolution of disputed fact issues while, at the same time, giving him sufficient guidelines and authority to conduct and enforce an expeditious hearing which will be neither unduly protracted nor financially burdensome. To my mind, these twin goals—of fairness and expeditiousness—are not mutually exclusive under the current law. I believe (and I may disagree with Mr. Goodrich here) that the answer lies in giving the hearing examiner more authority, rather than less, and it is in this area that we are investigating concrete suggestions.

For instance, I would like to see at least some of the traditional tools of discovery entrusted to the examiner so that the scope of factual issues to be contested at the hearing itself could be narrowed as much as possible.

This will not be easy, for, as you know, the Food and Drug Act, and the other acts entrusted to the FDA, do not provide for the use of subpoenaes in connection with administrative hearings. This raises difficult problems as to the means of enforcing and requiring discovery in such hearings. Such an omission probably means that some of the discovery tools common to the federal courts will not be available, but I do think it would be possible to use at least a few of them, particularly in the area of depositions and requests for admissions. For instance, parties are now required to exchange lists of proposed witnesses. If a party wished to take the deposition of an opponent's witness, the rules could provide for application to the examiner and if the witness or the opposing party failed to comply, the examiner could refuse to allow that witness to testify at the hearing.

But such discovery tools, if we are to avoid abuse and delays, would have to be very carefully controlled by the hearing examiner and he would have to be given clear guidelines, in regulations, so that he would be in a sound logical and legal position to enforce his demands under the authority granted him by either the Administra-

tive Procedure Act or the Food and Drug laws. As I say, this will not be easy, but the utility of discovery proceedings is too valuable a tool to be ignored. All of the recent commentators on administrative procedures are virtually unanimous in encouraging the use of discovery techniques as a means of preventing protracted hearings on the record. This is FDA's goal and it is our goal, and we would hope that everyone involved in these proceedings would cooperate in instituting at least some discovery techniques at the FDA.

I would also like to see spelled out a clear statement of the hearing examiner's authority over the conduct of hearings, including his authority to require advance written testimony, to regulate and limit undue cross-examination, to insure that the opinion of scientific experts are fully explored, to regulate the presentation and argument of purely legal motions, and, generally, to state, in detail, what will be expected of all those who participate in FDA hearings, be they government counsel, industry or consumers. The conduct of hearings at the FDA is not an easy task. As many people have already pointed out, Section 701 of the Act is virtually *sui generis* in that it requires a hearing on the record on what often seem to be broad fact questions bordering on the imponderable. It is for this reason that I believe we should give as much detailed guidance as possible to the examiner as to what he can do and how he can do it.

In this area of hearing control, provisions will have to be made for both the simple hearing and the protracted type hearing involving many parties. In the protracted type hearings, I would like to see the regulations impose upon the examiner, the FDA, and the participants, the obligation to abide by the principles in the *Handbook of Recommended Procedures for the Trial of Protracted Cases*, promulgated by the Judicial Conference of the United States. This handbook has already been of considerable assistance in trials and its utility to large administrative hearings is manifest. For instance, in such protracted cases, and perhaps even in all cases, I would like to see the hearing examiner, with the assistance of government counsel and the participants, charged with the responsibility of determining, as far as possible, the real fact issues which are to be in dispute at the impending hearing. How this can be accomplished is one of the difficult problems which our Committee faces. I have thought that a possible solution would be to bring into the prehearing conference the written objections to the regulations in question which are already on file with the FDA. These written objections should pinpoint the fact issues which are really in dispute and an

analysis of them, in open discussion in a pre-hearing conference, should bring into focus whatever factual disagreements there may be.

If this can be done in a productive manner before the hearing begins, then I believe that much of the prolixity of current hearings will vanish. Broad statements of issues, so often used now at FDA, couched in terms of statutory language, such as whether it will promote honesty and fair dealing to prohibit the advertising of certain truthful statements, only lead to equally broad and unwieldy direct examination and to an even more unwieldy cross-examination. It is particularly here that the hearing examiner, the FDA, and the parties can play a vital role, for if there has been any consistent failing in the FDA hearing procedures in the last few years, it has been a failure to adequately delineate what facts are actually in controversy. When we fail here, then obviously the hearing itself will be a failure.

Finally, if we are to give the hearing examiner the tools with which he can conduct a meaningful hearing on disputed fact issues, I believe we should also give him the duty of making the initial decision on these facts. After all, there never will be anyone in as good a position as he to render helpful advice to the FDA concerning the resolution of fact questions which have been presented to him. Not only is he in the best position to render this advice, but, by having him do it, we give to the FDA hearing procedures an element which is now lacking—a review of disputed facts by someone who is at least nominally independent of the thinking and considerations which went into the drafting of the regulations at issue.

Hearings under Section 701 and others at FDA are not held on tentative proposals which the agency is still considering. They are held to resolve disputed facts arising from final agency orders which go into effect unless someone raises objections to them. In other words, the FDA has already taken a fixed position on a given set of facts—a position which agency personnel have presumably carefully considered after long investigation—and which they will reverse only if the record at the hearing clearly requires them to do so. Obviously, in such a situation, the hearing is not a mere "fact finding excursion," as the government so often categorizes 701 hearings, and to that extent, FDA hearings are far different from the traditional rule-making hearings discussed by the text writers or the cases. Because they are so different, to my mind it is most important that someone independent of the agency hear these disputes and make the initial fact decisions resolving them.

As matters now stand under Section 701 Administrative Regulations, which govern most of the hearings at FDA, the examiner is

only authorized to file a report and to certify the record to the Commissioner. Furthermore, this report does not appear to constitute a part of the record of the hearing as FDA defines "record" in its own regulations. To illustrate the gravity of this situation, after the vitamin hearing, Mr. Harris, the examiner, could fully comply with the regulations by merely putting the transcript and exhibits together and forwarding them with a letter saying "enclosed is the transcript and exhibits of this hearing." This surely is not enough. But even worse, if he did file a detailed analysis of the evidence presented in this very long hearing, FDA might very well, under its own regulations, not permit his findings to constitute a part of the record of the hearing—the record which goes to the reviewing courts. Furthermore, there is no requirement, under current regulations, that the parties ever be given a copy of the examiner's report.

To my mind this is a disgraceful situation and an injustice to those who are forced to enter FDA hearings. Instead, it should be mandatory that the examiner make initial findings and that, throughout all subsequent proceedings, his findings constitute a part of the record. His decision, then, would go to all parties and the reviewing courts.

## Authority for Initial Decisions

Such a requirement would not in any way impede the FDA in its regulatory activities. The Administrative Procedure Act provides that the agency may entrust the initial decision to an examiner even in clearly rule-making proceedings, but that, if the agency is not satisfied with the findings, the agency may review them and it then has all the powers it would have possessed had it never granted the examiner this responsibility. Furthermore, no time will be lost because, as matters now stand, the FDA itself publishes a tentative decision after a hearing and the decision by the hearing examiner would be simply substituted in lieu of that tentative decision. There is, thus, absolutely no prejudice to the government nor to the consumer and, instead, we have an independent person reviewing the facts. That this will increase public confidence in FDA hearings procedures and the conclusions FDA makes after such hearings goes without saying. Also, under the doctrine of the *Universal Camera* case, such findings of the examiner do constitute a part of the record on appeal to the courts.

It should be accepted by everyone that the best way to assist the reviewing court of appeals is to provide to that court the initial decision of the hearing examiner. While it is true that the question of whether there is substantial evidence of record to support an

agency's decision depends upon the entire record before the agency, it is equally true, as the Supreme Court stated in *Universal Camera*, that a hearing examiner's initial decision is a part of that record. I see no reason why we should deny to the reviewing courts the benefit of the opinion of the man who heard the testimony. Indeed, the Supreme Court has stated that one of the purposes of the Administrative Procedure Act was to give significance to the findings of examiners. The Court, in *Universal Camera*, did recognize that examiners' findings do not rise to the significance of the findings of a trial judge but clearly stated the proper role of an examiner's initial decision when it said "We intend only to recognize that evidence supporting a [agency] conclusion may be less substantial when an impartial, experienced examiner who has observed the witnesses and lived with the case has drawn conclusions different from . . ." the agency's. I would think it most important for reviewing courts, and the public as well, to know when this occurs, particularly when it involves the type of products regulated by the FDA.

## Other Goals

These, then, are some of the principal areas in which we are working. There are others, including the question of granting the examiner complete independence from the FDA, and a separation of functions at FDA of the personnel preparing the case for the government and the personnel deciding the case for the government. We are also looking into meaningful methods of governing the conduct of agency and industry contacts prior to, during, and subsequent to hearings in a manner that will both insure fairness and continued contact with the agency by the regulated companies. Finally, we are also investigating the advisability of providing for hearings to review other administrative actions at FDA which are not now the subject of any administrative hearings. Some examples of such procedures include the threat of summary suspension of certification of antibiotics without prior hearing and the refusal to permit further investigations on investigational new drugs.

We may not accomplish all these goals and we would like whatever advice and assistance you might wish to offer. With such assistance, I can assure you that we will, very soon, present some concrete regulations for the conduct of FDA hearings and other procedural improvements. We will make these proposals, to the ABA and then, hopefully, to the FDA, as part of our responsibility as members of the Bar, and we are confident that the officials at FDA will consider them in that light. **[The End]**

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