VOL. 16, NO. 7 JULY 1961

Food Drug Cosmetic Law JOURNAL

Authority, Drugs and the Practice of Medicine . . . ADRIEN L. RINGUETTE

An Evaluation of the Contributions of an Advisory Committee in the Enforcement of State Food and Drug Laws . . . . . ROLAND B. SMITH

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

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.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $20 per year. Single copies are $2 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

July, 1961

Volume 16 • Number 7

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

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VOLUME 16 NUMBER 7

Printed in United States of America

REPORTS

TO THE READER

FDA Authority.—"The public policy historically applicable to medicine in this country has been to preserve substantial freedom in medical practice. This means, among other things, noninterference by government. . . ." *Adrien L. Ringuette* uses this argument, among others, in opposing the "Drug Industry Antitrust Act" in the article beginning on page 393.

Mr. Ringuette points out that our federal drug law was drawn in accordance with the principle of prohibiting wrongful conduct in business and otherwise leaving it free. The proposed "Drug Industry Antitrust Act" would put too much authority in the hands of the Food and Drug Administration, he claims. Authorities are cited who feel the proposed law would prohibit physicians from prescribing the most effective treatment for individual patients.

The author is an attorney in the Office of the General Counsel of Abbott Laboratories, North Chicago, Illinois.

State Advisory Boards.—Connecticut organized a committee of specialists in 1948 to provide technical and professional advice in relation to the enforcement of the state Food and Drug Law. The experience of the voluntary advisory board in Connecticut is drawn upon in outlining the problem of state law enforcement by the author of the article appearing at page 433.

This study of the Connecticut committee comprised part of the author's doctoral dissertation at Columbia University. Now Associate Professor of Advertising at the University of Connecticut School of Business Administration, *Roland B. Smith* reports that the expert committee has served to prevent sales of products having implicit hazards that could easily escape the notice of those without a technical background.

California Food and Drug Laws.—The first law prohibiting the sale of adulterated foods in California was signed into law in 1850. Since then, California has had a long history of food and drug legislation and is today one of the strongest proponents of uniform food and drug laws.

The author of the article beginning on page 443, *Milton P. Duffy*, discusses the California Pure Foods and Drugs Acts and related laws. Illustrating the laws with case studies, Mr. Duffy gives a comprehensive picture of the enforcement situation in his state.

Mr. Duffy, who is Chief of the Bureau of Food and Drug Inspections, State Department of Public Health, California, originally presented this paper as a lecture at the University of Southern California Law School.

Scientists' Forum.—*Dr. Bernard L. Oser*, Scientific Editor of this JOURNAL, utilizes the Forum this month to outline the work done by the Expert Panel on Food Additive Matters which he organized for the Flavoring Extract Manufacturers' Association.

Distaff Side.—*Miss Nancy R. Duckworth* has been appointed to the staff of the U. S. Department of Agriculture's Meat Inspection Division, according to Division Staff Officer K. F. Johnson.

WASHINGTON

ACTION AND NEWS

Recent Court Decisions

Decomposed Fish. — Holding that frozen fish fillets identified as Class 3 (having a decidedly strong odor of decomposition) are a decomposed substance within the meaning of Sec. 402 (a)(3) of the Federal Food, Drug, and Cosmetic Act, seizures of frozen ocean perch fillets for which the aggregate pre-seizure and post-seizure organoleptic tests by Food and Drug Administration personnel resulted in a finding that 6% or more were Class 3 fillets have been upheld, even though the claimant's quality controls were found to be above average for the ocean perch industry and other testimony on its behalf was to the effect that test results showed little or no presence of Class 3 fillets. The court noted that its conclusions made it unnecessary to determine (1) whether a *"de minimis"* exception could apply under Sec. 402(a)(3), (2) whether an administrative tolerance of less than 6% Class 3 fillets was permissible, (3) whether a Class 2 fillet (slight but distinct odor of decomposition) is a decomposed substance, or (4) whether a food product consisting at least partly of a decomposed substance, but not unfit for food, is "adulterated." *129 Cases * * * Ocean Perch Fillets,* DC Maine, FOOD DRUG COSMETIC LAW REPORTS ¶ 7661.

Misbranded "Health Device." — A "micro-dynameter" sold for use in diagnosing a number of diseases or general health, but which the court found was simply a sensitive instrument for measuring electric current (a galvanometer) and not useful in such diagnosis, was misbranded in violation of Sec. 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act. A series of bulletins carrying titles identifying them as operating instructions or research reports pertaining to the device and its use in diagnosing health or disease, together with cards, pamphlets and leaflets with similar titles and contents, all of which accompanied the device or were distributed in connection with it, were part of the "labeling" of the device. *Ellis Research Laboratories, Inc.,* DC Ill., FOOD DRUG COSMETIC LAW REPORTS ¶ 7660.

Products Liability.—Notwithstanding any arguments based on elimination of the requirement of privity of contract in other states as a condition on suits based on breach of an implied warranty, the courts in Delaware will continue to require a showing of privity in such product liability suits, the Delaware Supreme Court has held. The Court stated that an exception might be appropriate for poisonous or extraneous substances in food or beverages, but then noted the possibility that even then negligence liability might prove to be an adequate basis for relief. Accordingly, it held that a verdict was properly directed for a defendant bottling company, in a damage suit for injuries sustained when a bottle containing a carbonated beverage broke as it was being opened by the storekeeper purchaser's minor child. The Court also concluded that since the bottling company's testimony indicated that it had complied with all the usual procedures and safeguards in bottling, and there was no showing of what had happened to the bottle during the twenty or more hours that had elapsed from the time it had been delivered to plaintiff's store, there was no ground for inference of negligence by the bottling company. *Ciociola,* Del. Sup. Ct., FOOD DRUG COSMETIC LAW REPORTS ¶ 22,681.

Vol. 16, No. 7 July, 1961

Food·Drug·Cosmetic Law
Journal

Authority, Drugs and the Practice of Medicine

By ADRIEN L. RINGUETTE

The Author is an Attorney in the Office of the General Counsel, Abbott Laboratories, North Chicago, Illinois. In This Paper, He Makes a Case Against Vesting More Power in the Food and Drug Administration.

IN A LLOYD-ROBERTS LECTURE delivered in Manchester, England, not very long ago, an English physician described certain dangers which he felt were threatening the practice of medicine.[1] On the one hand he referred to internal matters of primary import to the medical profession. He indicated these stem from the rapidly increasing use of applied science in medicine and the corresponding tendency among physicians to neglect the practical and intellectual arts in medicine. The danger in this trend, he said, is the consequent treatment of the human person merely as a sort of complicated machine capable of summary in terms of electronics and biochemistry.

Perhaps related to but going beyond these internal matters, one of the other principal dangers to medicine he cited is authoritarian control of the practice of medicine by government. This external threat to medicine is a matter of concern to lawyers. The British physician made the point that there is a trend in England toward

[1] Dr. F. M. R. Walshe, "The Arts of Medicine and their Future," 2 *Lancet* 895 (1951).

central detailed direction and organization of the activities of physicians. A manifestation of this trend, he said, is "the progressive destruction of the Common Law of England, and its replacement by skeleton legislation and Ministerial regulations." The danger in this trend is its concomitant adverse effect on the art of medicine. He felt that a profession such as medicine, with its unique individual relationships and its quality as a combination of arts and applied science, can flourish only where "the State confines itself in general to creating conditions under which expert knowledge and initiative of individuals are given the widest scope and adequate support."

It is not our purpose to evaluate the law of England. Rather, the object of this paper is to consider whether or not there exists an external threat to the practice of medicine in the United States resulting from a trend towards detailed regulatory control of the development, production and use of drugs. In view of the increased importance and variety of drugs in the treatment and cure of illness,[2] the exercise of judgment as to their use in treatment is certainly an important part of medical practice. To the extent that the law substitutes the judgment of an administrative body for that of the physician on the use of drugs, this may be said to constitute an external threat to medicine.[3]

To a certain limited extent, power to determine the proper use of drugs is now being exercised by the Food and Drug Administration in accordance with its interpretations of the Federal Food, Drug, and Cosmetic Act, and amendments thereto.[4] A bill recently introduced in Congress, however, bearing the title "Drug Industry Antitrust

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[2] Somers, *Doctors, Patients, and Health Insurance* (1961), pp. 513-4, hereafter cited as *Somers*. The authors state: "From a role of relatively minor importance the drug industry has recently emerged as a major issue in medical care financing and organization. Drugs purchased directly by consumers (exclusive of those dispensed through hospitals, doctors' offices, industry medical plans, or government facilities) account for one-fifth of the nation's private medical bill. They are approaching doctors' fees and hospital charges in importance."

[3] Thus, Dr. Louis M. Orr, past president of the American Medical Association, stated in a recent symposium: "Because I as a physician must make the diagnosis, I feel that I must decide precisely what drug is to be prescribed for my patients. This is my responsibility in caring for my patients. Unless patients are willing to make someone else responsible for the results of therapeutic treatment, I do not wish to surrender my responsibility or to share it." "Freedom to Practice Good Medicine," 1 *Journal of the American Medical Association* 100 (1961).

[4] 52 Stat. 1040, approved June 25, 1938, as amended; 21 USC Sec. 301 and following. This statute will hereafter be referred to as the *FDC Act*.

Act,"[5] aside from its antitrust aspects,[6] would, if enacted, confer far-reaching additional powers upon the Food and Drug Administration and pose grave questions as to its effects upon the practice of medicine.

The discretionary powers which the proposed "Drug Industry Antitrust Act" would confer upon FDA[7] include the following: (1) power to determine standards of manufacture necessary to insure the continued chemical structure, strength, quality, purity, safety and efficacy of prescription drugs, and to issue and revoke licenses for prescription drug manufacturer;[8] (2) power to prohibit the marketing of new drugs not approved as efficacious for use;[9] (3) power to cause the withdrawal of drugs already on the market if found to be not efficacious in use;[10] (4) power to determine the "official name" of any drug in the interest of usefulness and simplicity,[11] which name

[5] S. 1552 (Kefauver) and H. R. 6245 (Celler), 87th Cong., 1st Sess., introduced April 12, 1951. These are identical bills, and are hereafter referred to as *Bill*.

[6] The bill is divided into three sections. Section 2 amends the Sherman Anti-Trust Act (26 Stat. 209, approved July 2, 1890, as amended; 15 USC Sec. 1 and following); Section 3 amends the Patent Code (66 Stat. 792, approved July 19, 1952, as amended; 35 USC Sec. 1 and following); and Section 4 amends the *FDC Act*.

[7] For ease of expression, we are taking the shortcut throughout this paper of substituting FDA wherever the statute confers powers on the "Secretary," meaning the Secretary of Health, Education, and Welfare. By virtue of delegation of authority, the FDA is responsible for exercising the functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act. Department of Health, Education, and Welfare, *Statement of Organization and Delegations of Authority*, issued March 24, 1955, Sec. 10.20, as amended.

[8] *Bill*, Sec. 4(13), adding new Sec. 508 to *FDC Act*. The term "prescription drug" as used in this paper refers to a drug limited by Sec. 503(b) of *FDC Act* to dispensing upon the prescription of a licensed practitioner. This includes certain habit-forming drugs, drugs not safe for use except under the supervision of a licensed practitioner, and drugs so limited under Sec. 505 of the statute. This term is closely related to the term "ethical drug," which means a drug primarily advertised to physicians and usually a prescription drug, but which may include some over-the-counter drugs. Ethical drug sales at manufacturers' level are approximately $2 billion, compared to $700 million in sale of non-ethical or proprietary drugs. Statement of Dr. Austin Smith, *Hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary*, U. S. Senate, 86th Cong., 2d Sess., pursuant to S. Res. 238, Part 19, Administered Prices in the Drug Industry, p. 10,721. *Note:* These hearings commenced in the 86th Cong., 1st Sess., pursuant to S. Res. 57 and cover Parts 14 through 26 (1959-60). Hereafter, they will be referred to as *Hearings on Administered Prices*.

[9] *Bill*, Secs. 4 (9) and (10), amending Secs. 505(c) and (d), respectively, of the *FDC Act*.

[10] *Bill* Sec. 4(11), amending Sec. 505(e) of the *FDC Act;* and *Bill*, Sec. 4(1), amending Sec. 201(p)(1) of the law.

[11] *Bill*, Sec. 4(13), adding new Sec. 509 to *FDC Act*.

must appear with specified prominence on the label of the drug as well as in all advertising;[12] (5) power to determine warnings which must be included in all advertising pertaining to a drug,[13] and to prepare and disseminate a list of dangerous drugs, including therein such information relating to the dangerous or harmful effects of those drugs as may be considered in the best interest of the public health;[14] and (6) power to determine whether or not the therapeutic effect of certain drugs is significantly greater than that of related drugs, an affirmative finding being a necessary prerequisite to the patentability of such drugs.[15] In addition to these discretionary powers, the bill would provide FDA with certain controls over the promotion and advertising of drugs and to the dissemination of scientific information at purely scientific meetings and in purely scientific journals.[16]

In considering the regulation of the drugs industry, and its impact on the medical profession, we will examine this proposed legislation from a practical, rather than a constitutional, approach. Thus, one object of this paper is to evaluate the selectiveness of the provisions of the bill to remedy problems existing in the drug industry in the light of broad public welfare concepts. To do this, we must first review public policy in drug regulation and in the regulation of the practice of medicine.

Historic Limitations in Regulation of Drugs

Historically, regulation of availability and use of drugs has not been the subject of federal regulation. Instead, Congress has defined in the basic statute itself certain dangerous or misleading practices and has made such conduct illegal. FDA has been given certain

[12] *Bill,* Secs. 4(4), amending Sec. 502 (b) of he *FDC Act; Bill,* Sec. 4(5), amending Sec. 502(e) of the law; and *Bill,* Sec. 4(7), adding new Sec. 502(m) to the law.

[13] *Bill,* Sec. 4(7), at new Sec. 502(m) (2)(B) of the *FDC Act.*

[14] *Bill,* Sec. 4(13), adding new Sec. 510 to *FDC Act.*

[15] *Bill,* Sec. 3(b), amending Sec. 101 of the Patent Code. Actually, the bill applies to "any molecular modification or other modification of any patented or unpatented drug or for a combination of two or more drugs." The section applies to human prescription drugs.

[16] *Bill,* Sec. 4(7), adding new Sec. 502(m) to *FDC Act.* A scientific meeting would be within FDA's jurisdiction when a presentation is made on behalf of a drug manufacturer discussing any product of that manufacturer. Section 502(m)(2) would apply to "all advertisements and other descriptive printed matter" issued on behalf of the drug manufacturer, and the term "advertisements" includes "all forms of advertising, whether transmitted directly to physicians, published in medical journals or other media, and whether in printed or oral form."

regulatory and enforcement powers, but in general, Congress has relied upon the drug industry to comply with the statutory standards, and the FDA must resort to the courts and prove that the offending drug merchant has adulterated or misbranded his merchandise. On its face, the law does not provide for administrative control of the production and use of drugs.[17]

Our federal drug law is in fact grounded upon the prevention of fraud and unfair competition, and was drawn in accordance with the principle of prohibiting wrongful conduct in business and otherwise leaving it free.[18] Thus, it was not intended to impose "on honest industrial enterprise" any hardship "which is unnecessary or unjustified in the public interest." [19]

On more than one occasion Congress has resisted major efforts to alter this basic concept of the law. For example, such an effort

[17] See the following statement at Dunn, "Our Food, and Drug Law with Some Observations on its Major Statute," 9 FOOD DRUG COSMETIC LAW JOURNAL 383, 394 (1954): "The fourth trend is a growing FDA disposition to transform the 1938 Act into a government permission control one, to a basic extent. This trend should be approached from the standpoint that the Act has been designed, since its 1906 inception, to express the legislative philosophy of free institutions in their application to private industry. It is the philsophy of objectively regulating the conduct of such industry as required by the public interest, to prevent what is injuriously wrong and to command what is beneficially right; whereby its members are otherwise normally left free to achieve the economic success won in a competitive order, by their individual business efficiency and public service. An exception to this philosophy, for the substitution of a government permission control over private industry, is only justified to the extent it is unavoidably essential to assure the public safety."

[18] In his review of the first ten years under the Federal Food and Drugs Act of 1906, Dr. Carl L. Alsberg, Chief of the Bureau of Chemistry, said: "The Food and Drug Act was among the first of that group of laws which today would be classed as laws, for the prevention of unfair competition. The suppression of fraud upon the consumer and of unfair competition among business rivals are but the two faces of the same coin." Reported in Food Law Institute Series, *Federal Food, Drug and Cosmetic Law Administrative Reports,* 1907-1949, p. 367. See, also, Dunn, "Original Federal Food and Drugs Act of June 30, 1906 as Amended—Its Legislative History, 1 FOOD DRUG COSMETIC LAW QUARTERLY 297; Hoge, "The Drug Law in Historical Perspective," 1 FOOD DRUG COSMETIC LAW QUARTERLY 48 (1946). Like the 1906 Act, the 1938 Act is also firmly grounded in a system of private enterprise. Hoge, "The Federal Food, Drug and Cosmetic Act and the Drug Industry," 3 FOOD DRUG COSMETIC LAW QUARTERLY 178 (1948); Kleinfeld. "Legislative History of the Federal Food, Drug and Cosmetic Act, 1 FOOD DRUG COSMETIC LAW QUARTERLY 532 (1946).

[19] Senate Committee on Commerce, reporting S. 5, later enacted with some amendments as the 1938 Act. Dunn, *Federal Food, Drug and Cosmetic Act* (1938), p. 687, quoting from S. Rep. No. 152, 75th Cong., 1st Sess., March 8, 1937.

was made when Congress began consideration of revising the original Food and Drugs Act of 1906.[20] The first measure leading to passage of the Federal Food, Drug, and Cosmetic Act of 1938 was the Tugwell bill, introduced in 1933.[21] This bill would have conferred extensive discretionary powers upon the FDA, including authority to determine conditions of manufacture, to issue permits, to designate drugs as narcotics or hypnotics, and to designate diseases wherein self-medication may be especially dangerous.[22] These provisions were subjected to extensive criticism on the ground, among others, that they permitted control over the use of drugs.[23] They were omitted prior to enactment in 1938.[24]

As enacted, the FDC Act was principally directed, as was its predecessor, to the prohibition of the interstate shipment of adulterated or misbranded drugs.[25] Its main impact was to considerably enlarge the definitions of adulteration and misbranding, but this was largely done, as before, by objective standards set forth in the law itself. While the statute was not free from provisions conferring administrative powers upon the FDA,[26] none of these provisions was contemporaneously construed as enabling the FDA to determine which drugs should be available or the proper use of such drugs.[27]

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[20] 34 Stat. 768, approved June 30, 1906.

[21] S. 1944, 73rd Cong., 1st Sess., introduced by Senator Copeland on June 12, 1933. The movement for revision of the Federal Food and Drugs Act of 1906 was initiated by Rexford G. Tugwell, then Assistant Secretary of Agriculture, and the bill became known by his name. Cavers, "The Food, Drug and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions," 6 *Law and Contemporary Problems* 2 (1939).

[22] S. 1944, Secs. 12(a), 12(b), 8(b) and 9(c). The Tugwell bill may be found at Dunn, cited at footnote 19, at pp. 37-50.

[23] Cavers, cited at footnote 21, pp. 8-9.

[24] For a description of the changes wrought between the introduction of the Tugwell bill and the enactment of the *FDC Act*, see Cavers, cited at footnote 21, at pp. 22-25, 31-40.

[25] Sec. 301(a). Violations are subject to injunction proceedings in Federal district courts (Sec. 302), and criminal action (Sec. 303). The violative merchandise may be seized (Sec. 304). For purposes of effective enforcement, factory inspection is authorized (Sec. 704).

[26] Chief among these were: power to list coal-tar colors which are harmless and suitable for use in drugs and to certify batches of such colors, Sec. 504 (replaced by the Color Additive Amendments of 1960, 74 Stat. 397, approved July 12, 1960); and power to review the evidence of safety of new drugs prior to the marketing thereof, and under certain circumstances to prevent the marketing of such drugs on grounds related to safety, Sec. 505.

[27] For example, the following statement by FDA contained in an informal opinion dated March 14, 1940, is typical of the contemporary attitude: "The responsibility for determining whether or not any particular drug is 'dangerous,' as that term is used in Section 502(j) must rest upon the manufacturer and

Another major effort to alter the basic concept of the drug law was made when Congress in 1951 enacted the prescription drug amendment to the FDC Act.[28] Among other things, this amendment, commonly known as the Durham-Humphrey law, contains a definition of drugs which can legally be dispensed solely upon the prescription of a licensed physician.[29] This definition thus classifies drugs into two categories: those which may be sold over the counter and those which must be dispensed on prescription. Drugs in the latter category are misbranded if sold by the manufacturer without a label containing the statutory prescription legend, but the judgment as to whether a drug belongs in one or the other category rests initially with the medical profession and the drug manufacturer, subject to the traditional methods of enforcement of the law in the case of noncompliance.[30]

Significantly, the Durham-Humphrey law was not enacted in the form in which it was presented to Congress and endorsed by the FDA. As proposed, the bill would have conferred upon the FDA the power to make the decision as to which drugs are unsafe

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(*Footnote 27 continued*)
distributor. The Administration, while it has given a few examples of what it regards as dangerous drugs, when they are indiscriminately distributed, has not undertaken to bear the burden of determining in all instances whether or not drugs are too dangerous for use except under professional guidance. The Administration has no intention of assuming this burden." TC-165, Kleinfeld and Dunn, *Federal Food, Drug and Cosmetic Act—Judicial and Administrative Record 1938-1949*, p. 634. That FDA was essentially regarded as a "police" agency, see Fuchs, "The Formulation and Review of Regulations under the Food, Drug and Cosmetic Act," 6 *Law and Contemporary Problems* 43 (1939).

[28] 65 Stat. 648, approved October 26, 1951, amending Sec. 503(b) of the *FDC Act*. See footnote 8 for the definition of prescription drugs.

[29] The history of the Durham-Humphrey legislation is fully described in the following articles: Wheeler, "Prescription Refills," 5 FOOD DRUG COSMETIC LAW JOURNAL 746 (1950); Crawford, "The Federal Drug Law and the Druggist," 5 FOOD DRUG COSMETIC LAW JOURNAL 312 (1950); Hoge, *"The Durham-Humphrey Bill,"* 6 FOOD DRUG COSMETIC LAW JOURNAL 135 (1951); Dunn, "The New Prescription Drug Law," 6 FOOD DRUG COSMETIC LAW JOURNAL 951 (1951). Pressure for the amendment was generated following the announcement by the Commissioner of Food and Drugs of a new administrative policy limiting the widespread practice by pharmacists of refilling prescriptions without specific approval.

[30] For traditional methods of enforcement, see footnote 25. However, by regulation, FDA must approve removal of a prescription drug from prescription dispensing requirements. 21 CFR Sec. 130.101, adopted November 13, 1954, at 19 *Federal Register* 7347. This rule applies to drugs originally marketed under the new drug section of *FDC Act* (Sec. 505). For discussion, see Kleinfeld, "New Drugs and the Durham-Humphrey Amendment," 12 FOOD DRUG COSMETIC LAW JOURNAL 617 (1957).

or ineffective for use without the supervision of a physician. After considerable debate, Congress struck this administrative power out of the bill, and also deleted the reference in the bill to efficacy as a factor to consider in the definition of prescription drugs.

Testimony on behalf of the medical profession indicated that the delegation of authority to an agency to decide which drugs must be sold only on prescription is "extremely dangerous and wholly unwarranted." The basis for this opinion was that delegation to an administrative agency of the power to determine the therapeutic value of drugs "will result in unnecessary and undesirable control of the practice of pharmacy and the practice of medicine." This power was considered to be "a traditional and time-tested function of the medical profession." [31]

Despite this legislative record, there has been some expansion of the discretionary powers of the FDA since 1938. Some of this has occurred by virtue of certain amendments to the Act granting additional authority to that agency. Most important among these are the antibiotic amendments.[32] Prompted by uncertainties in the fermentation process, Congress provided for FDA certification of indi-

[31] Testimony of Dr. Martin, *Hearings Before the Subcommittee on Health of the Committee on Labor and Public Welfare*, U. S. Senate, 82d Cong., 1st Sess., on S. 1186 and H. R. 3298, September 13, 1951, pp. 212-3. Typical of the industry objection was the testimony of Mr. Paul Gerden, *Hearings Before the Committee on Interstate and Foreign Commerce*, House of Representatives, 82d Cong., 1st Sess., on H. R. 3298 (1951), at p. 187. Mr. Gerden testified in part: "Our third objection is that this provision is basically unsound and appears to constitute a substantial step toward the Government control of medical practice. This provision reverses the philosophy of the present law in that it transfers the primary responsibility of determining which drugs are to be available for self-medication and which drugs are to be used under medical supervision from the medical profession and the drug manufacturer to the Government. The determination as to the availability of drugs for self-medication should be continued as in the past, for by what reasoning can it be said that the decision of an administrative body as to the availability of self-medication should be substituted for the determination of this factor by the medical profession?" See also Hoge, "Major Drug Law Problem," 6 FOOD DRUG COSMETIC LAW JOURNAL 933 (1951); and Clutter, "Federal Control—A Problem in the Drug Industry," 6 *Food Drug Cosmetic Law Journal* 936 (1951).

[32] Penicillin: 59 Stat. 463, approved July 6, 1945; streptomycin: 61 Stat. 11, approved March 10, 1947; chlortetracycline, chloramphenicol and bacitracin: 63 Stat. 409, approved July 13, 1949, as amended by 67 Stat. 389, approved August 5, 1953. These amendments added Secs. 502(1) and 507 to *FDC Act*.

vidual batches of any drug composed wholly or partly of any kind of certain antibiotics prior to the distribution of such drug.[33]

The amendments empower the FDA to promulgate regulations prescribing those characteristics of identity, strength, quality and purity of the listed antibiotics as necessary to adequately insure safety and efficacy of use. It does not appear that this provision was thought to confer upon the FDA jurisdiction to determine the efficacy of these drugs. These antibiotics are clearly efficacious, and the purpose of the law as revealed in its legislative history was the standardization of production. Accordingly, the law was advocated as a temporary measure, and a provision was inserted authorizing the exemption of any drug or class of drugs from the requirements of certification.[34]

Nevertheless, the FDA has construed the law as giving to that agency the responsibility to "insure safety and efficacy of use" of

[33] A detailed account of the history and background of antibiotic legislation is provided by Powers, "Some Aspects of Certification of Antibiotics under the Federal Food, Drug and Cosmetic Act," 4 FOOD DRUG COSMETIC LAW QUARTERLY 337 (1949), who states at p. 340: "Penicillin was not only a new drug in a new field, but one which had been rushed through normal laboratory and pilot plant stages of development because of the urgency of war. In 1943, when it was first made available to our Armed Forces, little was known of its chemical structure. Its stability was questionable, its properties varying almost from batch to batch, and, most important, there was no well-established and completely reliable method for its assay. Its original use was by parenteral administration principally in life and death cases. These circumstances required, in the opinion of many, that unusual control be maintained."

[34] FDA recommended the antibiotics section as a temporary measure. See, for example, letter from Watson B. Miller, Acting Administrator, dated May 15, 1945, to Hon. Sam Rayburn, reported in H. Rep. No. 702, 79th Cong., 1st Sess., June 7, 1945. The foregoing House report stated: "Section 507(c) directs the Administrator to promulgate regulations discontinuing the requirement for certification when, in his judgment, the certification procedure is no longer necessary to insure the safety and efficacy of any drug subject to this section. A primary reason for the type of control proposed by this bill is the fact that penicillin is produced by a biological process and is subject to the vagaries inherent in all such processes. Furthermore, the potency of penicillin is determined by biological assay, which itself must be carefully controlled and checked in order to insure its accuracy. Because of the newness of penicillin and the new products that will be made from it, it is impossible to forecast what developments may occur in manufacturing technology or otherwise that may render the need for this special type of control unnecessary with respect to particular drugs. If such developments occur, this provision will permit the issuance of a regulation exempting any such drug from certification requirements and the drug will then be subject only to the general provisions of the law."

the antibiotic drugs covered therein.[35] Virtually absolute discretionary powers over the production and use of these antibiotic drugs are therefore being exercised by the FDA.[36] Few drugs have been exempted from these controls, despite the solution of the production problems that caused the antibiotic amendments in the first place.[37]

An example of the FDA's assumption of responsibility for control of the use of drugs subject to the antibiotic law is the case of the antibiotic chloramphenicol, originally marketed in 1949.[38] It is a highly potent and effective therapeutic agent and is useful for certain infections not susceptible of treatment with other drugs. Neverthe-

[35] Crawford, "Legislative and Administrative Progress under the Federal Food, Drug and Cosmestic Act," 5 FOOD DRUG COSMETIC LAW JOURNAL 16, 22-4 (1950).

[36] See Gerden, "A Further Review of the Antibiotic Law," 9 FOOD DRUG COSMETIC LAW JOURNAL 710 (1954).

[37] Statistics compiled from data furnished by FDA have indicated that batch certification serves no useful purpose. In fact, numerous antibiotics recently placed on the market and not covered by the antibiotic law have been subject to the general provisions of the *FDC Act* without FDA batch certification and without undue consequences. Furthermore, FDA has adopted the policy of issuing regulations under the antibiotic law which continue the controls by FDA over the marketing of certain antibiotic drugs but exempting them from batch certification. For example, 21 CFR Sec. 146.25. Accordingly, the retention of regulation under the antibiotic law "represents a situation wherein extreme controls are continued though the reasons therefor have disappeared." Gerden, cited at footnote 36, at p. 719. FDA declined to exempt drugs from these controls pursuant to Sec. 507(c) of the *FDC Act* on the ground that agency was responsible under the antibiotic law to "insure safety and efficacy of use." Yet, as recently as 1950, the FDA thought that certification should neither be permanent nor widely extended. Thus, Commissioner Crawford stated: "The statement of what we think Section 507(c) means should not be taken as what we think the section ought to be. We think the section should be changed because we do not believe that once a firm operates under certification it should necessarily do so for all time. Nor do we think that certification should be widely extended; it would be wholly impracticable and unnecessary to apply certification to drugs generally. But we cannot escape the fact that these important antibiotics are widely used in cases of serious and often fatal illness; that if they are in fact what they purport to be they will surely save the lives of hosts of people, whereas if they are not there will be many needless deaths." Crawford cited at footnote 35, at p. 24. This position should be contrasted with the position FDA now takes, which is to extend the controls provided in the antibiotic law to all antibiotics. See S. 3815, 86th Congress, 2d Sess., introduced by Senator Hill on July 2, 1960, Sec. 5. This was an administration bill, which died in committee.

[38] This product was the subject of much testimony in the *Hearings on Administered Prices*. See, particularly, the testimony of Harry J. Loynd, president of Parke, Davis & Company, sole producer of the drug, which is marketed under the trade name Chloromycetin, at Part 24, pp. 13,957-14,091 (September 12-13, 1960); and the testimonty of Dr. Maxwell Finland, of Harvard Medical School, at Part 24, pp. 13,928-13,929, and pp. 13,945-13,957 (September 12, 1960).

less, when reports of blood disorders attributed to chloramphenicol were received, the FDA surveyed case records in hospitals and clinics, and requested that the information be evaluated by the National Research Council. The National Research Council reported that the label of the drug should contain a warning against indiscriminate use or for minor infections. Thereupon the FDA announced it "has weighed the value of the drug against its capabilities for causing harm and has decided that it should continue to be available for careful use by the medical profession." Certain labeling statements were prescribed by the FDA. This action occurred in 1952.[39]

Thereafter, on April 30, 1960, a report of the Council on Drugs of the American Medical Association was published, indicating the existence of additional reports of blood disorders associated with administration of chloramphenicol and the use of the drug by physicians (despite repeated warnings given by the manufacturer) for minor infections.[40] Again, the FDA consulted the National Research Council, this time specifically asking for an opinion, among other things, on whether chloramphenicol should be "allowed to remain on the market," considering the availability of antibiotics which were not on the market in 1952.[41] Upon receipt of an affirmative reply, the FDA announced its agreement that the drug should remain on the market.[42]

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[39] See letter dated August 7, 1952 from NRC to FDA printed as Exh. 79 in *Hearings on Administered Prices*, Part 26, p. 15,833; and press release of Federal Security Agency dated August 14, 1952, printed as Exh. 80 in *Hearings on Administered Prices*, Part 26, p. 15,834.

[40] Council on Drugs, *Blood Dyscrasias Associated With Chloramphenicol (Chloromycetin) Therapy*, published in Journal of the Medical Association, April 30, 1960, and printed as Exh. 81 in *Hearings on Administered Prices*, Part 26, p. 15,837.

[41] Letter dated November 28, 1960 from FDA to NRC, printed in *FDC Reports*, January 30, 1961. The NRC was also asked to consider whether or not the use of the drug should be restricted to hospital cases, and the matter of warnings and other pertinent information necessary "in order to insure proper use of the drug."

[42] Press Release of FDA, dated January 26, 1961, enclosing letter from NRC to FDA dated January 11, 1961. The following statement on the responsibility for educating the physician appeared in the NRC letter: "A knowledge of the untoward side effects that may occur with this drug should be adequately known to all prescribers. The information should be disseminated as a warning on the drug label and elaborated in an enclosure in the drug package. Beyond this, there is need for the continuing education of the physician through the media of medical meetings and the medical literature. *This, of course, is a responsibility of the leaders of medicine and not of the Food and Drug Administration.*" (Italics supplied.)

This case is one of several under the antibiotic provisions and the new drug section in the law which have been reported in the trade press as exemplifying the policy of the FDA to evaluate the potential benefits of a drug against the risks inherent in its use. It is similarly reported that this policy involves comparisons between older and newer drugs, raising basic questions in medical research, education and practice, and resulting in the withdrawal of several drugs from the market.[43]

Under the new drug section of the FDC Act,[44] the FDA has come to regard efficacy and safety as inextricably integrated. It is felt that the maximum of safety is attained when the value of the drug for therapy is weighed against "the possible toxic effects of this same drug as well as against risk and effectiveness of other agents which might be available." [45]

The new drug section was not conceived as a licensing statute, but was "intended merely to prevent the premature marketing of new drugs not properly tested for safety." [46] Prior to marketing a new drug, the manufacturer must file with the FDA, among other information, full reports of investigations which have been made to show whether or not such drug is safe for use. After a specified period of time he may market the drug unless the FDA has issued an order containing a finding to the effect that safety of the drug has not been demonstrated. It has become apparent, however, that the power to pass upon safety has enabled the FDA to exercise some discretion as to the use of new drugs. This power extends beyond the initial marketing of such drugs, since the FDA can cause withdrawal of a new drug from the market if clinical experience shows that the drug is unsafe for use.[47]

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[43] See *Drug Research Reports*, February 8, 1961, pp. 8-13.

[44] Sec. 505; new drug defined, Sec. 201(p).

[45] Nelson, "Twelve Years of the New Drug Section," 6 FOOD DRUG COSMETIC LAW JOURNAL 344, 350 (1951). See also Nelson, "New Drug Requirements of the Federal Food, Drug and Cosmetic Act, 4 FOOD DRUG COSMETIC LAW JOURNAL 227, 229-31 (1949).

[46] H. Rept. No. 2139, 75th Cong., 3d Sess., April 14, 1938. The House Committee also said: "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." For other references to the legislative history, see Jurow, "The 'New Drug' Law of the Federal Food, Drug and Cosmetic Act," 10 FOOD DRUG COSMETIC LAW JOURNAL 611 (1955).

[47] It should be noted that the degree of control exercised by FDA over new drugs has been accomplished primarily through refinement of administrative techniques. Originally, its policy to evaluate efficacy was limited to drugs

Among the products which have been withdrawn from the market recently as a result of the exercise by the FDA of responsibility for the use of drugs are the anti-depressant drug iproniazid [48] and iron-dextran complex, a preparation of iron for intramuscular injection.[49] In neither case was it necessary for the FDA to resort to legal action. But it has been reported that in both cases the likelihood of legal action was a factor in the withdrawal of the products. Yet there is evidence that these drugs remain valuable medicines, despite the risk of side effects, in those situations where substitute medications are not satisfactory. Therefore, these actions raise serious questions about the use of administrative power to interfere with the judgment

(Footnote 47 continued)
offered for serious diseases. If they exhibited toxic properties but were not efficacious for such diseases they were considered unsafe. Herrick, *New Drugs* (1946), pp. 78-79. Today, the comparing of benefits to risks appears to have become a regular factor to consider. See *FDC Reports,* March 6, 1961, p. 19. One administrative technique which has increased the effective power of FDA is to require each manufacturer of a new drug to submit the same kind and amount of data on the drug, irrespective of information submitted by others establishing the safety of the product. See Duckworth, "Some Drug Observations on the Federal Food, Drug and Cosmetic Act," 12 FOOD DRUG COSMETIC LAW JOURNAL 300, 304 (1957). A measure of continuous control of the distribution of new drugs is obtained by the recently issued regulation substantially controlling the information which may be disseminated by a drug manufacturer to physicians after the new drug has once been marketed. 21 CFR 130.4(c)(9), and 130.9(a), as amended at 25 *Federal Register* 12,592 (December 9, 1960).

[48] Iproniazid was formerly marketed by Hoffman-LaRoche, Inc., under the trade name Marsilid. Originally offered for use in the treatment of tuberculosis, in 1957 it was also labeled for use in mental illness associated with depression. Since 1958 there have been reports of liver damage associated with the use of this drug. The incidence of liver disease is apparently very low, and as recently as January 1959, the FDA was of the opinion that the drug should be kept available for use by physicians. However, it has been reported that the availability of other anti-depressant agents has caused FDA to alter its opinion, and voluntary withdrawal of the product followed. See *FDC Reports,* January 30, 1961, p. 22. See also testimony of Dr. Hans Popper, of Mt. Sinai Hospital, *Hearings on Administered Prices,* Part 18, at pp. 10,351-10,363; and letter by FDA dated January 16, 1959, printed in *Hearings on Administered Prices,* Part 18, p. 10,579.

[49] Iron-dextran complex was formerly marketed by Lakeside Laboratories under the trade name Imferon. It has been commercially available in the United States since 1957, until its withdrawal in 1960 under threat of legal action by FDA. Although serious side-effects have been rare despite extensive use, its withdrawal was prompted by reports that repeated injections of large doses of the drug in mice and rats could produce cancer in those animals. However, this species has been found to be especially susceptible to the development of local cancer after injection of a variety of substances not causing malignancy in other animals. See Council on Drugs, "New Drugs and Developments in Therapeutics," 175 Journal of American Medical Association 388 (February 4, 1961).

of physicians in the exercise of their responsibility for the treatment of their patients.

Thus, the Council on Drugs of the American Medical Association has deplored the withdrawal of iron-dextran complex, stating in part: [50]

> Second, the withdrawal of iron-dextran complex deprives the physician of a useful drug, since, in some situations, parenteral administration of iron is preferable to oral administration. To the Council, the use of iron-dextran complex does not appear to be attended by any greater hazard than do the administration of the injectable forms of iron and the transfusions which physicians are now obliged to use as substitutes.

A recent editorial in the *New England Journal of Medicine* [51] indicated that most physicians who have used iron dextran have found it to be a "reasonably safe, highly effective agent," and when used as directed "there are few untoward effects." It was further indicated that the removal of this drug from general clinical use actually increased "the hazard of treating a patient with parenteral iron therapy." The editorial further stated:

> There is a distinct danger in giving any committee, no matter how excellent its individual members, the power to decide on whether an agent is therapeutically useful and to decide whether it should be made available to the practicing physician.

To some extent, the FDA has indicated a disposition to exercise responsibility for the use of drugs in the enforcement of the misbranding provisions of the FDC Act. Among other things, the statute prohibits labeling which is false or misleading in any particular,[52] requires labeling to bear adequate directions for use and adequate warnings,[53] and prohibits the marketing of articles which

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[50] See footnote 49.

[51] "Iron-Dextran and Sarcoma," 264 *New England Journal of Medicine* 886 (April 27, 1961).

[52] Sec. 502(a).

[53] Sec. 502(f). One administrative technique by which FDA has assumed considerable authority over the dissemination of information to physicians about prescription drugs has been to take advantage of a power conferred by Sec. 502(f)(1) to exempt any drug from the requirements of adequate directions for use if such requirements are not necessary for the protection of the public health. In the case of prescription drugs, FDA has construed the statute to the effect that adequate directions *for the lay person* cannot be written, and that therefore prescription drugs are misbranded unless marketed pursuant to *conditions* contained in regulations purporting to exempt such drugs from the requirements of adequate directions for use. Under regulations recently issued, FDA has assumed responsibility for prescribing the information which may be disseminated by manufacturers directly to physicians. 25 *Federal Register* 12,592 (December 9, 1960), as amended 26 *Federal Register* 294 (January 14, 1961), amending 21 CFR Sec. 1.106(b). The announced purpose of the revised regulations was "to assure that physicians receive adequate information about the drugs they prescribe." Press Release, July 22,

are dangerous to health when used as directed.[54] These provisions are clearly aimed at the labeling of drugs and not their availability to the medical profession.[55] In fact, the FDA itself issued the following statement of informal policy in 1940:[56]

> The Food, Drug, and Cosmetic Act was not designed to regulate medical practice and this Administration will not undertake legal action against harmless products which physicians desire to use as medicaments even though there is no scientific evidence that they are of any value whatever.

Yet, in more recent times legal action has been undertaken or threatened against harmless products or particular uses of harmless products, where the evidence supporting their use is not considered by the FDA to be "scientific."[57]

(Footnote 53 continued)
1960. Yet this is not a responsibility expressly conferred upon FDA. The regulations may even be interpreted to limit the distribution to physicians of reprints of informative scientific articles, since the term "labeling," used in the FDC Act, is now construed to include any mailing or promotional piece mailed or delivered to physicians. 21 CFR Sec. 130.4(c)(9) and Sec. 130.9, as amended at 25 *Federal Register* 12,592 (December 9, 1960). "Labeling" is defined in Sec. 201(m), and has never been judicially construed as broadly as this. Advertising of drugs, of course, is under the jurisdiction of the Federal Trade Commission, pursuant to the provisions of the Federal Trade Commission Act. 38 Stat. 717, approved September 26, 1914, as amended; 15 USC Sec. 41 and following. That statute prohibits false or misleading advertising. Secs. 5, 12.

[54] Sec. 502(j).

[55] See H. Rept. No. 2139, 75th Cong., 3d Sess., April 14, 1938, printed in Dunn, *Federal Food, Drug and Cosmetic Act* (1938), p. 815, 821-2. For excellent discussions and background see Wheeler, "Interference with the Practice of Medicine Under the Food, Drug and Cosmetic Act," 3 FOOD DRUG COSMETIC LAW QUARTERLY 364 (1948); Williams, "Exemption from the Requirement of Adequate Directions for Use," 2 FOOD DRUG COSMETIC LAW QUARTERLY 155 (1947); and Elson, "The Expanded Meaning of 'Adequate Directions for Use'", 7 FOOD DRUG COSMETIC LAW JOURNAL 743 (1952). The framers of the law were careful not to interfere with the practice of medicine by prohibiting claims where medical opinion differed. *H. Rept. No. 2139.* Senator Copeland stated: "Not only do the various schools of medicine differ in their valuation of remedies, but physicians of the same school are frequently at variance in their estimation of the same agents and if a large number of textbooks on thereapeutics are compared, scarcely any two of them will be found to be in complete agreement as to the therapeutic usefulness of identical drugs." Quoted by Wheeler, at p. 370.

[56] TC-343, December 13, 1940, Kleinfeld and Dunn, *Federal Food Drug and Cosmetic Act—Judicial and Administrative Record 1938-1949,* p. 704. Henceforth, this volume will be cited as *Kleinfeld and Dunn.*

[57] It appears that the FDA policy evolved with the case of so-called "inert" glandular materials. In 1941, FDA announced that such products should labeled to the effect that they do not contain any known therapeutically useful constituent of the gland or glands mentioned. TC-376, December 10, 1941, *Kleinfeld and Dunn,* p. 721. In 1945, FDA stated they would be considered misbranded if sold over-the-counter as drugs. TC-430, June 27, 1945, *Kleinfeld*

(Continued on following page)

One example is the current FDA enforcement program relating to vitamin B_{12} preparations.[58] These are prescription drugs not subject to the new drug section because of their recognized safety. They are used by many physicians as adjunctive therapy in a number of conditions in addition to those for which efficacy has been demonstrated to the satisfaction of the FDA. There are many reports by physicians in the scientific literature attesting to the value of the drug for their patients, but the FDA contends that in the absence of controlled clinical studies all reference to these reports and these conditions, however fairly summarized and qualified, must be deleted from the labeling of the drug. The FDA has informed manufacturers that in the opinion of its medical advisers, vitamin B_{12} should be offered and its labeling indicate its usefulness only for certain stated conditions.

In view of administrative developments since 1938, the real question posed by the proposed "Drug Industry Antitrust Act" is whether or not the basic drug law should be amended to place such developments on a sound legal footing and further extend them. In order to put this question in perspective, however, it is necessary to examine an underlying premise supporting the structure of the drug law as embodied in the 1938 Act. This brings us to the subject of freedom in medical practice.

Freedom in Medical Practice

The public policy historically applicable to medicine in this country has been to preserve substantial freedom in medical practice. This means, among other things, noninterference by government in medical controversies as between different schools of medicine. It also means that government should refrain from specifying the kind of remedy or treatment to be given to any person for his particular ailment.

(Footnote 57 continued)
and Dunn, p. 747. Finally, in 1948, FDA issued a statement of policy that they would be considered misbranded if distributed in any manner as drugs. 21 CFR Sec. 3.3, published at 13 *Federal Register* 1406, March 12, 1948. The legal argument of FDA is that the requirement of adequate directions for use includes a statement of the conditions for which a drug is to be used, but any statement offering a worthless article as a drug is considered to be false or misleading within the meaning of Sec. 302(a). The application of this doctrine to properly qualified labeling for a drug whose worth is genuinely in dispute is of doubtful validity.

[58] See *FDC Reports* for July 11, 1960, p. 19; August 22, 1960, p. 23; February 20, 1961, p. 30; March 13, 1961, p. 27; May 29, 1961, p. 25.

These matters should be left to "the direction of the patient and the discretion and wisdom of the individual doctor." [59]

Essential to the effectuation of this policy is the principle that there should be no interference by government with the prescribing by the doctor of any drug which in his opinion is necessary for the treatment of his patients. The principle of noninterference in prescribing was recently reviewed in England by a special committee to consider the cost of prescribing under the National Health Service Act. The report of this committee indicates that it would not be in the public interest to depart from this principle. This report states: [60]

> 181. The National Health Service Act, 1946 provides for the supply of "proper and sufficient drugs and medicines" and it is a doctor's duty by regulations made under the Act to prescribe whatever drugs are required for the proper treatment of his patients. The principle that there should be no absolute restriction on the prescribing by a general practitioner of any drug which in his opinion was necessary for the treatment of his patients was expounded by the Joint Committee on Prescribing. It has been accepted by Parliament and whatever guidance has been issued by the Ministry to help doctors with their prescribing has been in the nature of advice only.

The committee considered proposals suggesting that one means of reducing the size of the drug bill would be to impose some form of limitation on the doctor's present right to prescribe. In rejecting these proposals, the committee said: [61]

> 198. The clinical and academic freedom of the general practitioner must be maintained. The loss of self-respect consequent on any departure from the principle, which has been accepted as fundamental to the National Health Service in this country, that a doctor can prescribe any drug which he considers necessary for his patients, would lower the status of the profession and ultimately have an adverse effect on the whole medical service provided for the patient. The doctor must be the sole judge of his patient's requirements for treatment.

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[59] Kelly, *Regulation of Physicians by Law* (1925), p. 22-4. In fact, the legislature cannot constitutionally restrict healing under licensing statutes to any particular school of thought or practice. "Physicians and Surgeons," 41 *American Jurisprudence* Sec. 18. Some of the factors which have led to the formulation of this policy include differences of opinion as to the remedy or kind of treatment that will be effective in particular cases and changes in knowledge and teaching as to the treatment of diseases. The concern of the state is not with methods of treating diseases but with the occupation of healing the sick and ultimately for the creation of a body of physicians competent to pursue that occupation. "In fact the state's object always has been in these matters to avoid 'establishing criteria in regions where opinions are far apart.' (Mr. Justice Holmes in *U. S. v. Johnson*, 221 U. S. 488.)" *Kelly*, p. 23.

[60] Ministry of Health, *Final Report of the Committee on Cost of Prescribing* (1959), p. 57.

[61] Work cited at footnote 60, at pp. 62-63.

In the United States, the principle has most recently been enunciated by Dr. Hugh H. Hussey, Jr., Chairman of the Board of Trustees of the American Medical Association. He stated, on behalf of the AMA, as follows:[62]

> A physician is trained during his many years in medical school, internship and residency, and continuously learns after he enters into the practice of medicine, to use his professional judgment in determining what particular drug is best for a particular patient suffering from a particular disease or condition. We believe that only the physician has the knowledge, ability and the responsibility to make that decision in regard to that particular patient and that he should not be deprived of the use of drugs that he believes are medically indicated for his patient by a governmental ruling or decision. This would be the resulting situation, in our opinion, if these proposed amendments were enacted into law. Medical history and experience clearly demonstrate that the only possible final determination as to the efficacy and ultimate use of a drug is the extensive clinical use of that drug by large numbers of the medical profession over a long period of time.

Dr. Hussey, testifying before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U. S. Senate, opposed portions of the proposed "Drug Industry Antitrust Act." He concluded:[63]

> Even with the vast information resources at the disposal of the AMA we realize that the patient's physician must still be free to decide which drug will be most effective in the treatment of his medical problem. It is for these reasons that the House of Delegates of the American Medical Association at its meeting in New York City just a week ago voiced its strong and unanimous opposition to the provisions of this legislation which would amend the Food, Drug and Cosmetic Act to authorize the Food and Drug Administration to determine the efficacy, as well as safety, of a prescription drug prior to the approval of the New Drug Application.

This policy of freedom in medical practice should not be scrapped without full knowledge of the risks inherent in conferring upon an

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[62] Transcript of Hearing Before Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U. S. Senate, on S. 1552, Drug Industry Antitrust Act, July 5, 1961, pp. 65-66. Henceforth, these proceedings will be referred to as *Hearings on Drug Industry Antitrust Act*.

[63] Work cited at footnote 62, at p. 67. It should be noted that Dr. Hussey distinguished between the role of the AMA in efficacy evaluations and the provisions of the bill. The opinions of the AMA are offered to the profession as "advisory and educational." Dr. Hussey stated: "It is quite possible medical practices and the science of pharmacology being what they are, that the opinions of the AMA with more widespread experience could be proven to be medically incorrect. However, such mistakes could be corrected by the AMA and by the profession as a whole." Transcript, July 6, 1961, pp. 154-55. On the other hand, under the proposed bill, Dr. Hussey indicated that following an adverse determination by FDA on efficacy a drug would never reach the market. "Thus the profession and the public as a whole could be deprived of the benefit of what might have been a lifesaving drug." Transcript, p. 155.

administrative agency the power to control the availability and use of methods of treatment or of drugs. There would be a substantial risk of deterioration in the progress of medical knowledge.[64] The following excerpt from a recent editorial in *Medical Tribune* offers a sobering thought:[65]

> Now, a further question is raised concerning therapeutic effectiveness—and some have suggested that it might possibly be a good scheme to have a regulatory body pass upon effectiveness, too. We become disturbed and would consider it an awesome responsibility. It would have to be presumed that such people are omniscient.
>
> What authority would have been so impressed by the evidence as to make gold salts available, many years ago, for rheumatoid arthritis? Today nearly everyone grumbles over their cantankerous unpredictability—yet they rank well among the measures of rheumatologists (THERAPEUTIC TRIBUNE, January 9). None would have foreseen it; historically, the premise for gold salts was twice wrong, for they were thought indicated for tuberculosis, and rheumatoid arthritis was conceived a result (or complication) of that disease. No array of statistics could possibly have met the criteria for "conclusive scientific proof" of efficacy—or even properly reflect what gold salts might accomplish. And the effectiveness (which is accepted as fact) is even now attributed by many to "toxic" action. Thus, by present criteria, everything known of gold would have weighed authoritatively against its official acceptance.
>
> Given the best faith in the world, no group of men of whatever talent, in finite time, can meaningfully assess how well a new remedy will serve; it is the actual exhaustive experience of all physicians which brings the fact eventually to light—it is the clinical trial in vivo. In any select committee ordained to find out everything beforehand, thoughtful men would see, rather, a danger to free scientific inquiry and a likelihood of gravely hindering clinical progress for a long time to come.

As one doctor put the issue:[66]

> Another freedom closely tied to freedom of choice is freedom in the conduct of medical treatment.
>
> At the recent meeting of the World Medical Association in Havana, Cuba, Dr. Rolf Schloegell of Germany made a stirring defense of free conduct of medical treatment. He told us that the medical profession believes that the attending physician alone is competent to decide what measures he deems necessary and will apply in order to bring about the desired improvement. He warned too of the danger of excessive restriction on the freedom of the patient and the attending doctor.

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[64] It has been said: "Institutional resistance to change has long been characteristic of medical practice. Medical history is replete with persistent and costly obstruction to scientific innovation—on the part of doctors, patients, and society at large." *Somers*, p. 21. Nevertheless, the development of new drugs has been estimated to have saved at least 3 million persons over the past 20 years. *Somers*, p. 92. Accordingly, the question is raised whether these achievements could have been made in the face of institutional barriers to the availability and use of drugs such as are now proposed.

[65] "Omniscience or Judgment," *Medical Tribune*, February 6, 1961, p. 15.

[66] Dr. D. H. Murray, "Freedom in Medical Practice," 60 *Pennsylvania Medical Journal* 47 at 48 (1957).

Again: [67]

A recent editorial in the *New England Journal of Medicine* reviews the "Essay on the Art of the Practice of Medicine" presented by Dr. Sedgwick Mead to the staff of the Kaiser Foundation Hospital. One paragraph sums up the argument against authoritarianism in therapeutics:

"Dr. Mead uses Benjamin Rush, whose phenomenal prestige extended far beyond his day, as an example of benevolent, unassailable and *disastrous* authoritarianism. Sometimes called the American Sydenham, Rush exerted so great an influence that his therapeutic errors were blindly followed for a century."

Perhaps we should fear the same results from another form of authoritarianism, that of the government, even in those cases where it is backed by a learned commission of the highest calibre. It might be wiser to put greater faith in what someone has called, "the consensus of present day medical opinion." If a drug cannot be put on the market until a board of experts has passed on its comparative efficacy, a real stumbling block will be put in the way of medical progress.

The fundamental factor underlying the concept of noninterference in medical practice is the empirical nature of medicine, even scientific medicine.[68] In fact, the term "medicine," generically, has been defined as the science and art dealing with the prevention cure or alleviation of disease, and a "physician," broadly, as one who practices the art of healing disease and preserving health, a prescriber of remedies for sickness and disease.[69] Consistent with these definitions, it has been said that the practice of medicine is both an art

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[67] Letter dated April 12, 1961 from Dr. Austin Smith, president of Pharmaceutical Manufacturer's Association, to Hon. Abraham Ribicoff, Secretary of Health, Education, and Welfare, p. 11.

[68] The technological revolution in medicine has, indeed, produced changes in the practice of medicine. See *Somers,* Part Two, pp. 27-129. The trend toward specialization, for example, has led to "the fragmentation of medical practice" and "the fragmentation of the patient." Work cited at footnote 67, at p. 23. Accordingly, emphasis has been placed in recent years upon the concept of "comprehensive care," which means first, the totality of desirable health services, and second a "total" approach by the individual doctor to the individual patient. Ibid., pp. 34-37. Thus, the authors state: "Still the struggle for acceptance of new scientific findings goes on, albeit in changing context. The heirs of the Pasteurian rebels became the orthodox defenders of a mechanistic concept of disease, now widely challenged by a new school of medical thought growing out of psychiatry, endoctrinology, and other comparatively recent specialisms. With its emphasis on 'the whole man' and 'comprehensive care' (Chap. 3, p. 34), this latest approach has in some ways more in common with the old Hippocratic ideal of physical, mental, and emotional balance, so well summarized in the Roman aphorism *mens sana in corpore sano,* than with the exclusive concentration on physiology characteristic of medical science in the sixteenth to nineteenth centuries." Work cited at footnote 67, at pp. 23-24.

[69] 41 *Am. Jur.* "Physicians and Surgeons," Sec. 2.

and a science,[70] and accordingly it can never become an exact science unless each patient can be reduced to a standard form. This is because "the normal variations in individuals have such a wide range that both the automatic interpretations of facts and the mechanical prescription of treatment are prohibited."[71] In fact, the physician, through careful observation, is placed by our technology in a position wherein he contributes significantly to basic science. Pointing to this fact, one doctor has said:[72]

> This is but one of the ways in which we are reminded in an atomic age of our place in nature and of the balance between contemplative understanding and practical accomplishment necessary for human medical progress.

Basically, the empirical nature of medicine requires that the determination of whether or not to use a drug be an individual decision based on the facts of each case. As Dr. Hussey pointed out on behalf of the American Medical Association:[73]

> A drug which is, on the average, less efficacious than another, must still be available to every physician since it may be completely efficacious in treating the medical problems of one of his patients. We do not practice medicine on the average—we seek to solve or alleviate the problems of each and every patient.

As example of the foregoing conclusion, Dr. Hussey explained the difference between a disease condition and a patient, pointing out that physicians treat only individual patients. He stated:[74]

> This difference becomes especially important when he elects to use drug therapy in the treatment of these ten individual patients. He may find that the same dosage of the same form of the same drug will be efficacious in each and all of his ten patients. Or he may find that one or more of them need different dosages, or different forms of this same drug. He may, indeed, find that one, two or three of them are allergic to the non-active ingredients used in a brand of the drug and that a different brand, with other non-active ingredients, is the efficacious answer. Thus, in one patient, a specific dosage of a specific drug might be said to be efficacious. While in another, it would be described as totally ineffective.

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[70] Testimony of Dr. Hussey, *Hearings on Drug Industry Artitrust Act*, July 5, 1961, p. 68. See, Dr. W. L. Downing, "The Practice of Medicine: An Art and a Science", 46 *Journal of the Iowa State Medical Society* 233 (1956).

[71] Sir Lionel Whitby, "The Science and the Art of Medicine", *2 Lancet* 131 (1951). See, also, Dr. H. W. Williams, "The Clinician in the Mode of Today's Thinking," 41 *Rhode Island Medical Journal* 684 (1958).

[72] Dr. L. E. Farr, "Technology, Basic Science and Clinical Medicine in the Atomic Age," 59 *Northwest Med.* 1251 (1960).

[73] Testimony of Dr. Hussey, *Hearings on Drug Industry Antitrust Act*, July 5, 1961, pp. 64-65.

[74] Work cited at footnote 73, at p. 63.

Accordingly, while the power to regulate the practice of medicine is fundamentally vested in the state legislatures,[75] this regulation has taken the form principally of establishing standards of education and character as a prerequisite to obtaining a license to engage in such practice.[76] The public is thus assured that practitioners of the art of healing disease and preserving health are suitable persons to exercise judgment and command the confidence of their patients. Within that framework, the physician is left free as a matter of public policy to decide medical questions in accordance with his observations in each case.

This is not to say, however, that the physician has a license to act irresponsibly or to disregard the interests of his patients. An obligation is imposed upon him by the common law to exercise the amount of skill common to his profession and a degree of care commensurate with his position.[77] It has been said that the hazard of malpractice litigation has a definite impact upon the practice of medicine.[78] In this way, society has sought to provide for the responsible exercise of the practice of medicine while at the same time creating the conditions for maximum progress in medical science.

Beyond professional liability, the development of professional quality standards is a matter of serious concern to the medical profession itself. They constitute a form of professional self-discipline which encourages high standards of medical care.[79] Self-discipline was considered to be of importance to the British Committee on the Cost of Prescribing. Their report stated:[80]

> Having carefully weighed in the balance the probable financial returns from the introduction of a limited list against the weighty objections to such a course, we are unanimous in thinking that to place an absolute ban on the prescribing

[75] *Am. Jur. "Physicians and Surgeons"*, Sec. 7. However, such power is subject to the limitation that measures adopted to regulate the practice of medicine must be reasonable and appropriate for the accomplishment of legitimate objects within the domain of the police power of the state.

[76] Work cited at footnote 75, Sec. 15.

[77] Cline, *Professional Liability*, Proceedings, Medicolegal Symposiums, sponsored by Law Department and Committee on Medicolegal Problems, American Medical Association (1955), pp. 76-101. With the general dissemination of medical knowledge, with the publication of medical periodicals and with the meeting of medical associations, it has come to be recognized that the standard of care and skill is pretty universal. Work cited above, at p. 77. The physician and surgeon are most likely to be charged with knowledge of the great progress made in medicine. Work cited above at p. 99.

[78] Dr. A. A. Sandor, "The History of Professional Liability Suits in the United States," 163 *Journal American Medical Association* 459 (1957).

[79] *Somers*, pp. 111-119.

[80] *Report*, cited at footnote 60, at p. 63.

of certain categories of drugs would be the wrong way to attempt to control the drug bill. We prefer rather to rely upon the training of doctors to prescribe with care and discrimination coupled with their liability to justify themselves at an investigation by their colleagues whenever their prescribing costs are substantially above the average.

Under the circumstances which apply to the practice of medicine, the limits of discretionary power in the regulation of drugs become apparent. Whether or not to make drugs available to the medical profession and under what conditions to do so are not proper matters for decision by an administrative agency. The following principle would appear to be applicable: [81]

> An unqualified power to condition licenses confers the widest possible discretion. It is a power of special legislation, i. e., with the freedom of legislative discretion without the check inherent in a rule that must operate generally. It may introduce new policies, which should be settled by the legislature itself.

Yet we have examined administrative trends in drug regulation and pointed out that we have experienced the formation and execution of basic policies by an administrative agency without clear Congressional authorization. This has involved the assumption of control by the FDA of the proper use of drugs, a responsibility which may substantially interfere with our public policy of freedom in medical practice.

The duty to fashion a policy, "not only of great economic importance but also one that has divided the faiths and loyalties of classes of people, cannot appropriately be intrusted to the administrative." [82] It is up to Congress to formulate the rule containing a definition of policy in the regulation of drugs in the best interests of the public welfare, including not only protection of the public health, but also promotion of medical progress and improvement in the public health.

Effect of Drug Industry Antitrust Act

The proposed "Drug Industry Antitrust Act" would if enacted sanction the emasculation by the FDA of our public policy of no governmental interference in the prescribing of drugs. It would provide the FDA with vast administrative powers, sufficient to enable

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[81] Freund, *Administrative Powers Over Persons and Property* (1928), pp. 114-115.

[82] Landis, *The Administrative Process* (1938), p. 55. See, also, 1 Davis, *Administrative Law Treatise* 156 (1958); Jaffe, "An Essay on Delegation of Legislative Power" 47 *Columbia Law Review* 359, 369-71 (1947); and Cooper, "Administrative Justice and the Role of Discretion," 47 *Yale Law Journal* 577, 585-586 (1938).

this agency to assume the enormous burden of attempting to insure the safety and efficacy of use of all drugs by controlling their availability and use. In view of the propensity of the FDA to expand upon its powers, it must be concluded that this agency would make full use of the provisions of this bill in the direction indicated. The effect of the bill, therefore, would be to substitute authoritarian controls over the practice of medicine for a system of regulation which presently encourages responsible use of individual expert knowledge and initiative.

The bill is not absolutely without standards to guide the FDA. Thus, under the bill, in order to obtain a license to manufacture a prescription drug, an applicant must demonstrate that his establishment fulfills certain requirements. These requirements are to be prescribed by the FDA, however, and that agency is authorized to prescribe such standards as it "shall determine to be necessary to insure the continued chemical structure, strength, quality, purity, safety and efficacy" of the drug.[83] One need only refer back to the previous discussion of the FDA's interpretation of the antibiotic provisions of the FDC Act to appreciate the magnitude of the power this provision would give to the FDA.[84] It goes beyond the setting of minimum standards of manufacture. It could be construed, after the pattern of the antibiotic provisions, to justify control over availability and use of all prescription drugs. In fact, the standards set forth in the bill to guide the FDA are blank checks and not real limitations of power.[85]

We have seen that the antibiotic provisions in the law were advocated, not to control use of the antibiotic drugs, but to provide assurance of uniform potency. They were considered to be a temporary control to exist only pending uncertainties (long since solved) in the fermentation process of manufacture. Rather than subject all

[83] Proposed new Sec. 508(b) of *FDC Act. Bill,* Sec. 4(13). See footnote 8.

[84] Cited above, at pp. 7-9, dealing with Secs. 502(1) and 507 of *FDC Act.*

[85] The applicant must demonstrate, for each prescription drug, that his establishment fulfills the requirements set by FDA. Furthermore, his license may be suspended or revoked whenever FDA determines his establishment no longer fulfills those requirements *or* whenever FDA determines he has adulterated or misbranded the drug. Proposed new Secs. 508(a) and 508(b). Sec. 508(c) provides for inspection of licensed establishments. There is also provision for formal hearings, and ultimately for judicial review. Secs. 508(e) and 508(f). However, short of actual spitefulness or capriciousness, it is hard to visualize any situation in practice which would require a court to overrule FDA.

prescription drugs to the unusual controls exercised in the case of certain antibiotics, it would seem more consistent with public policy to remove antibiotics from such controls and place them under general provisions of the law.

The proposed amendments to the new drug section of the law, also, do not contain such standards as might limit the exercise of power by the FDA over the availability and use of drugs. First, any drug may be considered a "new drug" under the bill if not generally recognized as "efficacious for use." [86] Second, a "new drug" cannot be marketed until the FDA has determined, after the conduct of such tests as may be considered necessary, that the drug is "safe for use" and is "efficacious in use." [87] Third, a new drug may be effectively removed from the market if it is found "not efficacious in use." [88]

Taking these provisions together, it seems apparent that first, they legitimize present FDA practice of considering safety and efficacy as inextricably integrated. We have seen that the FDA under the present new drug section has on occasion interpreted the law so as to permit the relative comparison of drugs.[89] Hardly less could be expected under the proposed bill. In fact, what has probably amounted to a questionable practice not regularly undertaken could under the bill amount to standard operating procedure. As Dr. Hussey, of the AMA put it: [90]

> We are apprehensive that the Food and Drug Administration would, under these amendments to the Act, decide that it had the authority to refuse to allow a drug to be marketed merely because it was, in their opinion, not the most efficacious drug for the purpose intended or was not as efficacious as one might ideally wish.

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[86] Proposed amendment to Sec. 201 (p)(1) of *FDC Act. Bill,* Sec. 4(1). Presently only those drugs not generally recognized as safe are new drugs. This amendment could make any drug, new or old, a new drug merely because some doctors do not favor use of the drug.

[87] Proposed amendment to Secs. 505 (b), 505(c) and 505(d) of *FDC Act. Bill,* Secs. 4(8), 4(9), and 4(10). These provisions differ from present law in several respects. First FDA is authorized to review efficacy of a new drug as well as safety. Second, under the bill a new drug cannot be marketed until approved by FDA. At present it can be marketed unless disapproved within a specified time. There is no time limit in the bill. Third, the FDA is authorized to decide what investigations and tests shall be conducted. There is no such authority at present.

[88] Proposed amendment to Sec. 505 (e) of *FDC Act. Bill,* Sec. 4(11). At present, to revoke an effective new drug application, FDA must find the drug to be unsafe for use.

[89] Cited above, at pp. 9-12.

[90] Transcript, *Hearings on Drug Industry Antitrust Act,* July 5, 1961, p. 65.

Second, these provisions go beyond the construction by the FDA of the existing new drug law, for they authorize the FDA to have such tests conducted as may be considered necessary. Thus, the bill could initiate an era of comparative drug testing which could sharply limit the number of new drugs put on the market. This is especially true if the new drug section is considered in conjunction with the patent provisions of the bill.[91] Those provisions require, as a condition to obtaining a patent, the conduct of "such research as may be required" to determine whether or not the therapeutic effect of a drug is "significantly greater" than another drug which it modifies.

A considerable amount of control over the use of drugs would be conferred upon the FDA by the bill's provisions which relate to the general area of dissemination of information to physicians. We are concerned here with the power to determine the proper use of drugs and not with problems of misleading advertising. Such power exists to the extent the FDA may prescribe the conditions of use of drugs which are allowed to be marketed. It would seem that the exercise of this power is a threat to freedom in medical practice.

Accordingly, Dr. Hussey testified, on behalf of the AMA, that "the continuing education of physicians is the primary responsibility and prerogative of the profession itself and associated groups." [92]

The following provisions in the bill are pertinent to this discussion.

First, the FDA would be authorized to determine the name of any drug as it shall find necessary or desirable "in the interest of usefulness and simplicity." [93] This name becomes the drug's official name," and must appear with specified prominence on the label of the drug as well as in all advertising for the drug.[94]

Second, responsibility is conferred upon the FDA to prepare and disseminate a list of drugs "having the potentiality of particularly serious, dangerous or harmful effects".[95] There may be included with the list "such information relating to those dangerous or harmful effects" as may be considered "in the best interest of the public health."

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[91] Proposed amendment to Sec. 101 of the Patent Code. *Bill,* Sec. 3(b). See footnote 15.

[92] Transcript, *Hearings on Drug Industry Antitrust Act,* July 5, 1961, p. 57.

[93] Proposed new Sec. 509(a) of *FDC Act. Bill,* Sec. 4(13).

[94] Proposed amendment to Secs. 502 (b) and 502(e) of *FDC Act. Bill,* Secs. 4(4) and 4(5). Also proposed new Sec. 502(m) of *FDC Act. Bill,* Sec. 4(7).

[95] Proposed new Sec. 510(a) of *FDC Act. Bill,* Sec. 4(13).

Third, as to promotional material distributed to physicians, the bill would require that the manufacturer include therein (a) "a true and correct copy of all printed matter" which the FDA has required to be included in any package in which that drug is distributed or sold, and (b) in the case of new drugs, "a full, true and correct statement of all findings of fact and determinations" made by the FDA under that section with respect to that drug, as the FDA may require.[96] Though the language is not free from doubt, this provision could be construed as providing the FDA with virtually absolute control of the dissemination of information to physicians on behalf of drug manufacturers.

Fourth, with respect to advertising, broadly construed in the bill,[97] the manufacturer must include in all advertisements, in addition to a prominently displayed official name, (1) warnings prepared with the approval of the FDA "as to any dangerous or harmful property or effect thereof," and (2) "a full and correct statement of its efficacy".[98] By empowering the FDA to determine the warning statements which must appear on advertising, this provision also affords that agency a measure of control over the use of drugs.

Considering these several provisions in the area of dissemination of information, they would confer upon the FDA an impressive armament by which to prescribe the information that is given to the medical profession. This even applies to purely scientific meetings. Little room is left for the exercise of responsibility by honest industrial firms or by the medical profession.

The potential effect of the proposed bill is well illustrated by considering its provisions in the light of a recent speech by the Deputy Commissioner of Food and Drugs, Mr. John L. Harvey.[99] He stated that "a profound and continuing change" is occurring in the administration of the food and drug laws. As described by Mr. Harvey, the nature of this change is to substitute the Food and Drug Administration for the federal courts as the principal interpreter of these laws. Thus, the individual "who wishes to abide by the law" need no longer wonder how the courts will apply the law to his product. He need only "abide" by the rules of compliance issued by the FDA.

[96] Proposed new Sec. 502(m)(1) of *FDC Act. Bill*, Sec. 4(7).

[97] See footnote 16.

[98] Proposed new Sec. 502(m)(2) of *FDC Act. Bill*, Sec. 4(7).

[99] Harvey, "Evolution in the Food, Drug and Cosmetic Law Area," 16 FOOD DRUG COSMETIC LAW JOURNAL 90 (1961).

The usefulness of "conventional legal actions" will primarily be in the enforcement of the regulations.

Certainly, recent laws relating to pesticides, food additives and color additives tend to support the analysis of Mr. Harvey. Commenting on the responsibility these laws impose on the FDA, Mr. Harvey stated:

> We are assigned the heavy task of so restricting the use of additives that directly or indirectly enter our foods that no harm can come.

Of course, Mr. Harvey recognized that this kind of responsibility placed "very heavy scientific and legal burdens" upon the FDA. It requires scientific personnel "with an unusual degree of competence" and "a greatly increased staff in the field" to effectively administer the new rules.

In the drug area, Mr. Harvey cited the insulin and antibiotic sections of the law as illustrative of the evolution in the law, stating:

> [T]he certifiable antibiotic and insulin may be marketed only in accordance with regulations that set forth in detail conditions that must be met and only after a sample from the lot in question has been examined by the Food and Drug Administration and found acceptable.

It must be understood that to assign FDA the responsibility in the drug area generally, as in the field of additives, of "so restricting" the use of drugs that are prescribed by physicians "that no harm can come," to do this is to undermine our traditional public policy of freedom in medical practice, and to possibly limit medical progress. It is probable that no major advance in medical technology has been made under circumstances that guaranteed that no harm or risk of harm could occur.

Is the Drug Industry Antitrust Act Necessary?

Another matter remains to be considered. This is whether or not granting to the FDA powers contrary to historic principles underlying the regulation of drugs and physicians is justified. In other words, notwithstanding the risk involved to the further progress of medicine, are these controls necessary to promote the public welfare?

Extensive hearings were held during 1959 and 1960 by the Senate Judiciary Committee's Subcommittee on Antitrust and Monopoly.[100]

[100] Referred to herein as *Hearings on Administered Prices*. For full citation, see footnote 8.

The subject of these hearings was "Administered Prices in the Drug Industry". They constitute the principal basis for the arguments made by the sponsors of the proposed bill in justification for its provisions. To paraphrase their thesis,[101] the sponsors contend that ethical drug prices are generally "unreasonable and excessive." Next, they allege that these prices are made possible by the existence of "very tight control" of the market for ethical drugs. Finally, it is argued that there is a "high level of concentration" in the industry stemming from three principal sources: (a) persuasion of physicians to write their prescriptions in terms of brand names rather than generic names, (b) intensive and costly advertising and sales efforts directed to physicians, and (c) the practice of granting product patents on drugs.

Accordingly, the objective of the bill is as follows:

> The fundamental purpose of the bill is to bring about lower prices of drugs by infusing competition into this monopolistic industry.

This result would be accomplished by remedying the alleged "sources of monopoly power." Thus, the objects of the bill might be described as follows: (a) to establish bases for a substantive increase in the writing of prescriptions in terms of generic names, (b) to improve the quality and reduce the quantity of advertising and promotion, and (c) to impose limitations on the patent grant. Of these objects, the first two are sought to be achieved by the various amendments to the FDC Act discussed previously. The third is handled through the patent and antitrust laws and is outside the scope of this paper.[102]

As might be expected, the charges of the sponsors of this proposed legislation have been sharply controverted.[103] For one thing, it has been pointed out that they are not charges of violations of law, but rather of deviations from some concept of "reasonableness," which is subject to varying interpretations. For another, it is alleged that they are based in large part on the opinions of biased witnesses who

[101] The thesis was enunciated by Senator Kefauver on July 5, 1961. *Hearings on Drug Industry Antitrust Act*, transcript, pp. 4-36. The same thesis is advanced in S. Rept. No. 448, *Administered Prices, Drugs*, a Report of the Committee on the Judiciary, made by its Subcommittee on Antitrust and Monopoly pursuant to S. Res. 52, 87th Cong., 1st Sess., June 27, 1961, pp. 1-262. S. Rept. No. 448 will be referred to henceforth as *Report on Administered Prices, Drugs*.

[102] Proposed limitations on the patent grant include provisions for compulsory patent licenses, prohibition of certain patent agreements, and restriction of patentability to certain drugs.

[103] See individual views of Senators Dirksen and Hruska, *Report on Administered Prices, Drugs*, pp. 263-368; also individual views of Senator Wiley, at pp. 369-374.

presented a distorted image of the drug industry, and of the medical profession in general.

Those dissenting from these charges contend that drug prices are not unreasonable and that the drug industry is highly competitive. It is argued that competition for new products is an important form of competitive activity in the drug industry and that such competition necesssarily entails extensive research and requires considerable educational effort in order to develop improved products and bring them to the attention of the medical profession. They contend, further, that the patent system provides the incentive to engage in this competition, and that trademarks provide the incentive to engage in competition for superior quality standards.

We need not attempt to evaluate the arguments on either side of this controversy. Hearings on the proposed bill have only just begun, and undoubtedly a considerable amount of evidence will be amassed on these issues. For our purposes, however, it will be sufficient to consider the objectives of the bill on their face value. On analysis, it does not appear that any of these objectives requires that the FDA be given power to control the availability and use of drugs.

Undoubtedly, the effect the drug industry now has upon the practice of medicine is far greater than ever before.[104] The growth of the industry and the development of numerous "wonder" drugs, it is said, have produced large and successful corporations which "exercise a profound influence over medical practice". On the one hand, the doctor has been equipped with "invaluable weapons" against disease. But on the other, "he has found it difficult to keep up intelligently with the therapeutic qualities of the mounting flow of new products."

Congress has been asked to deal with this problem. There have been many suggestions.[105] The rather simple approach of the sponsors

[104] See *Somers*, ch. 5, *The New Role of the Drug Industry*, pp. 91-105.

[105] The testimony reveals that there was no uniformity of opinion or general agreement as to the solution to the drug problem. Consider advertising, for example. Dr. Chauncey D. Leake, of Ohio State University, testified that physicians in general "should be skeptical" of the descriptions of new drugs offered by pharmaceutical manufacturers, and should wait for "impartial evaluation" of new drugs in the medical profession before using them. But on the matter of further legislation, Dr. Leake indicated fear of the "increasing development of authoritarianism." He also said: "I am of the opinion that in this country where we depend upon freemen exercising responsibility in a free economy, freemen should regulate themselves. Now I think government should require certainly that there be this regulation, but I doubt very much indeed, and here

of the proposed bill is to substitute government responsibility for the responsibility of industry and the medical profession. It permits an administrative agency to shape medical practice, at considerable risk to the future of research in the development of new drugs and to progress in medicine, and accordingly, cannot offer any assurance of competition.[106] We will consider each of the alleged sources of market control to which the bill is directed.

Encouragement of generic name prescribing.—To encourage physicians to prescribe generically, the means selected by the draftsmen are twofold. They are the licensing of prescription drug manufacturers under standards set by the FDA and the provision for FDA determination of generic or "official" names.[107] The first remedy, we are told, is intended to assure the physician that any drug in this country is of "adequate and acceptable quality." The second is to provide for useful and simple generic names of drugs.

Clearly, the marketing of substandard drugs should be prohibited. In fact, the FDC Act presently provides that drugs not meeting specified standards are deemed adulterated,[108] and thus their interstate shipment is prohibited. This prohibition applies, among other things, to any drug which has been manufactured under "unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."[109] If the evidence shows that this provision is not satisfactory to enable the FDA to proceed to clear the channels of commerce of substandard merchandise, then it

(Footnote 105 continued)
I am speaking as a citizen, that any further government regulation as such would be helpful." *Hearings on Administered Prices*, Part 18, p. 10,439. On the other hand, among other witnesses proposals for additional legislation varied widely, all the way from elimination of direct promotion to doctors (Testimony of Dr. James E. Bowes, ibid., p. 10,453) to giving to FDA jurisdiction over advertising (Testimony of Dr. Nathan S. Kline, Ibid., Part 16, p. 9321) or expanding FTC's jurisdiction over advertising (Testimony of Mike Gorman, Part 16, p. 9004).

[106] Senator Kefauver has indicated that his approach to administered prices is to foster competition rather than to impose price controls as in the case of public utilities. Remarks on July 5, 1961, *Hearings on Drug Industry Antitrust Act*, Transcript, pp. 34-35. But the power to license producers and to control the marketing of drugs will not necessarily eliminate alleged administered prices and will impose rigid governmental controls upon the drug industry.

[107] Remarks of Senator Kefauver, July 5, 1961, *Hearings on Drug Industry Antitrust Act*, Transcript, pp. 13-16.

[108] FDC Act, Sec. 501.

[109] Ibid., Sec. 501(a)(2).

should be strengthened.[110] This can be done, however, without licensing or other controls over the availability and use of drugs. For example, a drug might be deemed adulterated unless manufactured under conditions of good manufacturing practice sufficient for the drug to meet the standard of strength, quality and purity set forth in the law.[111] Such a provision might be supplemented by the requirement of periodic factory inspection of all drug establishments so as to facilitate enforcement of the law by the FDA. The proposed bill, on the other hand, is subject to the criticism that it is not reasonably limited to the objective which is sought to be achieved.[112]

It is equally clear that generic names should be useful and simple. The present law requires that each drug label bear the common or usual name of the drug or each active ingredient contained therein,[113] and the present procedure is that the common or generic name of a new drug is determined by the developer of the drug with the approval of the American Medical Association, and in cooperation with the official

[110] Proposed drug legislation introduced on behalf of the Administration in the 1960 session of Congress (S. 3815, 86th Cong., 2d Sess., introduced by Senator Hill on July 2, 1960) was based on this principle. Among other things, Section 4 of the bill would have amended Sec. 501(a)(2) of the FDC Act by providing for standards for the manufacture of drugs. While this was not a licensing provision, its effect would have been tantamount to licensing. Under this bill, FDA would have been authorized to determine by regulation standards of manufacture for a drug adequate "(i) to insure that its identity and strength do not differ from, and that its purity and quality do not fall below, those which such drug purports or is represented to possess, or (ii) to insure that such drug will not be injurious to health when used in accordance with directions for use on its labeling, or when used in accordance with a prescription of a licensed practitioner (which prescription is consistent with the labeling of such drug), or (iii) to insure that its labeling is not such as to cause such drug to be adulterated or misbranded." As with the proposed "Drug Industry Antitrust Act," this bill would have permitted control over availability and use of drugs.

[111] Sec. 501(b) of FDC Act presently provides that a drug recognized in an official compendium must equal the strength, quality or purity set forth in such compendium, unless its difference therefrom is plainly stated on the label. Otherwise, pursuant to Sec. 501(c), the drug must equal the strength, quality or purity which it purports or is represented to possess.

[112] Of course there is now license control over narcotics and over biologicals under laws administered by agencies other than FDA. These are special classes of drugs, however, which require controls over and beyond those applicable to drugs generally. See, e.g., Banta, "Federal Regulation of Biologicals Applicable to the Diseases of Man," 13 FEDERAL DRUG COSMETIC LAW JOURNAL 215 (1958). Gregg, "The Single Convention for Narcotic Drugs," 16 FEDERAL DRUG COSMETIC LAW JOURNAL 187, 188-193 (1961).

[113] FDC Act, Sec. 502(e). But this requirement does not apply to a drug designated solely by a name recognized in an official compendium.

drug compendia and the World Health Organization.[114] The American Medical Association is of the opinion that the proposal for determination of "official" names by the FDA would not be effective, and that problems of drug nomenclature can and should be solved by the profession itself. Accordingly, the AMA and the U. S. Pharmacopoeia have recently formulated a joint program for non-proprietary names. This program is designed to facilitate the selection of suitable non-proprietary names for drugs and to encourage the use of such names wherever indicated in labeling, in advertising, as titles in the official compendia, and in the scientific literature.[115]

Since there is no assurance that the provisions of the bill respecting "official" names would be effective, they should not be adopted. Among other things, it is not necessarily good medicine to prescribe by generic name, and physicians generally could not be expected to do so merely because the name was selected by a government agency.[116]

Quality and quantity of advertising and promotion.—To accomplish the objects of the bill with regard to advertising and promotion, provisions have been included seeking "to prevent physicians from being misled about the therapeutic properties and dangerous consequences of drugs." In support of these provisions the sponsors cite testimony that it is impossible for the practicing physician to make his own evaluation of a new drug, and that, inevitably, reliance must be placed on advertising and promotional material.[117]

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[114] *Hearings on Drug Industry Antitrust Act,* testimony of Dr. Hugh H. Hussey, Jr., July 5, 1961, p. 59.

[115] Work cited at footnote 114, at pp. 59-61.

[116] For example, Dr. Charles O. Wilson, of Oregon State College, testified: "May I point out here that a generic name is used for a specific chemical substance and has no connection with the pharmaceutical dosage form or brand name product. In regard to brand names, there is no such thing as a generic equivalent. Brand name is used in reference to a finished pharmaceutical dosage form and is never used in reference to the pure chemical substance." *Hearings on Administered Prices, Part 21,* p. 11,521. Dr. Louis M. Orr, past president of AMA, recently said: "Furthemore, few prescriptions involve a single chemical and even these must often be combined with a vehicle or carrier to enable a particular method of administration or to preserve the medication from deterioration or both. Even the vehicle can have significance for the patient which means that the doctor must select that vehicle for each prescription which will best enable the individual patient to absorb the medication it contains. Knowing the exact constituents behind each brand name, he uses this means of specifying the medicine which most precisely meets his patient's needs." "Freedom to Practice Good Medicine," (N.S.) 1 *Journal of the American Pharmaceutical Association* 100 (1961).

[117] Remarks of Senator Kefauver, July 5, 1961, *Hearings on Drug Industry Antitrust Act,* Transcript, pp. 21-25.

Accordingly, the measures which are advanced in support of this purpose are the following. First the FDA is required to determine whether or not a new drug is efficacious. Second, a warning approved by the FDA and complete information on efficacy must be included in all advertisements. Third, information transmitted to physicians must contain certain materials approved by the FDA. Fourth, the FDA is required to list drugs having the potentiality of particularly serious, dangerous or harmful effects.

We need not discuss these provisions individually. Taken together, they go far beyond the mere prevention of misleading information. They do not selectively limit the remedy to the problem raised but assign to the FDA responsibilities which contravene the principles of our public policy.

Thus the American Medical Association has gone on record in opposition to the entire approach of the draftsmen of the proposed "Drug Industry Antitrust Act". Dr. Hussey testified as follows:[118]

> We believe that the continuing education of physicians is the primary responsibility and prerogative of the profession itself and associated groups. We are now participating with the Association of American Medical Colleges, the American College of Physicians, the American College of Surgeons, the American Academy of General Practice and others in a project designed to expand and improve post graduate educational facilities and programs. This important activity, together with the expanded drug information program, should insure the dissemination to the practicing physician of complete, objective and authoritative information on new drugs when they are first introduced, and up-to-date information on all significant developments in drug therapeutics.
>
> In summary on this point, we believe the information programs designed and administered by the medical profession itself will continue to be effective to that end and that the passage of a law for this purpose will be less effective.

In the past, the Council on Drugs of the AMA has published its evaluations of drugs in the Journal of the American Medical Association. In addition, it has published annually a bound volume, *New and Non-Official Drugs*, containing these evaluations and other pertinent drug information. The expanded drug information program is designed to provide for publication of a preliminary analysis of a drug at the time it is first marketed, and thereafter an extensive monograph will be prepared for inclusion in *New and Non-Official Drugs*. Additionally, a new handbook on drugs will be published annually by the AMA and designed to contain a digest of essential information to inform the physician on single entity drugs and drug mixtures identified under class headings.[119]

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[118] *Hearings on Drug Industry Antitrust Act*, Transcript, p. 57.

[119] Cited at foonote 118, pp. 53-56.

Under these circumstances, the expanded program of the AMA to provide the physician with impartial evaluations of new drugs and continuing information on drugs lessens the reliance which the physician must now place on advertising and promotional material. But truly misleading advertising should not be condoned. Since jurisdiction over drug advertising has been conferred by Congress upon the Federal Trade Commission, consideration might be given to removing the exemption contained in the Federal Trade Commission Act with respect to advertising directed to the medical profession.[120] This action would seem sufficient to remove any barriers to effective enforcement of the existing prohibition of false or misleading drug advertising contained in that statute.[121]

Limitation of patents.—While the proposed amendments to the Patent Code and the Sherman Act are not generally within the scope of this paper, nevertheless one of these provisions merits consideration at this point. This is the limitation on patentability of prescription drugs to certain drugs having the requisite superior therapeutic effect to be determined by the Secretary of Health, Education and Welfare (unless delegated to the FDA or some other agency).[122] Its stated purpose is to cut down on alleged "flow of manipulated molecules and useless combinations" currently said to flood the market.[123] Thus, it

[120] Sec. 15(a)(1) of the Federal Trade Commission Act defines the term "false advertisement." However, the following exemption is presently written into the law: "No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug." There is now pending in Congress a bill which would establish a separate standard for advertisements of prescription drugs. H. R. 6471, 87th Cong., 1st Sess., introduced by Congressman Dingell, April 19, 1961.

[121] Sec. 15(a)(1) of the statute reaches not only false representations but also failure to reveal material facts, considering the representations made or suggested, and also the consequences that may result from use of the drug under intended or customary conditions of use.

[122] *Bill*, Sec. 3(b), amending Sec. 101 of the Patent Code. It applies to any human prescription drug which is a molecular modification or other modification of any patented or unpatented drug or a combination of two or more drugs. The drug could not be patented until the drug is found to have a therapeutic effect significantly greater than the drug modified or the drugs taken separately.

[123] Remarks of Senator Kefauver, July 5, 1961, *Hearings on Drug Industry Antitrust Act*, transcript, pp. 31-33. This point of view has been expressed, among others, by Dr. Harry F. Dowling, of the University of Illinois, who recently wrote: "at the present time, competition between pharmaceutical companies is wasteful because it is mostly in the wrong area. Competition today usually involves minor modifications, which are

(Continued on following page)

is intended to reduce competition in marketing new drugs, and in this respect the proposed amendment to the new drug section of the FDC Act limiting the marketing of new drugs not approved by the FDA as efficacious would probably have a complementary effect.

There seems to be a preoccupation by the sponsors of this proposed legislation with the marketing of drugs of little or no value. On this subject, the position of the American Medical Association is as follows: [124]

> The vesting of the authority suggested by this legislation in the Food and Drug Administration would operate to limit research, the marketing of drugs and the exercise of discretion by the medical profession.
>
> The marketing of a relatively useless drug is infinitely less serious than would be arbitrary exclusion from the market of a drug that might have been life saving for many persons.

Here, again, the remedy selected by the sponsors of the legislation is not reasonably limited to the problem which is sought to be solved by legislation. Responsible business enterprise would not knowingly market and the medical profession will not consciously employ useless medication. It would seem that the government ought not to tamper with the constant competition for new products which has produced the wonder drugs and which has served to save millions of lives.[125] The prevention of useless drugs can be adequately achieved through the activities of the medical profession, coupled with rigorous enforcement of existing laws.[126]

(Footnote 123 continued)
devised, produced and marketed at a frenetic pace." But Dr. Dowling was quite concerned to preserve competition for original breakthroughs. While he proposed limitation of the patent grant in the case of minor modifications of drugs, he also proposed to *strengthen* brand name protection afforded to developers of significant drugs. One of his assumptions was the following: "In the first place, I should expect that, under the legislation I am proposing, the competition for the discovery of genuinely new drugs would be as intense as it is now for the discovery of modifications of drugs." "The Pharmaceutical Industry and the Doctor," 264 *New England Journal of Medicine* 75 (1961).

[124] Testimony of Dr. Hugh H. Hussey, Jr., July 5, 1961, *Hearings on Drug Industry Antitrust Act*, transcript, p. 68.

[125] It has been estimated that at least three million persons are alive today only because of medications developed over the past 20 years. *Somers*, p. 92.

[126] The *Report of the Special Committee Advisory to the Secretary of Health, Education and Welfare*, approved September 27, 1960, on the policies, procedures and decisions of certain divisions of FDA indicated that "the present resources of the FDA are less than adequate to meet existing responsibilities." However, the committee also made a number of recommendations for new legislation, some of them constituting an endorsement of the Administration's then pending "Factory

It is pertinent to refer to the conclusions of the British Committee on the Cost of Prescribing: [127]

257. The benefits which have resulted from developments in pharmacology and chemotherapy are widely recognised. If further advances are to take place the conditions for successful research must be assessed and correlated with other factors concerned with the costs of prescribing. Temporary economies might be effected by restrictive measures which would discourage the British pharmaceutical industry from its research activities. In the long term this would mean that fewer drugs would be discovered or developed in this country. British firms would lose their valuable export markets, we should become increasingly dependent on foreign firms for new advances and the final result would be a further increase in the cost of prescribing. Research is essential if the people of Great Britain are to reap the full benefits of advances in drug therapy.

The same conclusion would appear to be justified in the United States. The testimony of Dr. Nathan S. Kline, of Rockland State Hospital, in this respect is worthy of considerable respect. He stated: [128]

1. The rapid development of psychopharmaceuticals was the response of the drughouses to the desperate need of the State hospitals. Squibb, with whole root of *Rauwolfia serpentina;* Ciba, with reserpine; Hoffman-LaRoche, with iproniazid; and a dozen drughouses with related preparations. The field a few years ago was so unpromising that three or four of the major drug firms turned down the opportunity to lease the rights to chlorpromazine before Smith Kline & French took the risk.

I might add, parenthetically, these drug firms have been sorely upset since that time, since they didn't realize the potentialities.

If there are excesses, violations of the law, or other abuses, they are certainly not to be condoned—but at no time should we lose sight of the fact that it was the pharmaceutical houses that originated or produced the drugs which have revolutionized psychiatry.

2. There is a great tendency for pharmaceutical houses to imitate each other once the basis for a successful method of treatment has been found. An example of this is the variety of phenothiazine derivatives. The stimulus of possible profits has led to the testing of a tremendous number of variations on the basic chemical structure until today we have a number of phenothiazine derivatives which are superior to the original preparations. The development and

(Footnote 126 continued)
Inspection and Drug Amendments of 1960" (S. 3815, 86th Cong., 2d Sess., introduced by Senator Hill on July 2, 1960). In addition, the committee recommended that FDA be given statutory authority to require proof of efficacy of all new drugs. This recommendation was based on the fact that treatment of a patient with an ineffective drug may jeopardize his recovery. It is subject to the criticism that the concern of the committee was limited to the policies, procedures and decisions of FDA, and that no weight was apparently given to the relative roles of FDA and the medical profession or to the possible effect of the recommendation upon the development of new drugs.

[127] *Final Report of the Committee on Cost of Prescribing* (1959), p. 79.

[128] *Hearings on Administered Prices,* Part 16, pp. 9315-6. To the same effect, see testimony of Dr. Henry Brill, Deputy Commissioner, N. Y. State Dept. of Mental Hygiene. Cited at footnote 127, p. 9091.

evaluation of such variations is time consuming and relatively boring. An immense number of preparations must be tested, almost all of which will prove inferior to drugs already in use. The few new preparations that are more potent or less toxic or act in a slightly different manner are worth the effort, however. As with the antihistamines, a patient may fail to have his allergy respond to the first four drugs and react with complete relief to the fifth drug. Or he may respond to all of the drugs but develop side reactions, so that several have to be tried before a usable one is found.

3. The investigation of potentially useful new compounds of new chemical structure is an expensive and uncertain venture. Over the past 5 years the research facility has received grants totaling $40,000 or $50,000 from each of a number of companies to investigate new compounds, none of which proved to be marketable. On the other hand, one company has had three excellent drugs to be tested almost simultaneously.

Conclusion

The authoritarian approach to drug regulation appears to possess at least the following attributes. First, this approach is contrary to the traditional pattern of drug regulation. It relies principally upon the expansion of administrative controls over drugs in lieu of prohibition of wrongful conduct by law and enforcement of violations in the courts. There appears to be some concern that sufficient justification has not been advanced for such a radical transformation of our traditional philosophy that our government is one of laws and not men. As one writer has put it: [129]

> The national drug law is, of course, grounded in the constitutional grant of power to regulate interstate commerce and, as such, is fitted into the pattern of our federal government. To propose administrative controls on the possibility (more exceptional than usual in actual practice) of conflicting decisions among the districts is to challenge the soundness of the federal system. To utilize delays incident to litigation as grounds for claiming the power of decision is to challenge the constitutional arrangement for the interpretation and enforcement of our statute law. To exalt impatience with the vagaries of the jury system is to betray impatience with one of freedom's fundamental concepts. To insist that there must be "somebody" to decide is to advocate a continuing need for decision and for the subjection of others thereto—a proposition rather strange in a society where initiative, responsibility and freedom have been the beacon lights. They are the lights which must not go out anywhere along the line of American enterprise.

Second, the authoritarian approach negates the concept of serving the public welfare by encouraging individual responsibility, and relies instead upon detailed rules of conduct specified by a controlling body or agency having virtually unlimited discretion. The following statement is a good defense of freedom in medical practice: [130]

[129] Hoge, "Major Drug Law Problem," 6 FEDERAL DRUG COSMETIC LAW JOURNAL 933, 935 (1951).

[130] Testimony of Dr. Chauncey D. Leake, of Ohio State University, *Hearings on Administered Prices*, Part 18, p. 10,441.

It seems to me we have entirely too many bureaus as it is, too many bureaucrats. If we are going to maintain a free democracy, then we had better have free responsible men who will carry out their responsibilities in our Nation. We don't need any more bureaus in my opinion, if we can get the sense of responsibility across to the people that I think really are concerned. And I believe myself that the drug manufacturers, the major companies, are composed of responsible men. It is my opinion also that the members of the medical profession are responsible people, and I think the whole business with us is to get them to appreciate their responsibility and maintain it. Certainly I think we already have entirely too many bureaus, too much of a bureaucracy. The best way to kill our democracy is to get a lot of authoritarianism into it.

Third, authoritarianism is based on the concept of the omniscience of the regulator. There appears to be an exaggerated view of his ability to minimize error or harm. Consider the following statement by Deputy Commissioner Harvey: [131]

The pesticide, food additives and color additive amendments, all enacted in the last six years, present a serious challenge. We are assigned the heavy task of so restricting the use of additives that directly or indirectly enter our foods that no harm can come. We can meet this challenge, and thus protect the public health, only to the extent that we have good scientific appraisals of good scientific data to help us in drafting the rules for permissible use of additives, good inspectional techniques to detect any misuse of additives, and means of enforcing the established rules. We must have all of these things if this new approach to food safety is to succeed.

It is important for us all to realize that the facilities must be available to provide the three essential steps in regulation through administrative rule. We must have enough technical and other factual information, we must study and soundly evaluate this and formulate the rule and we must systematically enforce the rule on a basis that gives adequate assurance to all that the rule is being followed, and not disregarded. In a sense, we cannot limit the number of the players—but we must field all of the balls.

No one could reasonably contend that government does not have all necessary powers to protect the public health or regulate interstate commerce in the public interest. Furthermore, it seems clear that in the exercise of these powers our federal government may legally confer substantial administrative powers upon the FDA. In fact, the FDA is already invested with substantial administrative discretion.

But the question we have posed is what manner of regulation best promotes the public welfare in devising federal controls over the drug industry. The answer to this question depends on several factors, not the least of which includes respect for the values to be achieved by maintaining our traditional public policy of freedom in medical practice. Other material factors include a discriminating

[131] Harvey, "Evolution in the Food, Drug and Cosmetic Law Area," 16 FOOD DRUG COSMETIC LAW JOURNAL 90, 95 (1961).

balancing between the encouragement of price competition and promotion of new product competition. Finally, these factors must be considered in conjunction with any failures in performance which may be ascribed to private enterprise.

In relation to the practice of medicine, for example, a balance has been reached by holding the physician to a general standard of conduct fashioned by state court decisions allowing for evolution in social thought and scientific progress. And the marketing of drugs has been subject to controls designed to prevent fraud and unfair competition. In both areas, however, the individual is entitled to make independent judgments within the scope of the overall standards.

The pressure to change the system to one of more stringent authoritarian controls is apparently based, in part, upon overriding obsession with the possibility of error, and in part upon a fundamental suspicion of the principle of freedom and individual responsibility. But the alternative offered is to radically limit the use of judgment by establishing administrative regulations which by their nature tend to become ever more detailed, more conservative and eventually ends in themselves. The danger to democracy inherent in this trend toward administratively imposed conformity would appear to be self-evident. **[The End]**

FDA GRANTS CLEARANCE EXTENSION

The Food and Drug Administration has announced a time extension for obtaining safety clearances for food additives. The time was moved ahead 60 days, to September 1, 1961.

When President Kennedy signed a new law on food additives in April, FDA said that previously granted or pending extensions would be continued in effect until July 1, 1961, to enable submittal of the necessary information and its evaluation by the agency regarding substances for which further extensions are believed warranted. This date is now changed to September 1 and the order making the change was published in the *Federal Register* on June 30, 1961.

FDA said that it has a substantial number of requests for further extension of the effective date of the statute and that it will not be possible to accomplish the necessary thorough scientific review prior to July 1, 1961.

FDA pointed out that no extension has been or can be granted unless the substance involved can be shown to present no undue risk to the public health during the extension period.

An Evaluation of the Contributions of an Advisory Committee in the Enforcement of State Food and Drug Laws

By ROLAND B. SMITH

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TO PROVIDE TECHNICAL and professional advice needed by Connecticut Food and Drug law enforcement officials in coping with problems requiring scientific knowledge, an advisory committee composed of a variety of specialists was organized in 1948 and has been functioning as a voluntary advisory board. The board employs various procedures for studying the therapeutic status of products offered for sale within the state either over-the-counter or through advertising. While the committee at times has appeared to exceed the scope of its stated purpose, it has made notable contributions to law enforcement and public health in the subject area.

Enforcement of State Laws

The proper and effective enforcement of state food and drug laws often calls for a high degree of competence in, and a wide range of knowledge of a variety of specialized subjects—among them law, medicine, pharmacology, nutrition, pediatrics and dentistry. This demand places a heavy burden on the civil servants who are responsible for law enforcement, in the course of which they are often pitted against arrays of scientists and other specialists brought in as expert witnesses by commercial firms whose products or advertising (or both) have been questioned for their possible adverse effects on the public health. A few examples of cases investigated by the Connec-

ticut Food and Drug Commission (now called The Commission for Consumer Protection) will illustrate the nature of the problem.

The drug division learns of a new cosmetic containing estrogenic substances advertised for the removal of signs of wrinkles in the face. What is the effect of estrogens on the human system? The manufacturer of a colonic irrigation device claims in his advertising that by the use of his product more vitamins are absorbed by the human system during digestion. Is this consistent with present knowledge of physiology? Various shoe stores in the city are using X-ray equipment as shoe-fitting devices. Are these devices safe—for the customers, for the sales clerks?

A cough syrup appears on the market. Inspection of the label shows that the recommended dosage for infants is the same as that for children. Is this an error in labeling or is the dosage safe for use by both age groups?

The commission finds reason for questioning a company's advertising claims. The company appears for the hearing in the persons of physicians, chemists, dermatologists and other professional specialists. These witnesses produce clinical reports in support of the advertising, and are prepared to discuss the product in the terminology of the several professions. Where can the Commission turn for competent help in evaluating the technical evidence and testimony of these witnesses?

It was partially in answer to this need that the Connecticut Advisory Committee on Foods and Drugs was formed, in 1948, by Dr. William T. Salter, Yale School of Medicine.

Formal invitations were issued to the University of Connecticut at Storrs, to its college of Pharmacy (then at New Haven), to the Connecticut Agricultural Experiment Station, the Connecticut State Dental Society, the Connecticut State Veterinary Society, to the Food and Drug Commission [1] and to the State Department of Health to send a representative to the organizational meeting to be held in New Haven, June 22, 1948.

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[1] Because the opinions of the Committee would ordinarily be rendered, on request, to enforcement agencies it was considered at the first meeting that the best interests of all concerned could be served best if the enforcement agencies did not hold membership on the Committee but rather sent representatives to sit with the Committee at its meetings. In addition to the Food and Drug Commission and the Department of Health, the Pharmacy Commission was represented at all subsequent meetings.

The several organizations invited endorsed the purposes of the Committee and with all but one representative present the first meeting of the Committee was held as scheduled under the chairmanship of Dr. Salter. State agencies were represented.

Purposes of Committee

The general purposes of the organization are indicated in the following quotations from the original letter to the participating agencies:

In a very general sort of way, this Connecticut Committee would serve on a local scale the same function as is served on a national scale by the American Medical Association council, the council of the American Pharmaceutical Association, and other national groups organized along the same lines.

The purpose of this committee would be to supply state agencies and other interested groups with a disinterested opinion as to the therapeutic status of various remedies or other preparations which might influence health.

The committee would render confidential statements on the merits of preparations to well authenticated agencies or groups such as the State Board of Health, or to their officers. The majority of such statements would be based on experience, either personal or solicited. Occasionally chemical or pharmacological testing would be required. Therefore, the committee could add members on a temporary basis to cover specific situations as they arise.

The official state agencies have already pointed out that they would welcome the formation of such a committee to supplement their efforts. Already having received this endorsement, it is our proposal to organize this group so that it will become the semi-official agent of all the professional societies involved.

The following principles were adopted as basic policy:

(1) Because requests for opinions will usually come from the enforcing agencies, these agencies will not have membership on the committee, but will be invited to send representatives to sit in at the meetings . . . The Food and Drug Commission, The Pharmacy Commission and the State Department of Health.

(2) The primary concern of the committee is the welfare of the public. Ordinarily, opinions will be rendered only on the request of an official enforcing agency or one of the sponsoring societies and institutions. In rare instances of widespread danger to the public the committee may act spontaneously.

(3) The committee will not directly endorse or express disapproval of a product except as may be necessary for the protection of the public.

(4) It is not the intention of the committee to duplicate the work of the national councils of the professional societies, but rather to adapt and amplify this work as may be necessary to meet local problems arising in Connecticut.

(5) The actual minutes of the committee will be confidential, but a report of the actions of the committee will be sent to each society, institution and agency by the secretary after each meeting.

(6) All public statements of the work of the committee will be made by the secretary only.[2]

[2] Except as otherwise noted, quotations in this paper are taken from the "Reports" of the Committee.

Other general rules adopted since its inception provide:

1. That the committee would meet "about every 60 days," special meetings being subject to call by the secretary if the need should arise. This was further liberalized to permit the calling of a meeting on the request of any two members.

2. That no requests be accepted other than those from sponsoring agencies or other authenticated institutions or groups;

3. That "The committee would not take a stand contrary to that of any of the national councils on any question on which these councils had reached decisions."

4. That when requested to supply expert witnesses to state agencies the following principles would apply:

(A) "Requests for opinion, expert opinion, or expert witness or witnesses shall be channeled through the secretary to the proper committee member or members.

(B) "It is the responsibility of said member to investigate the problem and to decide which of the following courses of action shall be taken: (1) Decision by the member himself. (This . . . is . . . intended to apply in cases in which the answer is obvious and the member is completely confident of the support of his state society); (2) Decision by the member after consultation with an expert or experts nominated by the executive secretary or similar official of his state society (. . . . Written report with recommendations sent to the secretary.); (3) Decision by the member after consultation with an expert or experts appointed *at his* specific request by the appropriate . . . committee of his state society. (. . . Written report with recommendations sent to the secretary.)

(C) "In the event expert witness or witnesses are desired as a result of legal action arising out of [1, 2, and 3] the member shall make every effort to obtain such through his state society."

When presented with a problem the committee has tended to follow one of six general procedures:

1. An on-the-spot opinion by a member or members of the committee;

2. A report by an expert member after study and consideration, sometimes including analysis and tests;

3. A report by a sub-committee of members, based on discussions, tests, library research, and occasionally on the advice of a non-member consultant;

4. A report by a consulting expert, based on upon his knowledge or on tests, survey of the literature, etc.;

5. A decision by the committee based upon evidence requested, and supplied by the seller or advertiser of the questioned product or service; and,

6. Refusal to render an opinion, the subject being beyond the scope of the committee's activities. The problem may be referred to a more appropriate group.

Some examples of these methods will serve both to illustrate them and to reflect the various types of problems brought before the committee.

A bottle of heavy mineral oil bearing on its label the statement "May Be Used During Pregnancy" was submitted. The physician member of the committee gave his opinion that heavy mineral oil is not an abortifacient[3] and that the label statement was acceptable.

Study-report by member expert: When anti-enzyme toothpastes were being introduced the Federal Food and Drug Administration ruled that because of the therapeutic claims made for these dentrifices they would be considered new drugs and proper "new drug" applications must be filed. The Councils on Dental Therapeutics and Dental Research of the American Dental Association had issued a joint statement declaring that on the basis of the evidence then available actual or implied claims of anti-decay qualities for the new dentifrice "are premature." The dental member of the committee was requested to prepare a report on this subject.

Meanwhile an advertisement appeared in a Connecticut newspaper which contained claims of anti-decay properties Investigation by the committee member revealed that the claims were based on laboratory findings at a major university. Since it was judged that "at least a year will be required for clinical testing," the member's report recommended against committee approval.

In another case, concerning a "germ-fighting toothbrush," an intensive laboratory and subsequent clinical testing of the product produced positive results. The committee member, a specialist in bacteriology, returned a favorable report.

Since the advertising in behalf of each of these products was somewhat extravagant as judged by then-current standards it is

[3] Connecticut has well defined laws restricting all artificial approaches to birth control.

probable that the advertising in both instances would have been disapproved. By virtue of the scientific resources made available to then enforcement agents of the state by the advisory committee, the justifiable claims were identified and confirmed; the claims that were rejected were disapproved on the basis of scientific judgment and tests rather than on lay opinion.

The Expert Consultant.—On occasion, a problem arises requiring a kind of specialized knowledge not represented on the committee. A typical case concerned a depilatory of which a woman had complained, stating that painful burns under her arms had been caused by a certain trademarked product. In the opinion of the enforcement officer this complaint raised the question of the general safety of the product. Referred to a consulting dermatologist, the product was cleared of blame (1) because the complainant had not followed label directions to test the product for possible irritation on a small patch of skin, and (2) the label clearly warned that the product might be irritating to persons with unusually sensitive skin. Here, again, the scientific knowledge of a specialist enabled the commission to avoid unnecessary proscription against an established trademarked product.

Committee-Seller Exchange.—In some instances the committee has asked that the manufacturer either supply such written evidence as he may have in support of his product claims, or, that he or a representative discuss the product and its advertising in person. A case in point is that of an estrogenic cream. After reviewing an advertisement for the product, the committee requested that the firm be asked what evidence it had in support of its claims. There was concern because of an Information Letter[4] from the Federal Food and Drug Administration stating that "It is not possible to state with certainty what will be the effect of small amounts of estrogenic substances applied to the skin in a cream base. . . . We are very skeptical of the ability of these creams to accomplish the results promised, *but we are not at this time in a position to disprove the claims made for them.*"

Two representatives of the firm appeared before the Committee. The company stated that it would not knowingly approve an advertisement claiming that the cream would produce "a youthful skin." The phrase used by the firm was "would produce a more youthful appearance." The firm agreed that some of the cooperating stores in

[4] State Cooperation Information Letter No. 52, July 5, 1950, 581.8 (526.1).

their local advertising might have made more exaggerated claims than the company would have sanctioned.

After further discussion, including the decision that estrogenic substances did not cause cancer, the Committee gave as its opinion that "produce youthful skin" would be false, but that "produce a youthful appearance" would be technically correct. A physician member, however, opined that the average customer would not draw such a distinction.

Activities of Committee

In appraising the contributions of this Committee, it is proper to examine its activities in the light of the purposes for which it was constituted. It is also useful to compare the purposes of this committee with a theoretical optimum such as might be adopted in forming similar groups in other states.[5]

For a technical group to make the most effective contribution to food and drug law enforcement, it may be postulated that it should be representative in composition of the essential disciplines; it should be objective in its approach to the problems brought before it; it should confine its advice to those phases of a problem in which the group has technical competence; it must shun any move having political overtones; individually and collectively the members of the group must be independent, and such a group must develop operating methods that will enable it to attack problems and render its decisions with a minimum of loss of time and unnecessary effort.

In composition, the committee is representative of medicine, dentistry, and veterinary medicine, and of the several pertinent disciplines contributory to them—chemistry, bacteriology, pharmacology, and pharmacy. The readiness of the group to enlist the aid of other specialists as the need has arisen has added to the effectiveness of its work.

The general competence and command of the subject matter dealt with has been unusually high, particularly as a public agency resource.

Questions of legality, economic fraud, trade puffery, and misleading and/or false advertising are properly to be dealt with by the

[5] Nine other states have advisory committees of some kind. Michigan calls on state university personnel when needed, as does Oregon, Virginia, Kentucky, and Kansas. Massachusetts has a board representing the industries regulated by the commission. Wisconsin's board acts on the framing of regulations, while Pennsylvania and New Mexico have committees similar in character and function to that of Connecticut.

Commission. The acceptance by the Committee of various advertisements and labels for decision as to truth or falsity has constituted the acceptance of a function beyond its stated scope. The stipulated purpose of the Committee was to determine "the therapeutic status" of products not that of deciding whether an advertisement is misleading.[6] It would seem that a committee of this type can best serve the public interest if it functions in the manner of a ballistics expert in a court trial. He may properly testify that a bullet (that caused a death) was fired from a particular gun. He does not presume to declare the defendant guilty of murder.

With the exception of its (later) sponsorship of the Hazardous Substance Labeling Act, and more recently sponsorship of a bill to permit the use of stray dogs for medical research, the committee has succeeded in avoiding political involvement. There is no evidence to suggest that either as a body or as individual members has the committee been influenced by any political considerations, partisan or otherwise.

Because the reports of the Committee's activities do not reflect divergence of opinions among the members, it is difficult to appraise their individual independence of thought and decision. From discussions with members of the Committee, it is known that decisions were not always unanimous, but that by majority vote, decisions were made the decisions of the group. Inasmuch as Committee decisions, by postulate, carry weight with enforcement agencies, a statement of both the majority and minority opinions might well be issued and made a part of the permanent record of the Committee's work. It is particularly desirable that the reasoning and/or the facts on which such decisions are made be included. To some degree, this is being done in the reports distributed to sponsoring agencies, but more detail is desirable as is the identification of the disciplines represented by those participating in the decisions. Reports of opinions in each case considered are needed for proper enforcement decisions and they are important to those affected by the decisions

[6] It would seem that the consulting resources of the Committee might be enlarged to include a lawyer, for interpretation of legal matters and for consultation on the legal facets of follow-up procedures, as well as to aid in meeting with manufacturer legal representatives on more equal terms. A social psychologist (or perhaps a psychiatrist, for his grounding in medicine) might prove useful in helping to interpret human behavior with respect to various products, their labeling, advertising and so forth. Because some evidence submitted by manufacturers has been based on statistical techniques, the contributions to be made by a research statistician seem clear.

since the reasons or facts given may bear heavily on the future actions of the firms concerned.

Moreover, minority decision reports deserve notice since they also should bear on enforcement decisions. Any court action arising from enforcement might well have need of minority opinions.

Because the composition of the Committee changes over time, complete reports including both majority and minority views and the number of adherents to each should prove of considerable value to new members.

The stated purposes of the Committee do not include passing judgment on whether a particular advertisement is misleading or false. That is the function of the enforcement agency. The task of the Committee is to provide information, gained from its knowledge of the product ingredients or from suitable tests or analyses, upon which the commission can make its own decisions. To do otherwise is to risk the Committee's becoming a crutch with a consequent weakening of enforcement independence. While such a Committee ought properly to consider carefully and without preconceptions the therapeutic status of any product, particularly new drugs or devices, such a Committee's time can best be devoted to those products portending the greater public health hazards and to the technical aspects thereof. Finally, because products are sometimes embargoed pending a decision from the Committee it is important that such crucial issues be resolved with a minimum of delay. By avoiding consideration of matters beyond its scope, and of matters not requiring the attention of specialists, and by constant awareness of the importance to the business interests concerned of promptly-reached decisions the Committee can make its contribution to the public welfare even more substantial.

Contributions of Committee

The activities of the Connecticut Advisory Committee on Foods and Drugs during the first decade of its service have constituted a valuable contribution to the commission, to the public and to business.

The Committee has given enforcement officials much technical information upon which to base enforcement decisions. Advice gained from the Committee has enabled officials to prevent the sale of products having implicit hazards that could easily escape the notice of those without a technical background. It has also aided officials

to avoid mistakes in banning the sale of essentially harmless goods. Thirdly, it has helped officials to draw rational conclusions from conflicting evidence.

The presence of the Committee has given new stature to food and drug law enforcement by prestige and by direct assistance in meeting with the technical advisers of business firms. It has led to more vigorous, informed law enforcement; and from the discussions and opinions of the Committee enforcement officials have gained educationally.

The existence of the Committee in Connecticut has established a precedent of worth for more states to adopt. The work of the Committee members, often in their own laboratories, has saved the state the expense of buying comparable services in the open market.

By explaining the technical deficiencies involved, the Committee convinced the promoters of various questionable products of the economic and therapeutic futility of investing further in their production and distribution.

The mere existence of such a committee and the recognition of its influence acts as a deterrent to the promotion of products inimical to the public welfare, while at the same time representing a valuable resource for business whose products can meet the tests given them by competent technicians. Doubtless, also, the existence of the Committee has caused producers to take a second look at their labels and product claims before releasing them for public consumption in Connecticut.

In summary, despite the shortcomings that can easily plague a pioneering effort, the Committee has enabled the Connecticut Food and Drug Commission to achieve a higher level of service to the people of the state. **[The End]**

FDA DISCLOSES SAMPLE MISHANDLING

The Food and Drug Administration reported recently further confirmation of the dangers inherent in the mishandling of physicians' samples of prescription drugs. Recent seizures of such drugs brought the total of seizures to ten.

The latest label mixup was found in a pharmaceutical company. A seized package was labled Phenaphen, which is an analgesic mild sedative combination. However, the package actually contained Dexedrine capsules, a strong stimulant. The substitution of this drug for Phenaphen can cause serious consequences, particularly for elderly, debilitated persons, FDA said.

California Pure Foods and Drugs Acts and Related Laws

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This Article Was Presented as a Lecture at the University of Southern California Law School, March 1, 1961. The Author is Chief of the Bureau of Food and Drug Inspections, State Department of Public Health of California.

IT IS WITH A SENSE OF PRIDE that I again appear on a program at the University of Southern California at the invitation of your Dean—Robert Kingsley. It will have been seven years on May 15 that I first addressed a group here.

The Food Law Institute is doing a real service in sponsoring such a program.

I am addressing you as an administrator of a regulatory agency. I have been engaged in food and drug regulatory work for the past forty-seven years, and I have had a real opportunity to see the progress made in food and drug legislation over the years.

California has had a long and illustrious history of food and drug legislation. At the first session of the California legislature—which met in San Jose in 1849—California adopted an omnibus bill which included Section 125, pertaining to the adulteration of foods, which reads as follows:

> If any person or persons shall knowingly sell any flesh or any diseased animal or other unwholesome provisions, or any provisions or liquors, every person shall be fined NOT more than $500.00, or imprisoned in the County Jail NOT more than six months.

On April 16, 1850, Peter H. Burnett, our first governor, signed this bill. It is of particular interest to note that bills passed by the legislature were written in longhand.

This marked the beginning of food control in California.

In 1872, just two years after the establishment of the State Board of Health of California, this statute was incorporated into Sections 380 through 383 of the California Penal Code.

In setting up these laws, the legislature did not delegate any particular agency to administer them. Action was left to the discretion of local peace officers, which proved very unsatisfactory. Forward-looking men soon found that these laws were inadequate for the protection of the public health. Through their efforts the legislature approved the first California Pure Foods and Pure Drugs Act. On March 11, 1907, just one year after the famous Wiley Pure Food and Drug Law of June 30, 1906, the first California Food and Drug Law became effective.

The State Board of Health at that time established the State Food and Drug Laboratory, and Professor Meyer E. Jaffa, Professor of Nutrition, University of California, was put in charge as Director.

California always has been a strong proponent of uniform food and drug legislation. In 1939, I submitted to the California legislature the model uniform food and drug laws which were approved and became effective on January 1, 1940. Both the food and drug law are incorporated in the Health and Safety Code, under Division 21—namely: Chapter 3—Foods; Chapter 2—Drugs.

I call your specific attention to the following section of the California Pure Foods Act which is very important:

Section 26465. The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

The term "food additive" does not include any of the following:

(a) A pesticide chemical in or on a raw agricultural commodity; (b) a pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; (c) any substance used in accordance with a sanction or approval granted prior to the enactment of this section at the 1959 Regular Session of the Legislature pursuant to the Federal Food, Drug and Cosmetic Act (52 Stat. 1040), the Poultry Products Inspection Act (71 Stat. 441), or the provisions of the Act of March 4, 1907, Chapter 2907 (34 Stat. 1256); (d) any substance used in accordance with a sanction or approval granted pursuant to this chapter, Article 1 (commencing

at Section 301) of Chapter 1, Division 3 of the Agricultural Code, Article 2 (commencing at Section 377.1) of Chapter 3, Division 3 of the Agricultural Code, or Chapter 2 (commencing at Section 450) of Division 4 of the Agricultural Code, or Article 1 (commencing at Section 460) of Chapter 3 of Division 4 of the Agricultural Code, or Chapter 6 (commencing at Section 560), of Division 4 of the Agricultural Code, or Chapter 7a (commencing at Section 1081) of Division 5 of the Agricultural Code.

California was the first state to incorporate the food additive section.

Some of the current hysteria has been aroused by the misconception that chemicals are harmful, or the related idea that any amount of a "poison" is harmful. The fact is, that chemical additives or *food additives* as they are now called, have played a very important part in improving our food supply. Vitamins, baking soda or baking powder, iodine and salt itself form an important part of our diet, yet they could be harmful if consumed in excessive amounts. We must not be alarmed by the word chemical—food itself is a chemical compound consisting of fats, proteins, carbohydrates, vitamins, minerals, amino acids, etc. As Doctor Frederick J. Stare, Professor of Nutrition at Harvard, bluntly stated recently: "Goodness is still in our food. The poisons are in the pens and tongues of those who by peddling misinformation, half truths, statements out of context and downright falsehoods, gain some temporary notoriety, inflate their own egos and a few make a profit or hope to."

We do not underestimate the problem which can be created by the mis-use of pesticides or other chemicals. The Food Additive Amendment to our Pure Food Law now requires that all substances used in food be proved to be safe by the manufacturer under the conditions of proposed use before it is marketed.

I should like to review with you some of the common food additives:

Nutrient Supplements.—In order for bread to be called enriched, vitamins and minerals must be added. These are Thiamine (Vitamin B_1), Riboflavin (Vitamin B_2), Niacin and Iron. Vitamin A is added to margarine and Vitamin D to milk. Potassium Iodide is added to salt so as to prevent simple goiter.

Non-Nutritive Sweeteners.—In order to provide special foods for people who must restrict their intake of carbohydrates, sugar substitutes are permitted under special dietary regulations. Saccharin, and Calcium or Sodium Cyclamates are commonly used for such foods.

Preservatives.—There are many different types of preservatives, each having a particular effect in preventing spoilage due to the activity of micro-organisms or because of chemical change. Propyl gallate is an example of a preservative used to prevent rancidity in oils. This is called an antioxidant.

When used in bread to prevent mold or rope, they are called inhibitors or antimycotic agents—this group includes acetic acid (vinegar), lactic acid, mono-calcium phosphate and sodium and calcium propionate. Sorbic acid is an anti-mycotic used on cheese.

Some agents affect color, flavor or texture and are called sequestrants. Common ones used in dairy products include salts of citric, tartaric and pyrophosphoric acids. Preservatives familiar to you which are used to prevent food spoilage are benzoic acid, sodium benzoate, sulfur dioxide, and sugar, salt and vinegar (acetic acid).

Emulsifiers.—These are used to ensure uniformity, smoothness and keeping quality in such foods as bakery goods, dairy products, and confectionery products. Examples are: Lecithin, mono- and diglycerides, and propylene glycol. They are sometimes known as surface active agents.

Stabilizers and Thickeners.—Such products are sometimes used to provide a homogeneous mixture as in certain fruit juices. They include harmless pectins, vegetable gums (such as carob bean, carragheen, guar, tragacanth and acacia), and gelatin, or agar-agar obtained from seaweed.

Neutralizing Agents.—The pH—that is, the potential hydrogen or acidity of foods—is very important. This affects the flavor, keeping quality, and taste. Baking powder, sodium bicarbonate, calcium carbonate, and tartaric acid are all examples of chemicals used to control the acidity or alkalinity of foods.

Bleaching Agents.—Since fresh milled flour makes very poor dough, it is aged so as to react chemically with the oxygen in the air. This aging, with its accompanying storage problems, is avoided by the use of oxidizing agents such as benzoyl peroxide, chlorine, oxides of nitrogen, and potassium bromate.

Dough conditioners which act as yeast foods include ammonium chloride, calcium sulfate and ammonium or calcium phosphates.

A very large list of substances is included as flavors which are used in beverages, bakery goods, confectionery, etc. These may be

either synthetic or natural and chemically identified, as for example: amyl acetate, benzldehyde and methyl salicylate.

Mono-sodium glutamate obtained from plant protein is a useful food and a valuable seasoning agent. There are many others, including anti-caking agents, clarifying agents, antifoaming agents and colors. All are chemicals and some have jaw breaker names which may appear formidable. However, it is important to remember that the declaration of a chemical name on a label does not mean that the food is dangerous or of inferior quality. All have one thing in common, they are harmless when used according to good manufacturing practices.

I have stated that the term "food additives" does not include pesticides which are used on raw agricultural commodities. That is the reason we here in California have a cooperative relationship with our State Department of Agriculture and our Farm Advisors throughout the State.

Of particular interest in this regard is the fact that Governor Brown appointed a Special Committee on Public Policy Regarding Agricultural Chemicals on June 15. 1960, to suggest a compatible policy that will serve as a safe guide to all our agencies.

This Committee met once in Berkeley, once in Los Angeles, and four times in Sacramento, to receive testimony from many authorities regarding agricultural chemicals, their significance to health, and the protection afforded our people under the controls enforced by government and industry.

The findings of this Special Committee were as follows:

(1) Agricultural chemicals are necessary to production of food and fiber crops in the quantities needed by the increasing number of people in the United States.

(2) Safeguards are essential and are now provided in the use of agricultural chemicals to insure protection from deleterious pesticidal residues on food for humans and feedstuffs for livestock. Bees, fish and game, soil and water also require protection and are protected. Present laws, practices, and administrative procedures should be regularly reviewed to insure their continued adequacy. Vigorous enforcement should not be relaxed. The present security cannot be assumed to be continued in a situation that is still rapidly developing if official vigilance should be relaxed, or if governmental programs are not expanded as the problem grows and becomes more complex.

(3) All users of pesticides, farmers certainly, but home gardeners as well, should be encouraged through a continuous campaign of education, to follow directions explicitly, since directions are carefully prepared and are provided to assure safe and proper use without hazard to the applicator or danger of excessive residue. All identified poisonings caused by agricultural chemicals in California have so far been among users and applicators, or children, bystandards or workers accidentally exposed. Such incidents have happened in kitchens, and back yards, as well as and even more frequently than in fields.

(4) Public concern should be allayed by informing consumers of fruits, vegetables, meat, milk and other produce of the protection they are receiving. The comprehensive laws regulating agricultural chemicals in California complement the federal laws and provide the best protection afforded anywhere. The California State Department of Agriculture and other enforcement agencies should report factually more frequently on their work and the current situation.

(5) Research should be intensified in all areas pertaining to the use, toxicology and effects on health of agricultural chemicals and in finding better pest control measures. The research should continue to include not only development of safer pesticides and more efficient methods of analysis, but also alternative measures such as biological control and the development of pest-resistant varieties of crops.

(6) Since the cranberry incident in November, 1959, cooperation has improved greatly among government agencies at all levels, among those who deal in and use pesticides, and with the public. It is in the interest of all that cooperative attitudes be continued and encouraged.

(7) Agencies having responsibilities in the field of control, particularly the California State Departments of Agriculture and Public Health, the University of California and industry are to be commended for their effective work. The leadership of the California State Department of Agriculture in the marked improvement in 1960 in enforcement and regulation and understanding of the problem particularly in the dairy and farming community, is recognized by the committee.

The California Pure Foods Act, the California Pure Drugs Act, and the California Cannery Inspection Act and related laws are enforced by the Bureau of Food and Drug Inspections and may be found in the California Health and Safety Code.

This Bureau, which I direct, is in the State Department of Public Health, with its headquarters at Berkeley and with nine district offices throughout the State of California.

The Bureau is divided into two sections—namely: (1) Bureau of Food and Drug Inspection Section; (2) Cannery Inspection Section. Under the provisions of the California Pure Foods Act our work consists of the detection of the following: (1) Adulteration; (2) Misbranding; (3) False Advertising.

To put it in a nut shell, our job is to protect the integrity, wholesomeness, truthful labeling, and advertising of foods in the State of California.

With reference to the adulteration of foods, I should like to point out the following:

26470.—A food shall be deemed to be adulterated—

Poisonous or Deleterious Substances.—This can best be illustrated by the indiscriminate use of poisonous dusting power (Sodium Fluosilicate, "Floosie Dust") on dried beans which are susceptible to insect infestation, rodent contamination, etc. Such an incident happened in a certain locality; but, fortunately, we quarantined the product in question.

Soya Sauce Incident.—An error by the railroad in furnishing a tank car which had previously been loaded with sodium arsenate to a soy sauce manufacturer to transport sodium hydroxide resulted in thousands of gallons of finished soy sauce being quarantined and recalled from trade channels and destroyed.

DDT Residue on Spinach in the Field.—The Bureau—through trade channels—was notified that fields of spinach had been contaminated with DDT to control aphids. The dust had been applied too close to harvest rather than the prescribed time for safe use. An immediate quarantine was placed on the pack of 53,000 cases and later one fourth was destroyed under our supervision.

26470.—A food produced, packed, prepared or held under unsanitary conditions, whereby it may become contaminated with filth —Filthy, putrid, and decomposed products—

Poultry—Recently, the request had been made to ship in interstate commerce, from government inspected plants, some poultry to be used for animal food. It is fortunate that none had been received.

The matter was referred to the Attorney General's Office, which office reaffirmed that the California Pure Foods Act covers animals. I should like to point out here that this is where the Canned Animal Food Regulations protects the raw material going into cat and dog food.

Frozen Egg Products—Systematic inspection of frozen egg products stored in public cold storage warehouses in the Los Angeles area led to the discovery of nearly 70,000 pounds of unfit frozen egg products that had been stored in one warehouse by a small Los Angeles egg broker. The entire lot is under quarantine awaiting prosecution.

Strawberries—Rejected strawberries destined for use as hog feed were delivered to a jam and jelly manufacturer in Los Angeles area. Shipment was sampled and a large percentage of mold and rotten berries as well as extraneous material was found, including cigarette butts. The berries were diverted to a hog farm.

Macaroni—Drying tunnels in which alimentary paste products were hung to dry were found to be completely lined with a layer of grey-green mold more than four inches thick. The plant was immediately closed down and thousands of dollars were spent in cleaning and remodeling the plant.

Bakery—A large bakery was closed down after a detailed inspection revealed that the firm was using a very old flour transfer system which was heavily infested with insects. This infestation was found to have spread throughout the premises, even into electrical switch boxes where flour dust had accumulated.

Samples of finished bread were found to contain insect parts. The bakery was closed down, the old flour transfer system replaced, and the entire bakery fumigated and thoroughly cleaned. The operators were prosecuted for selling adulterated food.

26472.—This section provides that a food shall be deemed to be adulterated if any valuable constituent has been in whole or in part omitted or abstracted therefrom.

Economic Adulterations—(1) The use of yellow coal tar dye or carotene in egg noodles to imitate "eggs"; (2) Shortage of vegetable oil in the standardized product mayonnaise; (3) Shortage of fruit juice or berries in jams or jellies; (4) Excessive fat in hamburger—over 30 percent; (5) If damage or inferiority has been concealed in any manner; (6) In the case of pork sausage, if it contains more than 50 percent fat; (7) Refilling of whiskey bottles, (a) Substitution of

one brand for another—for example, cheaper or inferior brands; (8) Sale of imitation vanilla flavor for vanilla extract, (a) Flavor means the vehicle used is not alcohol, (b) Extract means the vehicle used is a hydro-alcoholic solution of the extractives of the vanilla bean.

Misbranding of Foods—Sections 26490 through 26496, California Pure Foods Act.

The mandatory information which must appear on the label of the food is that required by the California Pure Foods Act. This requires:

1. The product name; that is, the common name if any there be. Such a name should not be misleading and should give an accurate designation of the product.

2. The name and place of business of the manufacturer, packer or distributor. The place of business should include the street address if any, if the firm is not listed in a current city directory or telephone directory. If a person manufactures, packs or distributes a food other than at his principal place of business, the label may state the principal place of business in lieu of the actual place where each package was packed or distributed. If the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection the person has with the firm, as for example: "packed for," "manufactured for," "distributed by," or other phrases which express the facts.

3. The net weight. This should be in terms of the avoirdupois pound or ounces, or in liquid measure. The statement should express the number of the largest unit in the container; for example, 1 lb. 8 oz., or 1½ lbs., not 24 ozs.

4. The list of ingredients should be listed by their common name and they must be declared in descending order of predominance. If any ingredient is an artificial flavor, artificial coloring or chemical preservative, the label must state that fact.

Since the label is a "window" of a can or package, it should describe for the purchaser what is in the container in simple, clear, accurate language. It is our desire and the intent of the law that the consumer be thoroughly and completely informed regarding the product and that this information be provided in terms and with details that are easily understood. This required information should appear on the label conspicuously and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Most consumers have learned by

experience to rely on brand names or trade marks under which the particular type of product is distributed.

Additional information regarding distinguishing characteristics and methods of use are usually supplied. A high standard of integrity and fairness beyond technical truth and accuracy is expected. Any label which misleads or tends to deceive can be considered illegal and subject to action under the law.

I can best illustrate "misbranding" by the following statement:

Labels and labeling on products are the means of furnishing the customer the information he needs to be an intelligent purchaser. The label contains information required by the law for the consumer's protection so he knows he is getting his money's worth and guarding his family's health. The label is required to tell what is inside the package.

There is quackery in the field of nutrition as well as in the field of medicine. We have been particularly concerned regarding the promotion of health foods, food supplements or dietary supplements as cure-alls for conditions which really require medical attention. Modern, as well as ancient superstitutions and myths are revived and new ones are constantly exploited. For example: Fish and celery are represented to be brain foods; Oysters for increased fertility; Garlic pills are used in the treatment of high blood pressure; Grape and cabbage juices for the treatment of ulcers; Royal Jelly for impotence; Aluminum utensils as dangerous for cooking.

These promoters rarely make direct claims, their half-baked theories are written in books or are eulogized by self-styled nutritionists and health food clubs who hold meetings at regular intervals in cities throughout the State. Nothing is actually sold at these meetings; however, those in attendance are later circularized or visited by door-to-door salesmen. The scare technique and false ideas about foods are the stock in trade of these individuals.

Food faddists have questioned the nutritive adequacy of our ordinary daily diet. They have endeavored to undermine confidence in our food supply. As a result, some consumers have the impression that all food processing or preservation is injurious. They have fostered the belief that anything which is processed is "devitalized" or actually injurious. Actually, modern methods of food processing have been developed which protect the nutritive content of most of our foods.

Growing of special varieties, harvesting at the right time, and modern packing procedures have resulted in food production of high nutritional quality. For example, canned or frozen orange juice retains 98 per cent of the Vitamin C that is present in oranges picked from the tree.

The exploitation of people by those who sell "natural organic" foods is taking place. Fancy prices are being paid for imaginary properties and benefits. They spend their money on unnecessary products where, for much less, they can buy nourishing, common foods which give them all the nutrients a normal, healthy person needs in his daily diet.

This is just one of the reasons that the house-to-house hokum spouted by food supplement peddlers is dangerous By following these fads, the buyer runs the risk of depriving himself and his family of the essential nutrients found in a normal, conventional diet. Often children, who need plenty of nourishment for proper growth and development, are put on these deficient food supplement diets by their well-intentioned but misinformed parents.

I can call your attention to "prohibitions":

Section 26510.—The manufacture, production, preparation, compounding, packing, selling, offering for sale or keeping for sale, or advertising within the State of California, or the introduction into this State from any other State, Territory, or the District of Columbia or from any foreign country, of any article of food which is adulterated or misbranded is prohibited.

Section 26514.—Forging, counterfeiting, simulating or falsely representing, or without proper authority using any mark, stamp, tag, label or other identification emblem authorized or required by regulations promulgated under the provisions of this chapter is prohibited.

Section 26516.7.—It shall be unlawful to keep or display any perishable canned meats, canned meat products, and packaged processed fresh foods which will support the growth of pathogenic microorganisms at a temperature exceeding 50 degrees Fahrenheit. All such packaged food shall be conspicuously labeled, "Perishable—Keep Refrigerated."

Section 26516.4.—It shall be unlawful for any person to:

(a) Make, publish, disseminate, circulate or place before the public any advertisement relating to the sale of meat where the adver-

tisement contains any assertion, representation or statement which is untrue, deceptive or misleading or falsely represents the kind, classification, grade or quality of any meat so advertised; (b) Use any term of quality without using or having for sale the quality of meat advertised or offered for sale; (c) Designate any quality of meat as "A" or "AA" or any other term indicating grade; (d) Use the term "USDA", "U. S.," or any other term denoting that the meat is graded by the United States Department of Agriculture, unless the official grade is also designated; (e) Designate or use any brand name of a company unless the meat so advertised or displayed for sale is of a quality which the use or designation of the brand name of such company would reasonably indicate; or (f) Possess or use any meat marking stamp, instrument, label or tag depicting "USDA," "U. S.," or any other term implying an official meat grade unless the stamp, instrument, label or tag has been approved by the United States Department of Agriculture.

Section 26516.5.—It shall be unlawful to advertise or display for sale:

(a) Any meat of the ovine species that is two years old or over, as "yearling" or "lamb." Such meat must be clearly designated as "mutton." (b) Any meat using the words "Prime," "Choice," or "Good" unless such meat advertised for sale actually bears the USDA Federal meat grading stamp designating such grade; (c) Any ham unless the advertisement or display states whether the ham is skinned or regular; (d) Any ham portion as "one-half" or "half ham" that has had a center slice removed; (e) Any pork shoulder using the word "ham"; or (f) Any meat or meat product which has been branded or marked as imitation by a manufacturer or processor unless the advertisement or display clearly states that such meat or meat product is an imitation.

Section 26517.—(a) No person shall sell, offer for sale or keep for sale distilled spirits in any package which has been refilled or partly refilled; (b) No person shall refill or sell, or cause to be refilled for sale any distilled spirits package; (c) No person, who, in response to an inquiry or request for any brand, type or character of alcoholic beverage, shall sell or offer for sale a different brand, type or character, without informing the purchaser of such difference.

Section 26518.—The possession, sale, or offering for sale of any adulterated or misbranded article of food by any manufacturer, pro-

ducer, jobber, packer, or dealer in food, or broker, commission merchant, agent, employee or servant of any such manufacturer, producer, jobber, packer or dealer, shall be prima facie evidence of the violation of this chapter.

I mention these few sections because some of these provisions DO NOT appear in any other Pure Foods Act—either state or federal. They are an act of the legislature.

Advertising

26500.—An advertisement of a food shall be deemed to be false if it is false or misleading in any particular.

I can best illustrate this by mention of low calorie bread, selling mutton as lamb, and the sale of meat products such as imitation bologna for a regular meat product.

We interpret the law in regard to advertising to mean any representation made to induce the purchase of food by any means whatsoever. Since the Bureau has jurisdiction over the advertising of foods and drugs in California which is disseminated through any media—newspapers, magazines, billboards, radio, television—and when we consider the tremendous amount of advertising engaged in, you can readily understand the problem which confronts the Bureau.

I am positive that everyone here—as well as we—is seriously concerned with the callous way in which some advertisers exploit public faith in scientific findings. Test data are misused, particularly in the field of health aids. This is considered one of the gravest abuses in advertising today. Advertisers may employ test findings which may or may not have scientific validity and through exaggeration, distortion or perversion they misuse it to deceive the public. Legally, the government must disprove any phony test data or claim.

We have never objected to an emphasis of quality which a product admittedly possesses, since we consider this as legitimate "puffing". On the other hand, if qualities are attributed to a product which it does not possess, we consider this as false and misleading advertising.

There are heartening indications that advertisers and advertising agencies are accepting their responsibilities to present competent proof of claims when we question them. In order for advertising to continue to merit your confidence it is trying to abolish the cynicism that says:

Let's go as far as possible to the border, for although we cannot prove our claims it will be difficult for anyone to disprove them.

However, I should like to point out that it is only the minority of the industry that violates the law with regard to "advertising".

Section 26493.—Labeling of standardized foods. This section of the Pure Foods Act provides labeling exemptions for declaration of ingredients in food for which a definition of Standards of Identity has been adopted by the Board. The standardized food must bear the name of the food specified in the definition of the standard and must list the common names of the optional ingredients present in such foods. Examples of food which would fall into this classification are mayonnaise, salad dressing, alimentary pastes, tomato products, jams and jellies, canned preservatives, canned fruits, canned vegetables, flour, bread, etc.

Administration

The provisions of the Pure Foods Act and the Pure Drugs Act are administered by the State Department of Public Health in accordance with Article 6, Administration, commencing with Section 26540 of the Pure Foods Act and Section 26320 of the Pure Drugs Act.

I shall go into standards for food products first. For the purpose of uniformity, in the majority of cases, the State Board of Public Health is empowered to promulgate standards under Section 26541, which reads in part as follows:

> In prescribing a definition and standard of identity for any food or class of food, the board shall for the purpose of promoting honesty and fair dealing in the interest of the consumer and . . . . The standards adopted under this section shall not require a higher standard than the definitions and standards promulgated by the Food and Drug Administration or by the United States Department of Agriculture, and the United States Bureau of Internal Revenue for distilled spirits.

However, the exception is with regard to wine. California has its own standards for wine. We define wine as the normal alcoholic fermentation of the juice of sound, ripe grapes. California-produced wines are of the highest quality. I am now referring to table wines (dry wines).

Sections 26548 and 26553 provide that the Board or its duly authorized agents shall have free access to all reasonable hours to any factory, warehouse, or establishment in which foods are manufactured, processed, packaged or held for introduction into commerce for the purpose of:

1. Inspecting such factory or warehouse, and 2. Securing samples of any food suspected of being adulterated or misbranded.

Quarantine

The California Pure Foods and Pure Drugs Act authorizes the State agent to quarantine food which he has probable cause to believe is adulterated or so misbranded as to be fraudulent and to affix to such article a tag giving notice that the article is or is suspected of being adulterated or misbranded. It should be noted that this procedure is not authorized under the Federal Act.

Section 26582 states that the food shall not be thereafter sold, offered for sale, or removed or otherwise disposed of until further notice in writing is received from the Board of Directors, or Chief of the Bureau of Food and Drug Inspections.

Under Section 26586 procedures are established for proceeding against such quarantined goods. It further provides that if the Board fails to commence proceedings against an article which has been detained or quarantined within 90 days, if such article is detained or quarantined, the Board shall immediately release said article from quarantine. It is the Legislature's intent that this section not cause undue hardship to persons owning such foods.

Hearings.

In the administrative procedure of the Pure Foods Act and the Pure Drugs Act provisions are made for the Chief of the Division of Laboratories or the Chief of the Bureau of Food and Drug Inspections for the issuance of certificates of quarantines on official samples of food and drugs. When a certificate certified to by the Chief, Division of Laboratories or the Chief of the Bureau of Food and Drug Inspections shows that any provisions of the food and drug acts have been violated, a notice together with a copy of the Certificate of Findings is furnished to the parties or parties from whom the samples were obtained. At this time hearings are usually set at which the interested parties may appear in person or by attorney and may propound any interrogatories or submit oral or written evidence to show any fault or error in the findings made.

If the examination or analysis is found to be correct, or if the party fails to appear at such hearing after notice duly given, a certificate of the facts so found is forthwith transmitted to the district attorney of the county, or to the prosecuting officer of the city, in which the adulterated or misbranded food was found.

Decision Making

When is a case referred to the district attorney? A great deal of administrative judgment is used in determining this action. Factors which are considered are: (1) The effect on the public health. An example—when dangerous or poisonous substances are involved; (2) What caused the violation? (3) Has the manufacturer taken proper control measures to prevent such occurrences—past and future? (4) Is this a deliberate violation or an unavoidable error? (5) Is this party a chronic violator? (6) Does the party have reliable evidence to show that our findings are in error?

The law states that nothing in the Act shall be construed as requiring the board to report for the institution of proceedings under the Act, minor violations, whenever the board believes that the public interest will be adequately served by a suitable written notice of warning. Administrative action may be taken to correct the violation. It is not the intent of the law to destroy good foods.

If a firm has shown good faith and will take necessary steps, provided it can be done, to correct the adulteration or misbranding, the matter may be held in abeyance pending compliance with the provisions of the law.

Ignorance of the law is no excuse! The manufacturer is responsible for knowing the provisions of law. We have always contended that they should seek legal counsel to answer any question. Open door policy—The Bureau always welcomes discussion of our common problem. Our record in this field has not been most outstanding. Privacy of Bureau record—Information obtained under the provisions of the Act is classified as confidential. This is rightfully so because of our access to trade secrets. Records can be obtained however on court order.

Pure Drugs Act

The Pure Drugs Act carries the same general administrative provision as the Pure Foods Act. There are several provisions of this Act, however, which should be considered. Because of the inherent dangers of potent drugs, they are subject to much more exacting methods.

The specific differences which should be noted are: 1. *Labeling and Misbranding*—Section 26243(a)—Only the amount and kinds of active ingredients need be declared; Section 26243(b)—The percent of alcohol and amount of bromides, codeine, barbiturates, strychnine, etc., must be declared; Section 26254(c)—The quantity of morphine,

barbiturates, chloral hydrate, peyote, etc.; Section 26244(d)—Must give adequate directions for use as well as proper warning regarding unsafe dosage and possible physiological dangers or use by children.

Typical violations in this category are: (a) Failure to give proper directions for use; (b) Failure to give adequate warnings; (c) Failure to properly declare the active ingredients.

2. *Adulteration*—Sections 26230 through 26235 define adulteration. These sections of the California law are substantially the same as in the Uniform State Act and the Federal Act. As in these laws, the U. S. Pharmacopoeia, U. S. Homeopathic Pharmacopoeia and the National Formulary are used as standards of strength, quality or purity. A drug is deemed to be adulterated if its strength differs or its purity falls below the professed standard or quality under which it is sold.

We have had many cases of adulteration. Perhaps the most common example of this is the substandard drug. Also, drugs are subject to deterioration. For example: (1) loss of vitamin potency, (2) evaporation of solutions, (3) outdating of biologicals. The most dangerous example of the adulteration problem is the careless manufacturer who does not label raw materials or does not pack his product under strict controls and sanitary conditions. It takes little imagination to see the danger of this type of adulteration.

3. *False advertising of drugs or devices.*—The most striking feature of the advertising sections is the prohibition against advertising a drug or device to have *any effect* on diseases which the board has classed as unsafe for self-medication. Note: this does not require a claim for *cure*—only "any effect". Section 26286.5 lists approximately 50 diseases in this class—examples: heart disease, cancer, diabetes, ulcers.

California is a mecca for quacks and medicine-men because of its high population of retired elderly people who are more susceptible to chronic diseases and prone to be easy prey for quacks.

California has had an outstanding record in this field and has many examples of outstanding work. The administration of this type of activity requires a great deal of coordination of many scientific fields, such as medicine, legal (law), electronic, physics, chemistry and crime detection.

Case Examples

Turnip Juice Case—Cancer Cure.—In 1948 the Bureau prosecuted three individuals in San Francisco on a charge of conspiracy to violate provisions of the Pure Drugs Act. This involved the sale of turnip juice at $25 per vial for the treatment of cancer. Since then there has been a constant rise in the number of investigations and trials, amounting to a 10-fold increase during the past decade. A factor in this increase has been the steady rise in population and the fact that California attracts the elderly.

Calozone Case—Sold as "God's Gift to Humanity," the Calozone Ozone Generator was advertised to have curative effects on 47 diseases, including cancer, diabetes, heart disease and polio.

Over 3000 of these worthless devices were sold in California, for $150 each.

Competent medical authorities testified that the device was not only worthless as a therapeutic instrument, but that it could be dangerous because of the high concentration of ozone produced.

The four men involved in this action were charged with conspiracy to commit a misdemeanor—to wit: the false advertising of a device. All four entered pleas of guilty. The fine ranged from $2500 and one year in jail to 3 months in the county jail.

This case, as well as many other cases, was made possible through the outstanding efforts of the district attorney, who took a great interest in this work.

Film-O-Sonic—This device was advertised to have an effect on cancer. The device played a continuous tape-recording of "Smoke Gets In Your Eyes". The music could not be heard; however, the vendor claimed that electrical impulses from the music which entered the body through pads connected with the machine would cure cancer. The defendants in this case paid sizeable fines; one spent six months in jail.

Pearlie Savely Cancer Salve, Lemoore—1957—Another cancer quack in Lemoore used a concoction of blood root, galangal root, and zinc chloride.

The quack, Pearlie Savely, claimed he could diagnose cancer by applying the salve to the suspected spot. If the salve affected the skin, according to Savely, it was a cancer and he would continue to apply the salve until a sizeable piece of burned flesh would separate

from the surrounding flesh. Actually, of course, the salve had a powerful corrosive and caustic action on any flesh, acting much in the same manner of a powerful corn plaster.

Any victim who came to him with a skin blemish, mole, or wart of any kind would be told he was suffering from cancer and would eventually lose some portion of his anatomy.

Savely had several jars of various sized pieces of flesh preserved in alcohol which he boasted were cancers he had removed from people. He added that if he had saved all the cancers he had removed from people in over 58 years of practice, they would fill a wash tub.

Some of the specimens from the jars were examined by a pathologist who said he could find no evidence of cancer.

After diagnosing and treating a small mole on the shoulder of a volunteer operative as a "mole cancer," Savely was arrested by agents of the Bueau of Food and Drug Inspections and the Board of Medical Examiners.

February 19, 1957, Savely pleaded guilty to a charge of practicing medicine without a license and sale of a misbranded drug. He paid a fine of $400, made restitution of $250, and served the first ten days of a thirty day jail sentence. He was put on probation for two years.

Cannery Inspection

The Cannery Inspection Act is unique in the United States. It provides for the licensing of premises packing non-acid foods in hermetically sealed containers, and establishes an elaborate control system to ensure proper time and temperature cooks for such products.

The Cannery Inspection Section is a specialized section of the Bureau of Food and Drug Inspections whose primary function is the enforcement of the Cannery Inspection Act and the State Board of Health regulations relative to cannery and food and drug inspections.

The Act was enacted in 1925 after a series of 22 botulism poisoning outbreaks between 1919 and 1925 affecting 131 people, causing 58 deaths, and involving commercially canned California products. The entire canning industry of California was in serious jeopardy until the enactment of the Cannery Inspection Act, the start of daily cannery inspections, and the adoption of regulations governing the heat treatment of low acid canned foods.

It was at this time that the services of Dr. Karl F. Meyer, the world's foremost authority on canning technology and the prevention of botulism, were obtained by the canning industry to conduct research, and formulate controls for the prevention of botulism. Dr. Meyer is still actively engaged in this work as Chief Consultant to the California State Department of Public Health, and is directly in charge of the two laboratories maintained by the Cannery Inspection Section within the University of California, one at the Medical Center at San Francisco handling the work of fish research, and the other in Berkeley which handles the work for all of the other products under inspection.

All retorts used in canneries licensed by our Department are hooked up, vented, and installed according to the Retort Regulations of the Department, and are equipped with recording thermometers, mercury thermometers and pressure gauges as required by the Cannery Inspection Act. The recording thermometers are tested yearly and sealed by a representative of our Department. The retorts are vented and the cans processed at times and temperatures specified by the Regulations which are promulgated for each size can and each product. The recording chart is stamped with the seal and numbered by our Inspector for identification and each and every chart must be accounted for in a prescribed manner.

Each retort load is recorded on a production record kept for the Department on which the following information is recorded: temperature chart number, batch, retort number, size can, number of containers, code, time steam is on, time vents are closed, time cooking temperature is reached, time process is finished, the number of minutes that the batch is cooked at processing temperature, and recordings from the mercury thermometers, recording thermometers and pressure gauges at the begining and the end of the cook. Our Inspector checks the operation of the retort several times each day and observes the instruments. He calipers each temperature curve on the temperature charts to ascertain whether or not each batch has been given the regulation sterilization process with reference to time and temperature and whether the production record and charts have been recorded in the prescribed manner, by the retort operator.

The inspector is also responsible for the observance of the cookroom requirements which are designed to prevent any uncooked material from reaching the warehouse and also to prevent incipient spoilage in certain products before retorting. If the inspector's daily

inspection report, cutting report and examination of the temperature charts and production records reveal everything is in order, he stamps and signs the production record "released for shipment" and the duplicate production record and chart stay with the canner and the original production record and the inspector's reports containing all the pertinent information regarding the entire operation are sent to the Department for filing. These records are kept for a period of eight years. Any irregularities would result in the material being restrained and referred to the laboratory for their recommendation.

All of the official sterilization processes are developed by our two consultant laboratories by very intricate technical methods which include the determination of the rate of heat penetration and the use of thermocouples actually embedded in the center of the container. Much of this heat penetration work is done under actual working conditions at the canneries. The determination of processes also involves highly technical work on thermal death time studies, bacteriological examinations, etc.

Each retort operator is given a written and oral examination and if he shows proficiency is issued a retort permit by our Department. This entitles him to operate retorts for the sterilization of low acid products under our inspection.

The inspector is also responsible for conditions in the warehouse, enforcement of the spoilage regulations of the department, and restraining any abnormal material appearing in the warehouse, and also the labeling of the cans with reference to the requirements of the California Pure Foods Act.

The inspector is also responsible for the sanitary conditions of the entire plant and warehouse including unloading docks, and surroundings. He is instructed to make sanitation his number one item, and actually his sanitary inspection is carried out for the entire time that he is on duty. This includes rodent control, sanitary conditions during operation, daily plant clean up, and general good housekeeping.

Products coming under the provisions of the Cannery Inspection Act include fish, spinach, asparagus, olives, miscellaneous vegetables, specialties and animal food. The same regulations and inspection that apply to fish apply to these products from the time the material has been placed in the can. These products must comply with all the provisions of the California Pure Foods Act, must be free from spoilage, contamination and adulteration and meet any specific regulation

of the California State Department of Public Health, such as in the case of spinach—maximum cut-out weights, minimum gross weights; artichokes—maximum fill weights; animal food—certain formula requirements. Some products such as artichokes, Spanish rice, and vegetable juice are controlled by acidulation and the inspector is required to make titrations and pH determinations, and all such products must meet the pH requirements before being released.

Cannery Inspection has become instrumental in raising the quality and safety of California canned products to the highest in the United States. This fact is generally recognized by the trade, research institutions, and educators throughout the world, and is evidenced by continuous inquiries from all over the world for information regarding cannery inspection work in California. The success of the Cannery Inspection work has been due in no small part to the whole-hearted cooperation of the canning industry, and is an outstanding example of cooperative effort between industry and government. It is significant to note that there have been no outbreaks of botulism in commercially canned California products since the inception of daily cannery inspection in 1925.

During the past year there were 167 licensed canneries packing low acid products under our inspection. These canneries packed during the year a total of 51,547,330 cases.

Every container packed in the state of California under inspection, either tin or glass, is die-embossed code marked on the lid with the code which has been approved and is on file with the Department and which designates the plant where the material is packed, the year it was packed, the day, and the batch number, which would give us the time of the day it was packed. In case of any controversy at any time, by checking the code marking with our production records, it is possible to identify any can that has been packed under inspection with the packer, the time it was packed, the temperature curve reporting the sterilization process it was given, and through the Inspector's reports the condition of the material that was used, etc.

In fish canneries, we maintain continuous inspection and our inspectors have the responsibility of passing or rejecting all fish received for canning on the spot and the rejects during the year amount to many thousands of tons of fish, valued at hundreds of thousands of dollars. Last year there were approximately 6,000 tons of fish rejected, mostly tuna, valued at one and one-half million dollars.

Our inspectors apply an average of 275 restraining orders per year throughout the state, which involves many thousands of cases of canned goods valued at hundreds of thousands of dollars. In the enforcement of the Cannery Inspection Act, and the Fish Regulations of the Department of Public Health, covering commercial canning of fish in the state of California, the entire process is supervised and controlled by the cannery inspectors of this Department from the time the boat is tied to the wharf until the finished product is labeled, cased, and shipped from the cannery's warehouse. **[The End]**

DRUG BOOTLEGGING BOOMS

The bootlegging of amphetamine drugs is consistently being punished by Federal prison terms, the Food and Drug Administration reported recently

FDA said that a survey of cases in which jail sentences have been imposed for violation of the Federal Food, Drug, and Cosmetic Act since July 1, 1960, showed that prison sentences had been imposed 22 times—16 of them involving bootleg sales of stimulant amphetamine drugs to truckers.

"These sentences reflect a growing realization by district attorneys and the courts of the serious effect of such violations," Commissioner of Food and Drugs George P. Larrick said. "We hope that the severity of the penalties being imposed will act as a deterrent to other would-be violators."

In recent years there has been an increasing use of drugs which are either stimulants or depressants and which, when taken under proper medical supervision, prove helpful in selected cases of obesity, mental depression and a number of other conditions. However, when misued, they can produce excessive nervous stimulation, loss of desire for sleep, impairment of judgment, hallucinations and mental derangement.

Continued use of the drugs may require increased dosage to obtain desired effects and, in susceptible individuals, a dependency on them sometimes develops. Acute toxic effects which also can result may release tendencies toward suicide and homicide and may have adverse reactions in certain conditions such as high blood pressure, heart disease and diabetes.

They can become the accomplice of highway tragedy, organized crime, juvenile delinquency and drug addiction, according to Commissioner Larrick. For these reasons they must be sold under prescription. Of late, however, the illegal sale of these drugs has become a racket of major proportions, especially at truck stops where they are sold to drivers ostensibly to help them keep awake. Serious accidents have been attributed to the effects of these drugs.

The Scientists' Forum

By BERNARD L. OSER

President and Director, Food and Drug Research Laboratories, Inc.

This Article Explains the Work Done by the Expert Panel on Food Additive Matters Organized by Dr. Oser for the Flavoring Extract Manufacturers' Association.

IN THE COURSE OF ASSISTING its members to comply with the provisions of the Food Additives Amendment, the Flavoring Extract Manufacturers' Association early realized that a major problem arose in determining whether or not a particular food ingredient is generally recognized as safe (GRAS) and hence excluded from regulation under the Amendment. The background of this problem and the need for expert opinion on this question was discussed in an article by Dr. Richard L. Hall, Chairman of the FEMA Food Additives Committee, in 14 *Food Technology* 488 (1960). In accord with its announced program, the Committee authorized Dr. Bernard L. Oser, as FEMA's consultant on food additive matters, to organize an expert panel to advise whether or not each specific flavoring substance is GRAS.

The members of the expert panel were selected to represent a variety of scientific backgrounds and for their outstanding professional competence and reputations in their respective fields of interest. In serving on this panel, they have acted in their individual capacities, and not as representatives of the organizations with which they are affiliated. The panel consists of:

David W. Fassett, M. D., Laboratory of Industrial Medicine, Eastman Kodak Company, Rochester 4, New York.

Horace W. Gerarde, Ph. D., M. D., Medical Research Division, Esso Research and Engineering Company, Linden, New Jersey.

Maurice H. Seevers, Ph. D., M. D., Department of Pharmacology, University of Michigan Medical School, Ann Arbor, Michigan.

Howard C. Spencer, Ph. D., Biochemical Research Laboratory, The Dow Chemical Company, Midland, Michigan.

Jakob A. Stekol, Ph. D., Department of Physiological Chemistry and Nutrition, Institute for Cancer Research, Fox Chase, Philadelphia, Pennsylvania.

Lauren A. Woods, Ph. D., M. D., Department of Pharmacology, College of Medicine, State University of Iowa, Iowa City, Iowa.

In its early meetings, the panel established certain general criteria to guide it in its judgments. In subsequent meetings, the available evidence on approximately 1300 flavoring substances was thoroughly examined and decisions were made as to which are GRAS under the conditions of use. A report on the progress of the panel's deliberations was presented by Dr. Hall at the recent annual meeting of the Institute of Food Technologists in New York.[1]

Information used by the panel has come from an industry-wide flavor additive survey, available literature on the toxicology and metabolism of the substances under consideration and, in large part, from the expert panel's background of knowledge and experience.

The FEMA Flavor Additive Survey has provided information on all flavoring ingredients believed to be in current use regarding the foods in which they are used, their importance to industry, length of time in use, levels of use in various classes of foods, total estimated annual volume of use, and the available toxicological data.

Particular consideration has been given by the panel to information derived from biologic and metabolic studies, to the occurrence of the same and related substances in natural foods, and to the levels, volume, and pattern of use in foods. The substances were evaluated on the assumption that they conform to the identity implicit in their indicated names. The panel has repeatedly reviewed its actions, both with a view toward consistency of judgment and toward formulating more detailed and stringent criteria. Each determination that a substance is GRAS has represented the unanimous decision of the panel.

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[1] Richard L. Hall, and Bernard L. Oser, "Recent Progress in the Consideration of Flavoring Ingredients Under the Food Additives Amendment, II." *Food Technology* (in press).

The original list of 250 flavoring substances and ingredients reported in April as GRAS, in the opinion of the expert panel, has recently been augmented to approximately 660. No conclusions were feasible on 12 substances not previously announced as dropped from consideration because of insufficient information or indication of commercial interest. One hundred thirty-two botanicals, essential oils, and extractives, not included on any of the FDA "white lists," could not be judged by the FEMA expert panel under its established criteria.

The FEMA has applied for an additional extension on the foregoing substances which are still under review. Some may require experimental investigation or the evaluation of other types of information. Where such data are obtainable or worth acquiring, industry is being given an opportunity to support the necessary activity. In many of the remaining cases, the limited commercial value of the substance may not justify further concern. Unless the companies affected act independently, these ingredients will doubtless disappear from use as the extensions expire.

This list will be appended to the report to be published in *Food Technology* (cited above), *What's New in Food and Drug Research* (the bulletin of the Food and Drug Research Laboratories, Inc., Maspeth, New York), *Food Processing* and other trade journals.

As has often been stated by FDA spokesmen such action is entirely permissible under the Food Additives Amendment. It is rather surprising that more industrial groups or trade associations have not availed themselves of the prerogative of promulgating lists of substances for whose GRAS status they are willing to assume responsibility. The FEMA activity with respect to flavoring substances relieves FDA of a tremendously costly and time-consuming burden of collecting and evaluating the data for what is by far the largest single category of additives to food. It is interesting to note that Dr. L. M. Beacham of FDA indicated in answer to a question from the floor at the IFT meeting that the Food and Drug Administration had no intention of challenging the decisions of this expert panel.

The FEMA expects that food firms will employ the published list of the expert panel as they do white lists in assuring themselves and their customers of compliance with the law. Interested persons may obtain further information from Dr. Richard L. Hall, Chairman of the Flavoring Extract Manufacturers Association Food Additives Committee, McCormick and Company, Inc., Baltimore, Maryland.

[The End]

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