VOL. 24, NO. 7 JULY 1969

Food Drug Cosmetic Law JOURNAL

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG 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: 1 year, $20; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

July, 1969
Volume 24 • Number 7

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . July, 1969

VOLUME 24 NUMBER 7

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Drug, Device, Cosmetic? Part II.—*Stephen Weitzman* presents the conclusion of his two-part article, beginning on page 320. Mr. Weitzman continues his analysis of the legal definition of "drug," "device" and "cosmetic" by summarizing facts involved in several recent cases. These cases provide sufficient subject matter against which case laws are examined. Mr. Weitzman has joined the law department of Borden, Inc., as attorney for advertising and labeling. The first part of this article was published in the May, 1969, issue of the FOOD DRUG COSMETIC LAW JOURNAL on page 226. The author has indicated that the following changes in Part I be noted: Page 235, paragraph 2, second and third lines, this report indicated [that] "within the third subsection . . . there were two distinct classes of products; and page 249, paragraph 2, first line, In 1953, a bill, H. R. 2244, 83 Cong. 1st Session. . . ."

The Rule-Making Authority of Boards of Pharmacy.—This article was delivered by *Henry Kane*, the Assistant Attorney General of Oregon, at a meeting of the National Association of Boards of Pharmacy, May 19, 1969. Mr. Kane says that in order to improve the rule-making process, it is necessary that attorneys, agency members and staff work in close cooperation in the planning and conduct of a rule-making hearing. The article begins on page 342.

Environmental Health Protection.—*Charles C. Johnson, Jr.* is Administrator for the Consumer Protection and Environmental Health Service of the Department of Health, Education, and Welfare. He warns that we are well on the way to creating a world which can have the most serious adverse effects on human health, and urges that all States re-evaluate and develop their environmental programs in an effort to establish a safe and healthy world for individuals and families. The article begins on page 348. In response to the interest that has been expressed in Mr. Johnson, as a key man in an area of increasing public concern, a brief outline of his background is included in this issue of the JOURNAL, at page 361.

GMPs—A Statistician's Point of View.—In *Charles DeWitt Roberts'* article, beginning on page 362, the author gives his views on "The inflexibility of some of the GMP regulations to take into account the highly developed mathematical theory of probability and statistics." Mr. Roberts is an Assistant Professor of Statistics at the Graduate School of Business Administration of New York University.

Vol. 24, No. 7 July, 1969

Food·Drug·Cosmetic Law
Journal

Drug, Device, Cosmetic?—Part II

By STEPHEN WEITZMAN

"Drug, Device, Cosmetic?—Part I" was Published in the May, 1969 Issue of the JOURNAL Beginning on Page 226. Mr. Weitzman Is a Member of the Law Department of Borden, Inc., as Attorney for Advertising and Labeling.

THE PURPOSE OF THE DEFINITION OF THE TERM "DRUG" was two-fold: It was intended to regulate both legitimate and fraudulent products. The definition of "drug" in the Pure Food and Drug Act of 1906[92] included any substance or mixture of substances intended to be used for the cure, mitigation or prevention of disease, and the Federal Food, Drug and Cosmetic Act of 1938[93] included drugs or devices intended to be used in the diagnosis, cure, mitigation, treatment or prevention of disease or articles intended to affect the structure or function of the body. Through this definition a representation that an article will prevent, be used in the treatment of, or have an effect on a disease brings that article within the statutory jurisdiction.[94] Regulation of fraudulently-pro-

[92] See 24 FOOD DRUG COSMETIC LAW JOURNAL 231 (May, 1969).

[93] See footnote 92, pages 226, 227.

[94] "It cannot be said, for example, that one who would put inert matter of a worthless composition in the channels of trade, labeled or described in an accompanying circular as a cure for the disease when he knows it is not, is beyond the reach of the lawmaking power. Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods and, in the nature of the case, can be deemed to have been made only with fraudulent purpose." *Seven Cases* * * * *Eckman's Alterative v. United States,* 239 U. S. 510 (1916)." The contention is made that the water condemned in this case is not a drug within the meaning as used in the 1906 Act. To confine the meaning of the word "drugs," as used in the third subdivision of section 8, to any definition of drug found in dictionaries or pharmacopoeias would in our judgment be entirely too narrow. As Justice Hughes says, in *Seven Cases*

(Continued on next page.)

moted products was a major goal.[95]

Intended use also includes use of legitimate drug products which are, of course, covered. Use and intended use, however, are not the sole criteria, since an article may be a drug because it is listed in an official compendium.

The Three Fact Situations[96]

Before continuing with an analysis of the statutory definition, a brief summary of the facts involved in the recent cases will be set forth to add concrete subject matter against which the rules in the case law may be examined.

The case, *United States v. Article of Drug * * * Bacto-Unidisk * * *,*[97] involved a product known as Unidisk, an antibiotic sensitivity disk, which is described as a circular cardboard disk having a diameter of just over three and one half inches, with eight circular paper units extending inwardly from the ring. Seven of these units are impregnated with different antibiotic drugs and the eighth one with sulfadiazine. The disk is referred to as a sensitivity unit. No part of the disk is administered to man or other animals, either internally or externally. It is used in hospital laboratories and in clinical practice in screening tests. In this test, the sensitivity or reaction of

(Footnote 94 continued.)
v. United States, 239 U. S. at 517, "That false and fraudulent representations may be made with respect to the curative effect of any substance is obvious," and when so made of water it seems to us it would be trifling to say that water ordinarily is not a drug in the true meaning of the word, and therefore does not fall within the condemnation of the third subdivision of section 8 of the Act. If the allegations of the libel are true, the claimant has the substance, water, in interstate commerce with the recommendation that it possesses certain elements or ingredients which are curative or at least alleviative for the diseases named in the label. He will not be heard now to say the substance recommended is water and not a drug. Such a construction would nullify the act of Congress." *Bradley v. United States,* 264 Fed. 79 (5CCA, 1920); in *United States v. VAPEX,* 59 F. 2d 446 (DC Md., 1932), the labels stated that the article was classified drug because of false claims as to its dietary power; see also *United States v. Hohensee,* 243 F. 2d 367, 370 (CA-3, 1957), cert. denied, 353 U. S. 976; *Nature Food Centres, Inc. v. United States,* 310 F. 2d 67 (CA-1, 1962), cert. denied, 371 U. S. 968. *United States v. Millpax, Inc.,* 313 F. 2d 152, 154 (CA-7, 1963), cert. denied, 373 U. S. 903; *United States v. 250 Jars * * * Cal's Tupelo Blossom U. S. Fancy Pure Honey,* CCH Food Drug Cosmetic Law Reports ¶ 40,185 (CA-6, 1965) aff'g. DC Mich. (honey claimed to be a "panacea for various diseases and ailments"). *U. S. v. 14 105 lb. Bags * * * Mineral Compound* 118 F. Supp. 837 (DC S. D. Idaho, 1953); *U. S. v. No. 26 Formula GM * * *, V. Kleinfeld & C. Dunn,* "CCH Federal Food, Drug, and Cosmetic Act" 1951-52, at 144 (1952).

[95] Dunn, 1053-54.

[96] See footnote 2, 24 Food Drug Cosmetic Law Journal 226 (May, 1969), where the citations for the four principal cases are listed.

[97] See footnote 96.

isolated cultures of the infectious bacteria or virus prepared from a specimen drawn from a patient is determined by the growth or absence of growth of the culture on each of the antibacterial units. In places where the antibiotic is effective, the culture will die or stagnate leaving a clear area. The patient's specimen may be sputum, urine, throat swab or other matter withdrawn from his body. The sole function of the disk is to furnish medical doctors with information which enables them to treat diseases. This procedure is much safer than drug experimentation on the patient himself, since each drug may not be effective against the disease and the testing of several drugs on the patient may be dangerous.

The Food and Drug Administration (FDA) seized the product and argued that the product was a drug. After the decisions of the District Court and the Court of Appeals decided in favor of the claimant, the Supreme Court reviewed the case, finding the product was a drug.

The second case is *AMP v. The Secretary of Health, Education, and Welfare.*[98] The two products in question were intended for use in tying off, or ligating, blood vessels which have been severed during surgery. The essential element in both of appellant's products consists of a nylon thread which is applied by a disposable plastic mechanical instrument. In one product, the instrument is in the form of a hemostat, a clamp-like implement. In the other product, the instrument is in the form of a long, slender tube. The ligature is applied to a severed blood vessel by inserting the hemostat or tube into the body and manipulating the instrument so that the ligature loop is placed around the severed vessel. Then the ligature loop is tightened and locked in place by a nylon button. The button functions as a knot does in conventional ligating methods. The excess part of the nylon thread is cut off, and the button and the rest of the nylon thread remain in the patient's body.

AMP sought the advice of the Food and Drug Administration and was told that the product was a "drug," and a "new drug," and instructed AMP to comply with the applicable provisions and agency regulations. AMP decided not to accept the FDA's advice and subsequently took the position that the product was a device.[99]

Another set of cases involves the question of classifying temporary wrinkle smoothers as drugs as well as cosmetics. The cases

[98] See footnote 96.

[99] The plaintiff also argued that its product could not be logically distinguished from prosthetic nails, classified as a device in *Orthopedic Equipment Co., Inc. v. Eustler,* 276 F. 2d 455 (CA-4, 1960), as well as by the FDA.

involved Coty's "Line-A-Way" and Bishop Industries "Sudden Change." The products consist of a protein lotion manufactured from bovine albumin which is applied to the skin and allowed to dry. The aqueous portion of the product evaporates after application and contractile film is formed. As the film forms, facial lines are smoothed away by the tightening film on the skin. In *Sudden Change,* the District Court found that the seized product was not a drug. The case was reversed by the Court of Appeals. In *Line-A-Way* the District Court found that the product was a drug. The case was appealed and argued but no decision has yet been rendered.

U. S. Pharmacopoeia and National Formulary

A Drug is an article . . . recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them . . .[100]

The United States Pharmacopoeia (USP), one of the publications named in the first subsection of the drug definition, is prepared by representatives of leading medical and pharmaceutical schools assisted by certain non-teaching medical groups such as the National Institutes of Health.[101] This publication, issued once every five years, sets forth purity standards in addition to listing such drugs as are considered to be of proved usefulness. Since its inception in 1820, the Pharmacopoeia has been revised seventeen times.

The Pure Food and Drug Act of 1906, as well as the 1938 Act, rely on the United States Pharmacopoeia in the definitions of "drug."[102] The compendia serve a second function in that the standards for purity of drugs set by the Pharmacopoeia are used as criteria for

[100] 24 FOOD DRUG COSMETIC LAW JOURNAL 226, 227 (May, 1969). *U. S. v. Hain,* V. Kleinfeld & C. Dunn, "FEDERAL FOOD, DRUG, AND COSMETIC ACT 1938-49," (Commerce Clearing House, Inc., 1949) at 265 (DC S. D. Calif., 1943).

[101] The Pharmacopoeial Convention was organized by Dr. Lyman Spalding, who, in 1817, proposed the formation of a National Pharmacopoeia to the Medical Society of the County of New York. His plan called for all medical organizations in the United States to divide into four districts (North, Middle, South and West); all organizations in the district were to call conventions to form their own Pharmacopoeia and send delegates to a General Convention to be held in Washington, D. C. From the material gathered, a National Pharmacopoeia was to be published. The plan was accepted by many medical societies and medical schools. At the first convention, only the North and Middle districts presented pharmacopoeias which were taken, revised, and published as the first *National Pharmacopoeia.* Printed in 1820, this was the first United States Pharmacopoeia (U. S. P.) (1942).

[102] See 24 FOOD DRUG COSMETIC LAW JOURNAL, 226—227 and 231 (May, 1969).

adulteration.[103] Since 1906 the scope of the Pharmacopoeia has changed.[104] One change was marked by the establishment within the pharmacopoeial convention of a committee on surgical aids and the publication by recommendation of that committee of a monograph on

[103] Sec. 501 (21 U. S. C. 351) a drug or device shall be deemed to be adulterated * * *

(b) "If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium."

[104] Its original object was "to select from among substances which possess medicinal power, those, the utility of which is most fully established and best understood; and to form from the preparations and compositions, in which their powers may be exerted to the greatest advantage. It should likewise distinguish those articles by convenient and definite names, such as may prevent trouble or uncertainty in the intercourse of physicians and apothecaries." [See facsimile of the "Preface" of the first Pharmacopoeia of the United States published in 1820, establishing the scope policy of the U. S. Pharmacopoeia, XI U. S. P. 1942].

The scope of the Pharmacopoeia of 1900 was as follows: "The Committee of Revision is authorized to admit into the Pharmacopoeia any producer of nature of known origin; also any synthesized product of definite composition which is in common use by the medical profession, the identity, purity or strength of which can be determined."

Included in VIII U. S. P. (at page 229) was a monograph (listing) of purified cotton.

The scope provisions of the Pharmacopoeia changed over the years but kept their original purposes. It was recommended that the Committee of Revision be authorized to admit into the Pharmacopoeia any medicinal substance of known origin. The list of substances was to be carefully selected, with standards for identity and purity as far as possible. Substances used only for technical purpose were not to be admitted to the next Pharmacopoeia, and a statement was to be placed in the preface to the effect that standards of purity and strength, prescribed in the text of the Pharmacopoeia, are intended solely to apply to substances which are used for medicinal purposes or in determining the identity and purity of the same. IX U. S. P. xxxi, (1910).

According to the Scope provision, the IX U. S. P. was only to contain medicinal substances or combinations of substances. Again, however, there was a listing for purified cotton (IX U. S. P. at 208). In addition, this revision included a chapter on sterilization: "Surgical Dressings—Cotton, bandages, gauzes, ligatures, etc., may be rendered sterile by treatment with steam in a pressure apparatus (autoclave) at 115 C. for fifteen minutes or by exposure to dry heat in an ordinary air-bath or sterilizer at a temperature of from 160 to 170 C. for two hours. It should be remembered that all surgical materials are not amenable to such thorough treatment without more or less deterioration taking place. Bandages must be folded or packed in such a manner as to permit the penetration of steam or dry heat during the process and should be so arranged that after the sterilization is completed, all subsequent contamination with bacteria will be prevented. This is usually accomplished by immediately enclosing them in glass containers or wrapping them in a number of thicknesses of previously sterilized parchment paper." (IX U. S. P. at 617).

This section on sterilization was slightly modified in the X U. S. P.: "Surgical dressing—Cotton, gauze, and ligatures (except catgut and other absorbable material) may be rendered sterile * * *" (at 461).

catgut sutures.[105] Since then, other surgical aids, including non-absorbable sutures, have been added.[106] This monograph on sutures was entered after Congress had passed the 1938 Act with the United States Pharmacopoeia designated as a reference work on which the

[105] The 1930 Convention instituted specialized Advisory Boards. The one we are concerned with was on sterile and other surgical products. This innovation was to signal the change in scope of the United States Pharmacopoeia.

XI U. S. P. was published in 1935. The Scope provision was substantially the same as in 1920. It contained a listing of purified cotton and a new listing of non-absorbent cotton (XI U. S. P. at 182, 505) and the same section on sterilization as the tenth revision. Congress enacted the Federal Food, Drug and Cosmetic Act in 1938.

There were two supplements to the 1936 XI U. S. P. The first was in 1936 and the second in 1939. The second supplement, however, changed the Scope of the Pharmacopoeia by popular demand.

"Another reason for the Supplement has been the establishment of standards for surgical sutures and surgical cotton, in direct response to urgent requests from surgeons and others. These standards have been developed through the efficient collaboration of the new U. S. P. Sterile Products Advisory Board who, in turn, have had the advice and counsel of the Surgeons General of the Army, the Navy, and the Public Health Service, the national medical, surgical and hospital associations, and the manufacturers of sutures and other surgical supplies. The establishment of U. S. P. standards for other supplies has been authorized by the Committee of Revision, but these are omitted from this Supplement because of the necessity for additional investigation and study (XI U. S. P. at 9). Thus, after Congress designated the listing in the United States Pharmacopoeia, the contents of a drug (under 201 (g) (i) (a)), were known, and the Scope of the Pharmacopoeia was radically changed.

The monograph on sutures was entitled "Surgical Gut" and described then as sterile gut prepared from "* * * the small intestine of healthy sheep."

[106] The twelfth revision followed the change and included listings for Absorbent Gauze (at 114), Sterile Absorbent Gauze (at 115), Sterilze Gauze Bandage (at 254), Adhesive Absorbent Gauze (at 116) Surgical Silk (at 133), and Sterile Surgical Silk (at 134). Thus, the Pharmacopoeia now included articles which Senator Copeland and William G. Campbell said were devices. The USP Scope policy was described in the XIV U. S. P. as follows:

"Today, each new Revision of the Pharmacopoeia and its Supplements endeavors to recognize the latest and most authoritative developments in medical and surgical practice and also the most advanced methods for drug standardization."

In the XIV U. S. P., the listings of sutures were retitled to Absorbable Surgical Sutures and Non-absorbable Surgical Sutures (at 597 and 598).

"Description. — Non-absorbable Surgical Suture consists of strands of material produced from other than segments of connective tissue of the small intestine of sheep. It may be composed of metal or of organic material and each strand is of substantially uniform diameter throughout its length. It may be composed of a single filament, or of filaments or fibres rendered into a thread by spinning, twisting or braiding, or by any combination thereof. It may be coated or uncoated and may either be untreated for reduction of capillarity, designated as Type A, Untreated, or Capillary, or may be treated to reduce capillarity, designated as Type B, Treated, or Non-capillary. It may be uncolored, naturally colored, or dyed with a suitable dyestuff. When

(Continued on next page.)

definition of drug is partially based. The constitutional repercussions of the addition of this class of products was not considered by the pharmacopoeial convention nor by Congress which had set no standards advising the compendia of the scope of their power.

The issue of the constitutionality of this subsection was never debated in Congress. Since 1938 the constitutionality of the delegation of power to set drug standards has been exhaustively discussed.[107] The basic argument against constitutionality of the standard section was the use of the uncontrolled private group. The first case in which this issue was presented and discussed decided in favor of constitutionality. The case was *United States v. Lehn and Fink*[108] decided in the District Court in 1912. The court responding to the charge of unconstitutionality said:

> To me there could not be a plainer instance than this act of the legislature's having made a complete and perfect criminal statute, not dependent at the time of its passage on the act of any other power or person and of them providing for changes in the meaning of the word "adulterated;" a word which in the nature of things may and should change its signification with advancing knowledge or increasing civilization.
>
> It is just as true that the meaning of "adulterated" in 1906 may be unsuitable in 1916, as that the phrase "unreasonable obstruction to navigation" should have had a meaning as applied to the Monongahela and Allegheny Rivers in 1874, different from that found proper in 1902. And it is just as reasonable and lawful for the pure food statute to operate on the meaning of the word "adulterated" as given from time to time by experts in chemistry and hygiene, as it was held to

(Footnote 106 continued.)

dyed, substantially, all uncombined dyestuff shall be removed from the material. If sterilized, Non-absorbable Surgical Suture may be impregnated with a suitable bacteriostatic agent and/or preserved in a suitable packaging fluid." (at 599).

The next change in the listings occurred in XVI U. S. P. when gauze products which were absorbent were put under one heading at (xliii).

In the latest Revision, XVII U. S. P. makes it clear that its Scope has changed and that it recognizes that change.

"1. U. S. P. Scope—It was recommended that the scope of the Pharmacopoeia be considered sufficiently broad to include substances used for internal splinting and vascular repair, agents for diagnostic tests not conducted on the patient, clinical thermometers, and devices used for the administration of drugs" (xliii).

A new section—surgical aids—was adopted: It includes:

Bandages, Adhesive—58

Bandages, Gauze—59

Cotton, Purified—150

Gauze, Absorbent—260

Gauze, Petrolatum—263

Suture, Absorbable Surgical—689

Suture, Non-Absorbable Surgical (Including Nylon)—691

Tape, Adhesive—696.

[107] Wheeler, "Validity of Official Drug Standards" 1 FOOD DRUG COSMETIC LAW JOURNAL QUARTERLY 588 (December, 1946), and Christopher, "Validity of Delegation of Power to a Private Agency" 6 FOOD DRUG COSMETIC LAW JOURNAL 641 (September, 1951).

[108] White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drug Act" 229 (DC N. Y.) (1934).

be by the meaning of "unreasonable obstruction to navigation" to depend for its signification upon the opinion of the Secretary of War for the time being when fortified by the opinions of the engineers of his department.

Thus, the sole justification for the court is that the Food and Drug Act deals with a dynamic field and that alone is sufficient to overcome the constitutional problem. The court's analogy to *Union-Bridge v. United States*[109] is misplaced since *Union-Bridge* involved delegation of regulatory power to a governmental agency, not a private group. It is difficult to see how this District Court case can be the controlling authority for the constitutionality of the standard-making powers of the Pharmacopoeia. In addition, the above arguments refer only to the question of standards and not the question of the scope of the definition of the term "drug."

The issue as to whether the definition of the term "drug" is constitutional was presented in *Wisconsin v. Wakeen,*[110] when the state druggist statute, which contains a definition of "drug" identical to that under the Federal Food, Drug and Cosmetic Act, was tested. In addition to repeating the arguments of *Lehn and Fink,* the Wisconsin court held that "this is not a case of delegation of legislative powers. The publications referred to are not published in response to any delegation of power, legislative or otherwise, by the statute .... The books were published independently of the statute for an entirely different purpose."

Advisory Statute

The court appears to view this subsection of the statute as merely advisory. The pharmacopoeia, it seems, is to be used only to indicate the nature or type of article considered a drug in other subsections of the entire definition. The fact that the pharmacopoeia is only advisory means that there is no issue of unconstitutional delegation of power. According to this interpretation, the pharmacopoeia is simply a reference which indicates the type of articles Congress intended to cover in this definition. When faced with the problem of classifying a product not in existence in 1938 when the statutes were passed, the types of articles included in the pharmacopoeia at that time must first be compared to the new articles being classified. If this interpretation restricting the pharmacopoeia to an advisory position is incorrect, any change in the scope of the pharmacopoeia would either be an unauthorized act which would have no legal effect or an autho-

[109] 204 U. S. 364 (1907).

[110] 263 Wis. 401, 57 N. W. 2d 364 (1953).

rized act pursuant to an unconstitutional statute which delegated power without guidelines.

This issue relating to the constitutionality of the drug definition was discussed by revisors of the legislation. Mr. Charles Wesley Dunn, the representative of the American Pharmaceutical Manufacturers Association and the one who requested that the definitions be amended to broaden the statutory scope to include mechanical articles, devices or apparatus, poisons or deleterious obesity remedies, stated that the statute should be further amended to make articles listed in the United States Pharmacopoeia and National Formulary definitions of the term "drug" subject either to approval or promulgation by the Secretary of Agriculture.[111]

Dr. Fullerton Cook, Chairman, Pharmacopoeial Revision Committee (USP) disagreed, as the record of this meeting reports:

> Referring to the suggestions of Mr. Dunn, in so far as they affected the U. S. Pharmacopoeia and National Formulary status in the food and drugs act and referring particularly to Section 7, in the case of drugs, first Dr. Cook brought out the following points in favor of the law as it now stands:
>
> In answer to the question of the constitutionality of the U. S. Pharmacopoeia and National Formulary, Dr. Cook cited Dr. J. H. Beal, who was one of those instrumental in the preparation of that provision in the act and who declared it to be constitutional. If it were a vital question it surely would have been discussed in the courts heretofore in the hundreds and thousands of cases coming before the courts. The U. S. Pharmacopoeia and National Formulary are merely measuring sticks by which the law can be enforced.[112]

Dr. Cook's answer that no court had yet declared the drug definition unconstitutional is of no legal consequence. His further statement that the compendia are measuring sticks also does not answer the challenge to the definition's constitutionality unless Dr. Cook agrees that the function of the compendia is only to indicate the nature of the products considered drugs. If he did not mean this, then any voluntary expansion of the scope of the pharmacopoeia for any reasons would have automatic legal consequences. Under the statute, the pharmacopoeia need not account to any one for error. Dr. Cook's answer merely avoids a confrontation on the constitutionality issue in order to preserve the statute.

This view, that it is best to avoid the issue and to use the pharmacopoeia as evidence of the nature of "drugs" and not as a final determining fact, however, negates the FDA proposition that the statute must be literally construed. Thus, in *AMP v. Gardner,* the FDA contended that sutures were listed in the pharmacopoeia and therefore there was no question that the product was a drug.

---

[111] Dunn, 1033-34.

[112] Dunn, 1037.

The FDA's Position

The FDA's position was stated in an answer to plaintiff's interrogatories:

> The ligators in issue are considered drugs because they are a new means of administering the essential component of the article, a nylon suture, which is recognized as a drug in monograph in the United States Pharmacopoeia. XVII USP 691-93 (1965). The hemostat and sleevelike plastic container part of each article are no more than containers of the drug, constituting new methods of administering the drug, similar to a disposable syringe. The sutures (drugs) in the ligators in issue do the work of tying off the blood vessels and remain in the body, in the same manner as the drugs contained in the disposable syringe. The sutures remain drugs even when packed for use in the hemostat or plastic tube.[113]

Thus, the FDA's basis for classification was the fact that the essential element of the product was listed in the United States Pharmacopoeia and that this element, the suture, remained in the body like any chemical pharmaceutical preparation.

Plaintiff argued that its product was a device and that as such, it was specifically excluded from the classification "drug" according to the last part of the drug definition which states that the term drug . . . "does not include devices." To contradict the FDA's argument that the article was a drug because it was listed in the United States Pharmacopoeia, plaintiff introduced an affidavit from the Scope Director of the United States Pharmacopoeia.[114] He explained that under the Constitution and By-Laws of the Pharmacopoeial Convention, the compendium "[i]s to provide authoritative standards for substances that are used in the practice of healing arts. He further stated that the scope of the pharmacopoeia was not limited to the listing of drugs, and it was not the intent of the compilers to "classify" as drugs all items listed in it.[115]

AMP did not raise any constitutional issues despite the Government's reliance on the first part of the "drug" definition, which states that an article is a drug because of its listing in the compendium of a private organization. *AMP* probably believed no court would seriously consider this argument. However, there is an interesting

---

[113] See *AMP v. Gardner,* Joint Appendix, Appeal No. 31829 at 16a.

[114] Dr. John C. Krantz, Jr., *AMP v. Gardner,* Record on Appeal 91-93.

[115] Thus, the United States Pharmacopoeial Convention of 1960 adopted the following resolution for reference to the incoming Board of Trustees and Committee of Revision: "1. U. S. P. Scope—It was recommended that the scope of the Pharmacopoeia be considered sufficiently broad to include substances used for internal splinting and vascular repair, agents for diagnostic test not conducted on the person of the patient, clinical thermometers, and devices used for the administration of drugs." Plaintiff's Memorandum of Law, *AMP v. Gardner,* No. 67 Civ. 2115, at 10-11.

aspect not noticed by plaintiff in this case which would make this constitutional issue more complicated. As mentioned above, in tracing the history and scope of the pharmacopoeia, it was found that three years prior to the introduction of the revisions of this act, a special committee of the pharmacopoeia was set up to prepare monographs on surgical aids.[116] The first demonstrable action of this committee was in the publication of a supplement to the pharmacopoeia which, for the first time, included absorbable catgut suture in 1939, after the Act's passage. It was not until later revisions that nylon sutures were included.[117] The only product listed in the pharmacopoeia prior to 1938 which was not absorbed by the body was cotton, a cellulose fiber.[118]

The District Court in *AMP* rejected the Government's contention that the listing of the product in the pharmacopoeia was a crucial distinction between drug and device.[119] The justification for that decision is fuzzy. First, the court said that if this were correct "the clause . . . that the drug definition does not include devices becomes meaningless." It then said that the mere listing of a product in the pharmacopoeia does not necessarily mean that such an item was a drug for purposes of the Act, citing *FTC v. Liggett & Myers Tobacco Co.*[120] The *Liggett* decision, however, did not stand for this proposition. All Judge Kaufman said in *Liggett* was that the listing of one derivative of the tobacco plant, tincture of tobacco, did not bring smoking tobacco within that listing and consequently not within the drug definition.[121]

The District Court in *AMP* concluded in this part of its decision that the pharmacopoeia is not an absolute standard but advisory:

> Moreover, a "suture" is listed in XVII United States Pharmacopoeia 691 (17th rev. ed. 1965). I do not agree with defendants that a listing in an official compendium is the crucial distinction between a drug and a device . . . The mere fact that an item is listed in the United States Pharmacopoeia does not necessarily mean that such item is a drug for purposes of the act . . . . On the other hand the listing should be some evidence that such item is a drug.[122]

This avoidance of the question makes it appear that the court was aware of the constitutional issue raised in the Government's contention that all items in the Pharmacopoeia are drugs.

---

[116] See footnote 105.
[117] See footnote 113.
[118] See footnote 104.
[119] See footnote 96, 275 F. Supp. 410, at 414.
[120] 108 F. Supp. 573 (DC S. D. N. Y., 1952).
[121] 108 F. Supp., at 575.
[122] 275 F. Supp. 410, at 414.

Bacto Conclusion Supported

In the *Bacto* case, the Court of Appeals and the District Court supported their conclusion that the product was not a drug by the absence of a listing for disks in the pharmacopoeia.

> Sensitivity disks are not recognized in (admitted to) the United States Pharmacopeia or the National Formulary which are "official compendia" under the Federal Food, Drug and Cosmetic Act (21) USC 32(i).[123]

In addition, the Courts justified their conclusion with the views of the medical profession in general and the pharmacopoeial convention in particular.

> In medical science the concept of "drug" is limited to articles administered to man or other animals, either internally or externally. This is the generally accepted view among physicians (Finding Number 9). The evidence affords no basis for the conclusion that the definition of "drug" in the Federal Food, Drug and Cosmetic Act 21 USC 321(g) was intended by Congress to extend beyond the meaning of that term in medical science, to encompass these sensitivity disks. The definition of "drug" is found in 21 USC 321(g). ... nor are such disks the kind of articles which are accepted for admission to the official compendia because, among other reasons, they are not regarded by the Committee on Revision (admission) of the compendia as drugs within the commonly accepted meaning of that term in medical science. In medical science those substances which are for administration to or for use on, a person for the treatment of disease or injury, are regarded as drugs. This is the commonly accepted view of physicians generally. A physician who testified for libellant could think of no example of a substance not taken into or applied to the body which he would "consider medically" as a drug.[124]

This view directly contradicts that of the District Court in *AMP* which rejected testimony of the Pharmacopoeia Scope Director.

> Whether the compilers ... consider a particular item a drug or a device given its ordinary meaning does not determine whether such an item is a drug or a device under the act.[125]

The Court of Appeals in *AMP* did not rely on the listing of sutures in the Pharmacopoeia. The Court's only comment was:

> AMP's ligatures are of nylon suture material of the type recognized in the United States Pharmacopeia, 691 (17th rev. ed. 1965), and such suture material has always been regarded as "drugs" by the Food and Drug Administration.[126]

This statement used as self-serving support to justify the Court's conclusion was not used as the basis of the court's holding and, in addition, is half false. FDA has in the past regarded sutures as products outside the "drug" category.[127]

The Supreme Court in *Bacto* did not consider the absence of a listing in the compendia or general medical opinion of any conse-

---

[123] 392 F. 2d 21, at 22.
[124] 392 F. 2d 21, at 23.
[125] 275 F. Supp. 410, at 414.
[126] 389 F. 2d 825, at 830.
[127] See 24 FOOD DRUG COSMETIC LAW JOURNAL 234 (May, 1969) for testimony contradicting the Court of Appeals unsupported statement.

quence. What was important was Congress' intent to define "drug" more broadly than does the medical profession.[128] No guidance was offered on the status of the compendia.

A drug is an article . . . (B) . . . intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals . . . .

The issue in *Bacto* as presented by the courts was whether the article was:

> intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; The district judge said in his opinion, "When it comes right down to the determination which we must make, a literal reading of (g)(2) which defines 'drug' as 'articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals clearly has application to the article libeled herein.' This is only true in an indirect sense.

The court found that this article did not meet the requirements of the definition.

> Certainly it has nothing to do with diagnosis or prevention of disease. In itself, it is not intended to cure, mitigate or treat disease. It only aids the physician to determine what antibiotics to use for the cure, mitigation or treatment of the patient's disease.[129]

The Court of Appeals agreed with the trial judge that it was not the legislative intent to apply the phrase "intended for use in the * * * cure, mitigation, treatment * * * in such an indirect manner.[130]

The Supreme Court reversed, saying that the disk had at least some role in the selection of the appropriate drug for treatment of the disease. Supporting the District Court decision was the first case under the 1906 Act which explained the corresponding subsection of the antecedent definition retained in the 1938 Act with minor change to incorporate the case law from 1906 to 1938.

> In the use of the words "therapeutic" and "curative," as set forth in the statute, it seems clear that these words were intended by the Congress to be given their ordinarily accepted meaning and while they have a certain meaning to the expert doctor, nevertheless, they are a part of the vocabulary of any intelligent person. "Therapeutic" to the medical world means to heal; to make well; to restore to health. It is that branch of medicine dealing with the proper use of the right medicines in the treatment of diseases. The medical student studies "therapeutics" for the purpose of learning about different medicines to prescribe for the many ills to which the flesh is heir, in order to assist nature to make a sick patient well.[131]

---

[128] 392 F. 2d 21, at 22.

[129] 392 F. 2d 21, at 22.

[130] Compare *United States v. Consolidated Laboratories, Inc.* and others, Kleinfeld & Kaplan, "FEDERAL FOOD, DRUG, AND COSMETIC ACT" 1961-64, at 168 (N. D. 111, 1963).

[131] *United States v. 23 7/12 Dozen Bottles* Article of Drugs * * * "Lee's Save the Baby" 44 F. 2d 831 (1930).

Drug or Cosmetic?

A drug is an article . . . (C) . . . intended to affect the structure or any function of the body of man or other animals . . . .

In 1964 the Government brought seizure actions against these two wrinkle smoothers. The libel in "Line-A-Way" alleged that the product shipped in interstate commerce was:

(1) a "drug" within the meaning of 21 U. S. C. § 321(g)(3) "intended to affect the structure . . . of the body of man . . ." 21 U. S. C. § 321(g)(1).

(2) A "new drug" within the meaning of 21 U. S. C. § 321(p) and hence shipped in violation of 21 U. S. C. § 355(a) since concededly no new drug application pursuant to 21 U. S. C. § 355(b) was filed or effective with respect to it.

In that case, the claimant argued that the product was a cosmetic with only temporary effect and meeting all the requirements of the cosmetic definition. Besides, Congress did not intend a product of that nature to be precleared as a drug.[132] The court disagreed and, relying on the *AMP* case, held that under the existing broad definition of drug, Congress intended that the scope of the statute should not be restricted to products commonly called "drugs."

Claimant in *Line-A-Way* contended that the literal language of section 321(b) (1)(c), "article intended to affect the structure and function of the body," was never intended to encompass its product.[133] Claimant's arguments, based on the legislative history of the act, failed to explain to the court the nature of the products classified as drugs as compared to its product. *Line-A-Way,* like other wrinkle smoothers, is an unusual cosmetic since it does more than color or camouflage faults in the skin: it temporarily tightens it.

In the *Sudden Change* case, the claimant took a different approach. The claimant first attempted to analyze the nature of its product as it compared to a "drug" to show that it did not belong in the same classification. Counsel for *Sudden Change* described the

---

[132] Compare *FTC v. Liggett,* 108 F. Supp. 573, at 576, where the court found that cigarettes are not drugs: The report from the Committee on Commerce on S-5, 74th Cong., 1st Sess. (1935) also cites "slenderizers" as an example of the type of article which the expanded definition was designed to encompass. These products have very decided effects upon the structure of the body and *the very purpose for which the product is consumed is to bring about such effects.*

[133] The third statutory definition of a "drug" is by far the broadest. Anything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man. Consequently any article which, used in the manner anticipated by the manufacturer thereof, comes into contact with any of the senses may be said to be an article "intended to affect the functions of the body of man" . . .

Surely, the legislators did not mean to be as all-inclusive as a literal interpretation of this clause would compel us to be.

product as a temporary mechanical means to smooth and firm the skin by tightening the surface, apparently without absorption by, or resulting in changes in the skin tissue from the application.

As in *Line-A-Way,* the government argued the literal language of the statute: that the intended use of the product was to affect the structure of the body. Claimant in *Sudden Change,* however, argued that the "structural" changes to the body referred to in the drug definition did not include superficial physical change.

The District Court held that the product was not a "drug" within the meaning of the act because it found that the statutory definition does not include cosmetics of this kind. The court examined the nature of the effect the product had on the skin and, on the basis of a report of the Committee on Cutaneous Health and Cosmetics of the American Medical Association,[134] found that the only effect on the skin was a physical temporary tightening of the surface. The bases of the above report were clinical evaluations and personal observation which found that:

> Bovine serum albumin products apparently have no *biochemical* or *physiological* activity when applied to the skin, and their application results only in temporary physical surface changes. The pertinent results indicate that the effect on the skin produced by these products can be (a) totally eliminated if the skin is washed with soap and water, (b) reduced significantly by vigorous use of the facial muscles of expression, (c) simulated by using test materials which produce contracting films when applied to the skin, (d) shown not to promote or retard the transportation of water through the horny layer of the skin (as demonstrated on isolated sheets of stratum corneum), and (e) correlated to no demonstrable changes in the histology of the skin.

Partly on the basis of the affidavits and other evidence, the court concluded that "Sudden Change does not affect the structure of the body" in the manner that a drug does.

Physiological and Physical Changes

Although claimant did not argue that its product was a device, it appears that the device definition would be applicable. As seen in the legislative history, devices affected the shape or physical structure of the body. Just as a girdle[135] used to support one's back has a physical effect on the torso, this cosmetic film has a physical effect on the face. The term, "intended to affect the structure of the body" in both definitions, really relates to two different types of structure.

---

[134] *Sudden Change,* Claimants Exhibit A.

[135] Contrary to Judge Weinstein's remarks [288 F. Supp. 29, at 34,] girdles might well be "devices" within the meaning of the Act. Compare 24 Food Drug Cosmetic Law Journal 234 (May, 1969), fourth paragraph.

Drugs are intended to affect the biochemical and physiological structure and devices are intended to affect the physical structure. "Cosmetics," on the other hand, affect physical appearance.

In reversing the District Court decision, the majority of the Court of Appeals held that, because of the claims, the product was a drug intended to affect the structure of the body. The Court said:

> It should be understood, however, that if the claimant ceases to employ these promotional claims and avoids any others which may fairly be interpreted as claiming to affect the structure of the skin in some physiological though temporary way, then, assuming incorrect arguendo that no actual physical effect exists, the product will not be deemed a drug for purposes of the Act.[130]

It is unfortunate that this court confuses the terms physiological and physical. The fact that a product has a physical effect does not mean it has a physiological effect and does not make it a drug. Here, plaintiff and the American Medical Association (AMA) testified that the product had only a physical effect. The claims "face-lift without surgery" and "lifts out puffs" imply physical action. The court could not believe that any consumer would believe that the cosmetic caused physiological changes, changes in their cellular chemistry. To get a "face-lift without surgery" one need only tie an elastic band under one's chin and around the top of the head. Claimant's product, through a slightly more sophisticated means, accomplished this result.

A physiological effect is an alteration of the chemistry of the body's tissue. This chemical alteration could be caused by the addition of chemicals to the tissue which penetrate and alter the pH of the cell interfering with the normal biochemical balance of the cell. Physiological change can also be induced by changing the temperature of the cell, (cryogenics is an extreme but a valid example), or by irradiating the cell in order to "crack" the chemicals.

In the dissent, Judge Mansfield recognized this difference:

> "Sudden Change" recognizes that wrinkles are but the irreparable footprints of time, and that they may be temporarily softened or masked, but not obliterated. The product does not enter the tissues, cells, or molecular structure of the skin, or work any physiological changes in the body. It merely alters the appearance of the face for a few hours by smoothing or toning the skin. Unless it is repeatedly applied at regular intervals, the tell-tale wrinkles return. The product poses no threat to public health. Unless claims were made for it in labeling or advertising to the effect that it possessed the properties of a drug, it would not fall within the definition of a drug as an article "intended to affect the structure of the body," 21 U. S. C. § 321(g)(1) (at 742).

---

[130] 409 F. 2d 734, at 742.

Resolution of the Cases: Definitions

The District Court in *AMP* first examined the two definitions "drug" and "device." It stated that the definitions were not mutually exclusive despite the entire definition of the term "drug" qualified by the statement that the term "does not include devices or their components, parts, or accessories."[137] The parties had argued that, because of this phrase, the terms "drug" and "device" were mutually exclusive. The court, however, disagreed and justified its conclusion with a quote from a secondary authority[138] which stated that the categories "drug" and "device" were not mutually exclusive. The basis of this secondary authority was a statement from a 1934 committee report[139] which was later negated by the insertion of a separate definition of the term "device" and the insertion of the above exclusionary phrase upon which the parties based their argument that the two classes were mutually exclusive. Once the court had established the erroneous premise that the terms were not mutually exclusive, it stated that it could easily classify the product as an article, and therefore a drug, but was less clear as to whether the suture was an instrument, apparatus or contrivance.[140]

However, the District Court in *Sudden Change* correctly stated that:

> The fact that an article is a cosmetic does not preclude its being a drug. See S. Rep. No. 361, 74th Cong., 1st Sess., reprinted in Dunn, "FEDERAL FOOD, DRUG, AND COSMETIC ACT 1938-1949," (Commerce Clearing House, Inc., 1949) at 239-40 (definition of drug and cosmetic not mutually exclusive). In 1962, Congress "to avoid any possible confusion" (H. Rep. No. 2464, 87th Cong., 2nd Sess. at 13 (1962), added a new section 359 to the subchapter on Drugs and Devices which provides that "[t]his subchapter . . . shall not apply to any cosmetic unless such a cosmetic is also a drug or device or component thereof."[141]

Resolution of Drug-Device, Drug-Cosmetic Conflict

In *AMP*, the District Court attempted to distinguish "drug" and "device" on the basis of the definition of "article" and the definition of "instrument," apparatus and contrivance, the basis of the introductory portion of each definition:

> An article would be defined merely as a thing or "group of things" and would include instruments, apparatus and contrivances. The definitions of the

[137] Section 201 (g)(1), see 24 FOOD DRUG COSMETIC LAW JOURNAL 227 (May, 1969).

[138] Section 4.15, Toulmin, "Law of Foods, Drugs and Cosmetics" (2d ed., 1963).

[139] S. Rep. 493, 73rd Cong. 2d Sess. (1934).

[140] 275 F. Supp. 410.

[141] 288 F. Supp. 29, at 33.

latter items are somewhat more specific, but all can be classified generally as appliances.

An examination of plaintiff's suture products reveals that they are arguably either articles or instruments, apparatus and contrivances. It is clear that the products fit into the broad definition of articles. Less clear is whether such items could fit within the definition of devices.[142]

The District Court, however, conceded that the product could fall into both definitions. It had disregarded both parties' contention that the definitions were mutually exclusive; otherwise the definition of drug would have required the article which could be classified as a device to be so classified. The Court stated that it had to classify the product as a drug because:

The public will be better protected by classifying plaintiff's product as a drug rather than a device so that proper testing, controlled by the Government, can be pursued. It would seem that a product coming within the two definitions, that definition according the public the greatest protection should be accepted.[143]

Under this test, any product could be classified as a drug, based on the argument that it was necessary for the public's health despite the fact Congress never enacted legislation recognizing the professional need. This contradicts Congress' mandate that if the product came within both definitions it was a device and was excluded from the term "drug."

Unlike the District Court, the Court of Appeals in *AMP* analyzed the legislative history of the Act to determine what was to be included with the terms "instrument, apparatus and contrivance." The Court did not analyze the legislative history to discover whether Congress intended products of the nature of the suture to be precleared.

The review of the legislative history is incomplete. As much a part of this history is the testimony of Walter G. Campbell, former chief, FDA, in hearings on the bill.[144] This testimony refutes the contention that FDA always believed sutures were "drugs." To the contrary, it was believed they were devices. Part of Mr. Campbell's testimony, however, was used only where it could support the court decision, not to refute it.[145]

---

[142] 275 F. Supp. 410.

[143] 275 F. Supp. 410.

[144] The purpose of the preclearance section and its intended scope are set forth in Part I of this article, 24 FOOD DRUG COSMETIC LAW JOURNAL 246, 247 (May, 1969). Nothing in the *AMP* decision shows that all Congress intended to do was cover products which had physiological effects and presented the danger that elixir sulfanilamide presented.

[145] The analogy made by the FDA (footnote 113, Part I—see footnote 144 above) to a drug and a syringe is more applicable here than in *AMP*.

The Court also misinterpreted the purpose of the preclearance section of the Act. Without analyzing the legislative history of this section the court concluded:

> That purpose was, very clearly, to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce. The product which immediately precipitated Congressional concern—"Elixir Sulfanilamide"—was a drug within the everyday, narrow sense of the word, but we would hardly suppose that when Congress incorporated the "new drug" bills resulting from the "Elixir Sulfanilamide" tragedy into an Act which contained an extremely broad definition of the word "drug," it intended that the operation of those provisions should be restricted to products commonly called "drugs" and that products such as ligatures, which might present the very dangers the provisions were designed to meet, should be excluded. We would, moreover, be reluctant to give a narrow construction to this statute, touching the public health as it does.[146]

The basis of the classification here is the danger of the product. This test for classification is part of the definition of new drug and the basis of that definition. Before an article is classified as a new drug it must first be classified as a drug. The court however was not entirely to blame for omissions. Plaintiff's briefs were incomplete.

The two tests here, whether the product was classified as a device in the legislative history and whether the public will be better protected, are far reaching. Under them, any new device developed since 1939 may possibly be classified as a drug, since there would be no record to the contrary. The court's test, whether the product presents the same dangers Congress sought to prevent, as a criteria for classification, has no basis in the legislative record. In the application of this test, this court required itself to decide whether the same dangers are presented by poisons and sutures. Without any scientific viewpoint on the toxicity of sutures in the record, just speculation, the court's decision is an application of its judgment that the public is better protected by preclearance no matter what Congress intended.

The section on the legislative history of the Act in the Supreme Court's decision, taken from the *AMP* decision, has greater application here than in *AMP* itself. As the Supreme Court correctly differentiates between drugs and devices, the device category includes certain quack contraptions and items characterized more by their purely mechanical nature than by the fact they are composed of complex chemical compounds . . . .[147]

---

[146] 389 F. 2d, at 285.

[147] CCH Food Drug Cosmetic Law Reporter ¶ 80,231, 89 S. Ct. 1410 1415, — U. S. — (1969).

According to this analysis, the suture in *AMP* used to tie off a bleeder (a small open blood vessel) would be a device because of its mechanical clamp action.

The District Court in *Sudden Change* first adopted the "mechanical" against the "physiological" approach. It did this by distinguishing the "effect" of a drug and the "effect" of a device. The appearance of the phrase "affect the structure of the body" in the device and drug definition is ambiguous by itself, but it is clarified when analyzed by the effect caused by products in the two categories. Although it was never argued originally, this cosmetic is a device under the Supreme Court's analysis. Because the definition of drug and device are mutually exclusive, the product could not be a drug.

The lower Courts in *Bacto* did not examine the legislative history of the Act, but instead, relied solely on the words of the statute. This was only an incomplete view of the problem. In contrast, the Supreme Court examined the legislative history, but only as thoroughly as the Court of Appeals did in *AMP*. Despite the Court's disclaimer,[148] its decision was partly based on the public's need for premarket certifications of antibiotic disks. This policy decision was not incorrectly made, since it was consistent with the findings of Congress behind the requirement for premarket clearance and certification of antibiotics. A contrary decision would undercut the value of even testing antibiotics since the use of the wrong antibiotic, because of an erroneous test, could cause complications.

Claimant, in *Bacto*, argued that the product, not being in dosage form, was not available for drug use. Claimant also argued that the article which was to be classified was the disk, not the chemicals. The dosage form is irrelevant in the definition and the fact that the chemical is on a disk does not change the chemical into a device.

Judge Weinstein's defense of his opinion, on the basis that the case involves an economic interest and not a health interest, may be appealing emotionally, but it does not justify different results when there is a technically correct answer which meets a precise legislative scheme. The *Dotterweich*[149] proclamation that the statute is to be

[148] The Court apparently distinguishes between complex chemical products like common drugs which have biological or physiological activity and devices which operate by mechanical action. See footnote 147.

[149] *United States v. Dotterweich*, 320 U. S. 277, 64 S. Ct. 134 (1943).

liberally construed may be applicable to the implementation of the statutory sanctions, but it should not be applicable to construction of these definitions where such broad interpretation alters the legislative scheme.

When the problem is to classify a new kind of cosmetic or device, a court may believe it wise to require preclearance and classify the product as a drug. If the courts implement their beliefs when they have not and are unable to fully investigate the problems involved, they are usurping the function of Congress which has the sole responsibility for conducting these investigations. Moreover, it is Congress which has the responsibility to enact legislation which would require preclearance of devices and cosmetics.

Conclusion

The question here is not simply whether a product is a drug and therefore within the jurisdiction of the Act, but whether it is one of the articles intended by Congress to be precleared.

It is an accepted fact that the literal language of this statute is not the sole criterion for classifying these products;[150] the legislative history also deserves great weight. Any analysis of the history cannot simply take note of part of the legislative history, but must consider all of it, including the history behind drug preclearance.

---

[150] The following is a discussion on Chemical Mace and whether it could be a "drug":

Senator Moss: Professor Page told us of the large number of chemical sprays that are available on the market. Have you considered what he suggested that there perhaps should be a premarketing clearance approach?

Dr. Ley: This is the the third, and to my way of thinking, most rigorous level of reaction to this problem, Mr. Chairman. That would be the new drug procedure approach to this category of agents. As I indicated in my earlier statements, I do not believe that this approach is desirable until it is—until we have had the opportunity to pursue the lesser levels of response to the problem...

Now, can we turn to Mr. Goodrich for a comment on this?

Mr. Goodrich. I agree with that, but we did disagree with a point that Professor Page discussed, whether or not these products could be classified as drugs. We concluded that they could not, if they came properly under the Hazardous Substances Act and were not drugs.

I suppose that pistols and bullets are intended to affect the function or structure of the body in the same way these are, but we concluded that the product could not properly be classified as drugs under the definition in the Food, Drug, and Cosmetic Act.

Testimony of Dr. Herbert Ley & William W. Goodrich: (Transcript of Proceedings before Senate Committee on Commerce, Subcommittee for Consumers, Hearing on Public Sale of Protective Chemical Sprays 21 May, 1969, pages 50-51.)

The immediate difficulty with any interpretation of the term "drug," which would require preclearance of articles such as devices, is the fact that Congress refused to pass device legislation proposed during the last thirty years. This fact apparently had no effect on these judicial decisions. No doubt there may be concern for better consumer protection, but it is for Congress, not the courts, to legislate.

If a rational approach is to be sought, then perhaps a simple attempt should be made to extrapolate from the legislative history the nature of the products to be classified as drugs, devices and cosmetics.[151] The Supreme Court and the District Court in *Sudden Change* apparently have made an extrapolation, and they distinguish devices from drugs by virtue of their physical, mechanical action versus the physiological action of drugs.

Such a method of distinguishing drugs from devices would allow the FDA to classify radiation or electromagnetic forces as drugs even though the machines that emit them are devices. Under the definition of new drugs, these devices could be required to be precleared if they are part of a new method of administering the drug to the patient.[152] This approach would negate the necessity of enacting part of the proposed new legislation since the mode of action and possible dangers are exactly the same for these articles as they were for Elixir Sulfanilamide. Articles which do not present the same dangers, such as surgical instruments, prosthetic devices and others intended to be covered by the "Medical Device Safety Act,"[153] would continue to remain outside the preclearance requirement until Congress acts. Judging from the concern expressed by the courts, it would appear to be timely for Congress to investigate the subject of medical devices. **[The End]**

[151] Compare *TGA v. Gardner*, 278 F. Supp. (DC S. D. N. Y., 1968).

[152] A drug may be "new" because of newness for drug use of some substance, or combination of substances, or proportion of a substance, or because of newness of the purpose for which it is to be used, or because of newness of a dosage or method of administration. 21 CFR 130.1(h).

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

The Rule-Making Authority of Boards of Pharmacy

By HENRY KANE

This Paper Was Presented Before the National Association of Boards of Pharmacy in Montreal, Canada, May 18, 1969. Mr. Kane is the Assistant Attorney General of Oregon. The Views Expressed Are Those of the Speaker and Not Necessarily Those of the Attorney General.

A BOARD OF PHARMACY SERVES AND PROTECTS the public by regulating the practice of pharmacy and, indirectly, the use of drugs by individual members of the community.

To meet changing conditions and to fill in the interstices of regulatory statutes, a state board of pharmacy generally possesses limited authority to adopt rules or regulations.[1] In recent years the legislative trend has been to grant state boards of pharmacy more discretionary authority to regulate the practice of pharmacy and the use of drugs. The effect of enlarging the traditional jurisdiction of a state board of pharmacy is to make the agency a little FDA.

The growth of the rule-making authority of a state board of pharmacy appears to be matched by more frequent appeals to the courts challenging a particular rule or action of an agency and, in at least the case of Oregon, the refusal to issue a drug exemption in the form of a rule.

This trend requires attorneys serving state boards of pharmacy to give meticulous attention to their state's rule-making requirements and the general case law interpreting the scope and application of the rule-making authority of administrative agencies.

Our experience in Oregon leads me to suggest that in order to improve the rule-making process and to have agency rules sustained on appeal, it is necessary for attorneys to work closely with agency members and staff in the planning and conduct of a rule-making hearing.

[1] *Oregon Newspaper Publishers Association v. Peterson*, 244 Or. 116, 415 P. 2nd 21 (1966).

Thus, before a proposed rule is scheduled for hearing, the attorney should determine that the agency is authorized to adopt the rule and that its language states in clear terms how the regulated are to comply with the rule's requirements or prohibitions.

Policy and Legal Considerations

A comprehensive checklist of policy and legal considerations to be applied to a proposed rule is found in the FOOD DRUG COSMETIC LAW JOURNAL.[2] The policy considerations are for the agency, not the attorney who limits his service to legal counsel. Written from the standpoint of the regulated, the checklist points are:

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

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

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

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

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

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

Prior to publication of notice, the attorney should review every procedural step in order to insure that the agency has complied with the hearing notice requirements of the pharmacy law and the state's Administrative Procedure Act.

The next step is to explain to the board members and staff, in non-technical terms, the duty to comply with the various statutory and case law requirements governing a rule-making hearing.

---

[2] Seligman and Stafford, "The Other Man's Shoes" 24 FOOD DRUG COSMETIC LAW JOURNAL 146 (March, 1969).

Impress on the board members that the purpose of a rule-making hearing is to give the public, as well as the regulated, the opportunity to be heard. Don't cite the case law on standing. Instead, advise that the board should receive the testimony of any individual or organization desiring to be heard in support of or in opposition to the proposed rule.

Suggest that the hearing record contain the facts or background of the situation that prompted the board or a petitioner to offer the proposed rule, the problem created by the situation, and the adequacy of the proposed rule to correct the situation.

The record should include rulings on objections and adequate reference to all matters of which the board took official notice. Witnesses should be required to explain in layman's terms the technical terms and exhibits used in their presentations. Board members will understand the technical terms without explanation, but a court reviewing the record on appeal may not.

As stated by Judge Harold Leventhal of the Circuit Court of Appeals for the District of Columbia in an address to administrative lawyers: "Elucidate the technical. You just can't make things too simple for a judge. * * * The lawyer can't take too many pains to make the technicalities too clear."[3]

Procedural Rules

It is assumed that every state board of pharmacy has adopted procedural rules governing a hearing. To the extent not already provided by rule, the board could adopt some form of the following proposals:

1. Briefs on legal points pertaining to the proposed rules are to be submitted to the board prior to the hearing.

2. A party intending to present a witness shall provide, prior to the hearing, a statement of the witness's background, a summary of his anticipated testimony, and copies of scientific articles upon which he intends to rely.

3. A party intending to present an exhibit shall submit the exhibit and an explanation of it prior to the hearing for identification and admission at the hearing.

4. Parties intending to express similar views for or against a proposed rule are encouraged to submit joint statements of position prior to the hearing.

---

[3] Leventhal, "Cues and Compasses for Administrative Lawyers" 20 *Administrative Law Review* 237 (March, 1968).

5. A party voicing an objection during a hearing shall state the grounds of his objection. If the objection is taken under advisement, the objection shall be overruled unless the party submits a brief in support of his objection.

These proposals would shorten hearing time, minimize surprise and, most important, enable the board and its staff to prepare to cross-examine witnesses during the hearing.

Let us now consider a topic as important as the proper conduct of a hearing—the findings of fact, conclusions of law and the order that complete the rule-making process.

State laws vary regarding the degree to which the record of the hearing on adoption of a rule must contain findings of fact to support the agency's decision to adopt the rule.

If the governing statute requires the agency to make findings of fact to support an order or rule, absence of such findings or inadequate findings is reversible error. Thus, the Circuit Court of Appeals for the District of Columbia said of the findings requirement governing the Federal Communications Commission:

> When Congress requires a finding, its instruction is not to be ignored or given only lip service. The need for articulation of findings requires the decision-making body to focus on the value to be served by its decision and to express the consideration which must be the basis of decision.[4]

A particular state law may or may not require the agency to make findings of fact in support of a rule. However, a rule may be subject to attack as arbitrary and capricious if the hearing record lacks facts justifying adoption of a rule. This may be especially true in those instances in which the agency is given a broad power to regulate pursuant to statutory standards, for example, designation of dangerous drugs.

Even where the court does not state that it has reviewed the factual rationale in support of a rule, such review appears to be implicit in decisions on interpretative rules. Thus, in *Angelos v. State Board of Dental Examiners,*[5] the Oregon Supreme Court upheld a regulation which prohibits licensees from advertising certain specialties unless the dentist so advertising meets certain standards. In apparent partial reliance on the factual matters found in the record and presented to the court on appeal, the Supreme Court held that "the Board reasonably could have concluded that the effect of the sign was to create the unwarranted impression that the advertising dentist was a specialist * * *." The decision could have been to the

[4] *Joseph v. Federal Communications Commission* 404 F. 2nd 207, 211 (CA D. C., 1968).

[5] 244 Or. 1, 414 P. 2nd 335 (1966).

contrary in the absence of a showing in support of the reasonableness of the challenged regulation.

Oregon Board's Experience

Let us turn now to the Oregon State Board of Pharmacy's recent experience with rule-making hearings.

Three persons convicted of illegal possession of marijuana petitioned the Oregon State Board of Pharmacy for a regulation to "declassify" marijuana as a statutory narcotic drug pursuant to a statute permitting exemption of drugs not having sufficient narcotic characteristics to warrant imposition of the provisions of the Uniform Narcotic Drug Act.[6]

My colleague, George Woodworth, devoted weeks of effort to gathering of scientific data and views on the issues raised by the petition, obtained witnesses, and following the board's decision, meticulously drafted the findings of fact, conclusions of law, and the order.

The board conducted three days of hearings on the petition to the accompaniment of front-page newspaper coverage and the glare of television lights in a small, crowded hearing room. The petitioners and opponents of the proposed rule were given full opportunity to present their respective views. After concluding the hearing, the board called for briefs on the legal issues from the petitioners and the Attorney General. The Oregon branch of the American Civil Liberties Union (ACLU) was on the brief for the petitioners.

The board reviewed the briefs and evidence and made findings of fact and conclusions of law and issued an order declining to grant the relief requested by the petitioners.

We were subsequently advised by an ACLU attorney that his organization decided not to appeal the order because it was not appealable. The petitioners, however, appealed, but the court sustained the board's demurrer to the appeal on the ground that the petitioners had not complied with the judicial review provisions of the Oregon Administrative Procedure Act. Subsequently, one of the three petitioners filed another appeal, but the court sustained the board's demurrer on the ground that the complaint did not state a cause of action. Again, the petitioner had not complied with the provisions of the Administrative Procedure Act.

In both instances the decisions were limited to the technical issues raised by demurrer. We were confident, however, that had the

[6] Oregon Revised Statutes, Ch. 474.

appeals been tried on the merits, the courts would have sustained the Attorney General's position that the board lacked the statutory authority to grant the relief requested by the petitioners.

One of the three petitioners appealed his marjuana conviction to the Oregon Supreme Court, which indirectly sustained the Attorney General's view that exemption of marijuana was a question for the legislature. The two-paragraph opinion said:

> We are presented with an extensive, Brandeis brief urging us to hold that the inclusion of marijuana in the statute, ORS 474.010(18), as a narcotic drug violates the Fourteenth Amendment and Art. I, § 11, of the Oregon Constitution. Present knowledge, it is claimed, compels the conclusion that marijuana is not a habit forming drug and its specification as such, in the statute, is now so arbitrary as to violate due process. It is secondarily argued that to classify the possession of marijuana as a felony is a "savagely indiscriminate treatment of violators."
>
> The opinions, on the subject, that are expressed in the brief do nothing more than express the best judgment of the persons who express the opinions. Other people, possessed of seemingly equal expertise, find a contrary result from the use of marijuana. The legislature must make the ultimate judgment on the issues presented, not the court.[7]

In another recent decision,[8] the Oregon Supreme Court upheld the validity of a State Board of Pharmacy regulation designating lysergic acid diethylamide (LSD) as a statutory dangerous drug under the Oregon Dangerous Drug Act.[9] The regulation was based on a designation by the State Drug Advisory Council. The court relied on two recent federal decisions[10] in upholding the regulation, but reserved judgment concerning the efficacy of the methods used by the Council in making the LSD designation.

Conclusion

In conclusion, our role as attorneys requires us to work with our agencies in the planning, preparation and conduct of a rule-making hearing and the subsequent drafting of appropriate findings of fact, conclusions of law and the order or resolution adopting a regulation.

Oregon's experience is that such close cooperation between a board and its attorneys helps the board to conduct a hearing and increases the likelihood that a challenged regulation will be upheld on appeal, and thus better enables a board to serve the public and the regulated. **[The End]**

---

[7] *State of Oregon v. Leppanen*, 87 Oregon Advance Sheets 861, 449 P. 2nd 447 (1969).

[8] *State of Oregon v. Sargent*, 87 Oregon Advance Sheets 883, 449 P. 2nd 845 (1969).

[9] ORS 689.650 and 689.660.

[10] *Iske v. United States*, 396 F. 2d 28 (CA-10 1968) and *White v. United States*, 395 F. 2d 5 (CA-1 1968), cert. denied, 21 L. Ed. 2nd 266.

Environmental Health Protection

By CHARLES C. JOHNSON, JR.

This Paper was Presented at the Southern Regional Legislative Seminar on Current Public Health Problems, sponsored by the Southern Conference of The Council of State Governments, April 12, 1969, Atlanta, Georgia. Mr. Johnson is the Administrator of the Consumer Protection and Environmental Health Service, Public Health Service, U. S. Department of Health, Education, and Welfare, Washington, D. C. Biographical Notes on Charles Johnson appear on page 361.

ENVIRONMENTAL HEALTH PROTECTION may well be the most important and urgent issue our generation has to face. It is important, and it is urgent, because the decisions we make today affect not only the health and well-being of our own generation but may well determine the health and well-being of our children and our children's children.

The fact is that we shape our environment, and then our environment shapes us. We have only to look around us to see that we are well on the way—particularly in our urban areas—to creating a world which can have the most serious adverse effects on human health.

Dr. Jerome Wiesner of the Massachusetts Institute of Technology said in recent testimony before a Senate Committee on Technology and the Human Environment, that we are "engaged in a race between catastrophe and the intelligent use of technology, and it's not at all clear we are going to win."

Environmental Problems

Environmental problems are of particular significance at this time to the Southern States because, with regard to certain of these —particularly those associated with rapid urbanization, industrialization, and population increases—you are at a point of critical decision, with options open to you which no longer exist for many highly urbanized areas in other parts of the country. Of course, you are no strangers to problems caused by misuse of the environment. Several of the states represented here have inherited the terrible after-

math of strip mining operations, and most of you have been battling for several generations the devastating effects of unwise agricultural practices. But such problems as pollution, crowding, noise, waste disposal—which seem almost beyond remedy in some of our northern states—are in an earlier stage of development in most of the South.

However, as seems always to be the case when we begin to look closely at environmental problems, it is already later than we think, even for you here in the South. Just one indication is this fact, which I will confess came as rather a surprise to me: 17 of the 32 fastest growing large metropolitan areas in the United States (those with a population of 250,000 or more) are in the 15 States represented by the Southern Conference. The rate of growth and change in your States is rapid. It's apparent that we are going to have to run faster and faster just to stay even with the developing problems.

It may seem, at first glance, unnecessary to state that all concern with the environment is essentially a concern for man—for his total health, happiness, and well-being. And yet, it seems to me it is worth stating and restating, whenever we are faced with decisions affecting the environment. For the environmental problems that plague us today are largely the result of our narrow pursuit of limited objectives—economic efficiency, fast transportation, agricultural abundance, for example—and our tendency to endow these activities with a life and purpose of their own, separate from or even superior to the needs of the human beings they were designed to serve.

The time has come when we must recognize that the various systems and subsystems which we devise to maintain ourselves on the planet—systems of economics, transportation, education, agriculture, etc.—that all these should contribute to the *total* well-being of the citizen and consumer.

The organization which I have the privilege, and the problem, of heading, The Consumer Protection and Environmental Health Service, has been established to provide a new impetus to our National effort to save the environment, and to provide a focus on man as part of that environment.

It includes the Food and Drug Administration, headed by Dr. Herbert L. Ley, Jr.; the National Air Pollution Control Administration, headed by Dr. John T. Middleton; and the Environmental Control Administration, headed by Assistant Surgeon General Chris A. Hansen. For the first time in the Department of Health, Education, and Welfare we have brought all these organizations, dealing with

protecting human beings from environmental hazards, together in a situation where they can be mutually supportive. We are finding that we are now able to take a more coordinated approach to environmental problems, and we are moving ahead as rapidly as possible to create a program which will have a real and lasting impact on these problems.

I will turn now to some of the specifics of environmental change that bear on human health. I know that you will want me to be as candid as possible in assessing some of the environmental problems of your states and the measures you are taking to combat them. Of course, perfect candor is not always easy to bear. I am reminded of a little story about Southern courtesy and hospitality which relates to that.

It seems a young couple—visitors from the North—were walking down Peachtree Street in Atlanta one day and had lost their way. They stopped a kindly little old lady and inquired how far it was to the State Capitol.

"Oh," she said, "it's at least 15 blocks."

Then she noticed how tired and crestfallen they appeared at the news, and she said, very sweetly and gently, "Oh, I think I'll make it 10 blocks. After all, you-all are walkin'."

Well, it is a temptation for me, too, to soften my comments, particularly in view of the kindness and hospitality you have shown me here. However, I know you are here to deal with facts, no matter how disturbing they may be. And, while I will have to point out areas in which I feel you in the Southern States are not moving fast enough against your environmental problems, I should make it clear that you are not alone. As a nation, we are not dealing adequately with these matters, even in other parts of the country where the damage is already far advanced. In other words, we are all on foot, like that couple in Atlanta, and we have a long way to go. We might as well know just how far.

Food Contamination

Let me begin with food, since this is one of the most basic requirements of man and a subject of special interest to your states, which produce and process so much of the nation's food supply. Maintaining uncontaminated food is a continuing and indeed a growing problem. It is estimated that over two million Americans are stricken with illness each year from microbiological contamination of food—chiefly salmonellosis.

What is more, the use of food additives to impart flavor, color or other qualities has increased 50 percent in the past ten years, and each of us now consumes an average of three pounds of these chemicals yearly. Pesticides leave residues on food crops, and traces of veterinary drugs occur in meat, milk and eggs—all this in addition to the chemical barrage that reaches us from other parts of the environment.

The Food and Drug Administration, which is now part of our new Consumer Protection and Environmental Health Service, is working toward a fuller partnership with the States which should benefit both interstate and intrastate food programs. It is developing agreements with the several states which will involve a full interchange of activities and resources, and, most importantly, will help to assure that foods marketed on a strictly intrastate basis are safe and wholesome. For example, in the control of medicated feeds, nine[1] of the states represented here have entered into formal arrangements to accept or share responsibilities for the inspection of medicated feeds to insure safe and effective animal medication while assuring man of a food supply free of drug residues. Another five states[2] are currently developing their capability to enter into a formal planning arrangement. Exploratory conversations have been held with the other state.[3]

We intend to move ahead as quickly as possible to extend this partnership approach to other areas of food protection, and I hope you will all be prepared to enter into this kind of cooperative planning to assure safe and wholesome food for all our people.

Pesticide Residues

Pesticide residues on food continue to be a problem. The value and the hazards connected with pesticide use are nowhere better understood than here in the fruit and vegetable garden of the nation. Federal regulatory authority in this area covers only interstate shipments, and here again we are faced with the fact that much of the food produced on farms never crosses state lines. Effective state surveillance is a practical necessity, and yet the truth is that most states in the South—and many agricultural states in other parts of the country—are not doing enough to protect their consumers against ingesting toxic pesticide residues on food.

[1] Florida, Georgia, Kentucky, Maryland, Oklahoma, Tennessee, Texas, Virginia, West Virginia.

[2] Alabama, Arkansas, Louisiana, Mississippi, South Carolina.

[3] North Carolina.

Just last week, the Food and Drug Administration found it necessary to impound some 28,000 pounds of frozen salmon taken from Lake Michigan which was destined for interstate shipment because of pesticide contamination ranging up to 19 parts per million. Up to now, pesticide residues in fish haven't presented a significant problem, and we are not sure why this one species from Lake Michigan has concentrated these excessive levels. It is an indication of the need for continuous re-evaluation of our environmental control efforts.

Our water hygiene program conducts periodic surveys for pesticide contamination of coastal water and estuarine areas, including the Southeast and Gulf Coast areas. Results to date have shown a low level of pesticide occurrence.

In addition, as part of a community water supply survey which we have begun in recent months, we are measuring the percentages of 10 chlorinated hydrocarbons in finished water from treatment plants served by surface sources and are doing selective measurements on raw water from surface sources and shallow wells. Our report on this nine-city survey will not be completed until September of this year, but I believe some preliminary results will be available earlier.

An adequate State pesticide program cannot be a hit-or-miss thing. It requires laboratories, crop analysis and inspection, control or permit systems to deal with major spraying and dusting operations; and it requires an informational and educational program to increase voluntary compliance. The State of Florida has established a very fine program, having most of these features; I would suggest that other States might contact the Florida Department of Agriculture for additional information.

State Legislation

The Public Health Service (PHS) has for many years provided assistance in the area of food and milk protection to states and local jurisdictions through a voluntary, cooperative, technical assistance program. I understand that while most of the Southern States have adopted our recommended 1965 Pasteurized Milk Ordinance and the 1962 Food Service Sanitation Ordinance and Code, there are several which have not done so. I would urge those that have not already adopted these codes to do so, as a step to implementing uniform food protection.

There is no question that there is much to be done, both here in the South and in other parts of the nation, before we will have adequate control over this problem.

Of course, the first requirement for protection in the whole area of food and drugs is an adequate legal base, and I am told by those who have examined state laws closely that most of the states represented here need to make a major effort to modernize, update, and strengthen their legislation.

In this group of 15 states, five[4] have food and drug laws based upon the original 1906 Federal Statute, now grossly out of date and inadequate. Six[5] others have patterned their laws after the more modern Federal Act of 1938, but do not include important later provisions requiring a preclearance for safety of food additives, and establishment of pesticide tolerances. Florida, Kentucky, Tennessee, and Texas have legislation which includes these later amendments regarding food. I understand that modern food and drug legislation is now before the West Virginia legislature.

As for drugs, lax state laws encourage quackery which presents serious threats to human health and drains the pockets of the very people who can least afford it. In fact, even some of the most sophisticated people fall victim to our generation's faith in "miracle" drugs, no matter how unproven, as we can see from the recent exposure to weight-control nostrums.

I can't urge you too strongly to move ahead rapidly in the area of food and drug protection.

Poisons

Before I leave the general subject of legislation to protect the consumer, I think I should mention another legislative area which should be given high priority for state action. These are the hazardous substances and products: poisons; products which are corrosive, irritant, flammable or explosive; products which offer threats from radiation. This is a growing problem, with thousands of new and untested, inadequately labeled, products being rushed to market every year. Some 3,000 deaths occur every year from accidental ingestion of poisons—most of these among children. In addition, other types of accidents, not including highway accidents, take the lives of about 50,000 Americans yearly, and many involve unsafe products or misuse of products. We have moved ahead at the federal level.

[4] Alabama, Maryland, Mississippi, South Carolina, West Virginia.

[5] Arkansas, Georgia, Louisiana, Oklahoma, Virginia, North Carolina.

We now have a Electronic Products Act which provides for federal regulation of products that produce harmful ionizing or non-ionizing radiation. These may include color television sets, microwave ovens and the like. Furthermore, we are now able to ban from interstate commerce any hazardous substance intended for use by children, or any which would not be adequately controlled by a label warning. But many such substances are produced and distributed locally and can be controlled only by state statute. Yet, only five states[6] among this fifteen have a Hazardous Substance Labeling Act, and none has enacted the stronger "child health protection" provisions.

Air Pollution

Let's move to another concern. Air pollution is one of those problems which is relatively new to the South. However, it is by no means a negligible problem here. Among the 65 metropolitan areas which the National Air Pollution Control Administration has listed as having the most severe air pollution, 14[7] are below the Mason-Dixon line (15 if we include Washington, D. C., with its Maryland and Virginia suburbs). Louisville, Birmingham, Nashville, and Washington are in the top 35.

Examples of major sources of air pollution are not hard to find. They range from the phosphate fertilizer plants in Florida to the vast industrial complex located in Houston, and from the chemical factories in the Kanawha Valley of West Virginia to the steel mills in Birmingham, and they include isolated industrial operations in scores of smaller communities and agricultural and refuse burning in many places scattered across the South. Furthermore, in the South as in the rest of the nation, reliance on the motor vehicle, coupled with population and industrial growth, can only increase the problem.

In fact, ranking cities as to the amount of air pollution always reminds me of another story. Two little boys were playing together, when one held up his hand and said proudly, "My hand's dirtier than yours." "No wonder," said the other one, "you're a year older." I guess the moral is this: wherever your city ranks in air pollution today, if you're growing you're going to get dirtier, unless you take steps to prevent it.

At the present time, toxic matter is being released into the air over the United States at a rate of more than 142 million tons a year,

[6] Kentucky, Oklahoma, Tennessee, Texas, Virginia.

[7] Baltimore, Louisville, Birmingham, Nashville, Houston, Chattanooga, Memphis, Richmond, Atlanta, Dallas, New Orleans, Fort Worth, Miami and High Point-Greensboro.

or three-quarters of a ton for every American. And what does this do to people? In the first place, there is no doubt that polluted air is a major contributor to emphysema, chronic bronchitis, and lung cancer—some of the major "diseases of civilization" which are on the increase, as the rate of many communicable diseases, which plagued our ancestors, declines.

Furthermore, since we are interested in the "whole man," let's see what it costs us in economic terms. The annual cost to U. S. citizens of air pollution has to be computed in billions of dollars. In figures that are more easily understandable, it is estimated to cost each of the 200,000,000 American citizens $65 per year; for those who live in highly polluted areas, the cost per person, including higher medical bills, household maintenance, and other expenses, can be more than $200 per year. The cost in damage to agricultural crops alone is more than $500 million every year.

In California, citrus growing has become unprofitable for many growers in the main citrus belt south of Los Angeles, and other crops have been hard hit as well. In New Jersey, air pollution is now considered a greater menace to farmers than bad weather, pests or insects. In Florida, it has been reported that fluorides from the phosphate plants threaten the very existence of the cattle raising and citrus growing industries.

In recent years, the South's response to air pollution as a community problem has been encouraging. Every state represented here, except Alabama, has an air pollution control program, and many cities and counties either have programs or are in the process of setting them up. Over the past four years, the Department of Health, Education, and Welfare has furnished states and communities a total of nearly $8 million in grants for pollution control programs.

Under the Air Quality Control Act of 1967, we expect to designate 14 metropolitan areas in the South as air quality control regions during the coming year. These are Atlanta, Louisville, Beaumont-Port Arthur, El Paso, Oklahoma City, Memphis, Houston, Dallas-Fort Worth, San Antonio, Birmingham, Chattanooga, Charlotte, New Orleans and Miami. As we move along further in this regional approach to pollution control, I feel sure this will provide a further stimulus to state and city efforts.

Occupational Safety

I want to mention with particular emphasis another type of environmental hazard which I believe should be given priority here

where industrialization is proceeding at such a rapid rate. This is occupational safety and health—the oldest and yet one of the most neglected of the whole spectrum of environmental problems. Every year, hundreds of new chemicals and chemical compounds are introduced into industry, along with countless operational innovations. Thousands of workers suffer from cancer, lung disease, hearing loss, dermatitis, or other preventable diseases because industry, unions, and government at all levels have failed to give adequate attention to occupational hazards. We are finding every year new and subtle threats to workers' health, growing out of our new technology, and yet we have made almost no progress in the last 50 years against some of the oldest occupational diseases of man.

Last December, in an effort to initiate some sort of sensible attack on the age-old plague of coal miners—"black lung," as it is called, or coal workers' pneumoconiosis—I issued a recommended standard for dust in soft coal mines. This calls for respirable dust levels not exceeding 3.0 milligrams per cubic meter. Legislation now before the Congress would establish this standard as a goal. We believe that enforcement of this standard can greatly reduce the incidence of coal workers' pneumoconiosis and slow the progress of the disease in persons already affected. The standard is long overdue in the United States. Today, 100,000 soft coal miners suffer, to some degree, from this serious disease, as you from the coal-producing States well know.

This is only one of several serious occupational diseases which we, as a nation, have neglected far too long. Let me tell you of one, in particular, which has special significance for you.

For years, it has been maintained by many that byssinosis—the lung disease caused by inhaling cotton dust—was not a problem for American textile workers. In Britain, where textile plants use American cotton, byssinosis has been recognized as a serious problem. There has never been a thorough study of the health of American textile workers, but for some reason (largely, I believe, on the basis of X-ray studies made years ago) we have had the comfortable illusion that byssinosis was not a threat to American workers.

Now, the scientists in our occupational health program tell me, we find this is far from the truth. Recent studies have shown a high incidence of byssinosis among textile workers here in the United States. In one mill, employing 500 people, 12 percent were found to have the disease, with 30 percent of those in the carding room affected. In another mill, 26 percent of those in the carding and

spinning rooms were victims of the disease. Social Security disability records bear out this finding. A recent PHS study showed a significant excess of chronic bronchitis and emphysema among textile workers as compared with the general population.

Byssinosis is a serious disease, progressing from "Monday morning chest tightness" in its earliest stages, to chronic bronchitis and emphysema, which cause permanent disability.

Of 230,000 cotton textile workers in the United States, over three-quarters, or 180,000, are employed in North Carolina, South Carolina, Georgia, and Alabama; other Southern States, of course, also have cotton textile mills.

We intend to give more attention to this and similar problems at the federal level, and I urge that you do so at the state level, as a means of protecting the health and strengthening the economy of your areas and the nation.

The truth is that very few states in the nation have occupational health programs that even approach adequacy. I understand that Tennessee, among those represented here, has a very fine program to protect workers' health. But, on the other side of the ledger, three Southern States[8] have no occupational health program at all—and I would venture to say that none of the others is staffed and equipped to do the job that ought to be done.

There is need for stronger legislation, both at the state and federal levels, to protect workers from occupational disease and injury.

Let me give you one chilling example of what happens in our present situation. Unfortunately, this involves one of your States. (Incidentally, this was brought out in hearings on the Occupational Safety and Health bill last spring, so is a matter of common knowledge.)

A few years ago, the State of Pennsylvania adopted a regulation prohibiting the manufacture or use of beta-naphthylamine within the State. This extremely dangerous dye ingredient has been found to produce bladder cancer in a very high percentage of exposed workers. Do you know what happened? The manufacturer moved his operation to Georgia. So the total effect was that Georgians now get bladder cancer instead of Pennsylvanians. Since beta-naphthylamine is so dangerous to health, and since there are satisfactory alternatives to its use, there is no question its manufacture should be prohibited or strictly controlled everywhere. At the present time, it is outlawed in most of the countries of the world, and manufactured only in the United States, Japan, Italy and Czechoslovakia.

[8] South Carolina, Alabama, Arkansas.

Drinking Water

We in the Consumer Protection and Environmental Health Service are also very much concerned about another problem which is growing in seriousness with every year that passes: the quality of drinking water. Most of the community water supply systems in this country were initially constructed over 30 years ago and were designed to serve population densities that were 20 to 40 percent less than today's. Despite efforts to modernize and increase capacities, many systems have fallen behind and are failing, in many respects, to meet today's needs.

These systems were designed to treat a high quality of raw water for removal of bacteria, with little or no capability for removing toxic chemical or virus contaminants. Today, both ground and surface water supplies have deteriorated. At the same time, the efficiency of treatment plants has deteriorated, and so have surveillance and health controls over public drinking water supplies. Almost all of the states have become complacent about the safety of drinking water. We can no longer afford such complacency!

I had our water supply people make up a list for me of the community water supply systems in your states which are presently given only "provisional approval" by your own survey teams as part of our interstate carrier sanitation programs. I was shocked myself, because it contained the names of almost 60 communities—and these are, by no means, obscure hamlets. Included are some of your largest and busiest cities.

I hasten to add that this "provisional approval" status does not mean that the water is not safe to drink, but it is a warning that deficiencies in the system's construction, maintenance, operation or quality control must be corrected if certification of the water for interstate carriers is to be retained. I might add that our own PHS standards for drinking water need to be updated, particularly with regard to chemical, viral, and radiological contamination.

I believe we are rapidly approaching a crisis stage all over the country with regard to drinking water. The time has come when communities are going to have to allocate substantial resources to modernizing their treatment plants and improving their distribution systems or continue to court serious health hazards from contamination.

Solid Wastes

Another environmental problem, which may well prove to be the most difficult and serious of all, is disposal of solid wastes. Every

year, we discard more than 190 million tons of garbage, cans and other refuse. This is just household waste. If we include industrial, commercial and agricultural wastes, the figure is something like 3.5 billion tons. Nonreturnable bottles, aluminum cans, and new types of disposable paper products complicate the problem.

Nationwide, collection and disposal of garbage and other solid waste cost an estimated $3.5 billion in 1967, and yet the methods used are little improved over those of 25 years ago. A colleague of mine in New York liked to point out that the only real improvement we had made in waste disposal in the last 50 years was putting an engine instead of a horse in front of the garbage truck.

In the inner city, accumulated garbage and trash create breeding grounds for rats, insects and vermin and constitute a major health problem. In the South, warm temperatures compound this problem by providing a long breeding season for these pests. Before we can do anything effective in the poor areas of our cities, we have to attack the problem of solid waste disposal through better storage and collection methods and, in fact, through education of the people. Our Environmental Control Administration is assisting rat control programs in Atlanta, Nashville, Norfolk, and Charlotte that will employ this comprehensive approach.

Yesterday's city dump is now in today's suburb, so that most cities in the country are now destroying out-of-the-way areas of natural beauty, and polluting land, air and water, in an effort to get rid of mountains of refuse. Our federal program is funding research and demonstration projects designed to develop alternative methods of dealing with the problem, including composting and recycling.

Under properly controlled conditions, use of solid waste as landfill material can restore certain areas to useful purposes. I understand Kentucky is considering the idea of using abandoned strip mine pits for sanitary landfill to dispose of garbage, an approach that has also been used in Pennsylvania. The problem of sanitary landfill as a disposal method, of course, is that many cities no longer have accessible areas where this is appropriate.

There is no question that existing systems for getting rid of trash are largely obsolete and inadequate. I strongly urge you to begin now, if you have not already done so, to plan for solid waste management on a Statewide and regional basis.

The Partnership for Health

We in the Consumer Protection and Environmental Health Service are prepared to assist the States in every way possible in plan-

ning and implementing their environmental programs. One mechanism which many states are overlooking as a means of developing their environmental programs is the assistance available under the Partnership for Health, the Comprehensive Health Planning program authorized under Public Law 89-749 in 1966 and expanded by amendment the following year. The intent of this legislation is to assist states and communities to achieve the "highest level of health attainable for every person, *in an environment which contributes positively to healthful individual and family living,*" and it offers financial assistance to accomplish this.

But we are finding that very few of these "comprehensive" health plans include the environmental factor. I cannot say specifically what your States are including in developing your plans. However, I was glad to note that at least seven of the states represented here[9] have included environmentalists on their Comprehensive Health Planning advisory councils, so that it appears they intend to give consideration to environmental planning under this mechanism. Three states[10] have not yet established advisory councils, and, so far as I could determine, the other five have not included any environmental disciplines on their councils.

I certainly would recommend that each of you make sure that problems of environmental control are given consideration in the preparation of your state and area health plans. I realize that every state has a multitude of health needs which this Federal program can help to meet. But we cannot ignore the fact that environmental deterioration, and particularly the terrible morass of environmental problems which afflict our inner cities and poorer rural areas, is a health problem. No health plan can be regarded as comprehensive unless it gives consideration to environmental improvement—a most important step in preventing disease.

I hope I have given you some suggestions which may be of use to you as you go back to your own states. As I promised when I began, I have tried to be frank. Perhaps those of us who are concerned with the environment in this time of environmental crisis have a duty like that of the preacher. Don't they say that "it is the duty of the preacher not only to comfort the distressed but to distress the comfortable"? While I do not represent myself as a preacher, I hope that I have been able to strike a happy balance between these two obligations. [The End]

[9] Arkansas, Maryland, North Carolina, Oklahoma, South Carolina, Tennessee and West Virginia.

[10] Louisiana, Mississippi, Texas.

Biographical Notes

Charles C. Johnson, Jr.

Administrator, Consumer Protection and Environmental Health Service

Charles C. Johnson, Jr. was born in September, 1921. He attended Dowling Junior College and received his Bachelor of Science and Master's Degrees in Civil Engineering from Purdue University. His schooling was interrupted by four-year service in the Marine Corps, from which he was honorably discharged as a Second Lieutenant in 1946.

Mr. Johnson began his career with the Public Health Service (PHS), Department of Health, Education, and Welfare (HEW). His first assignment was as a Sanitary Engineering Consultant with the PHS Mission to Liberia. In 1951 he became a Staff Officer with the Division of Sanitary Engineering Services.

In the Division of Indian Health, Mr. Johnson served as an Institutional Sanitation Consultant, coordinating field activities for the sanitation program. From 1960 until 1966, he was the Division's Chief of the Sanitation Facilities Construction Branch. He developed administrative guides and directed field activities for the first direct construction program undertaken by the PHS. The PHS commendation medal was awarded to him for sustained high quality work in this capacity.

Mr. Johnson then became Chief in the Office of Environmental Health. He was responsible for educational and motivational programs and services. As Assistant Commissioner of Health in New York City, he planned and implemented programs for 8,000,000 people.

Presently, Charles Johnson holds the rank of Assistant Surgeon General in Consumer Protection and Environmental Health. The Food and Drug Administration, National Air Pollution Control Administration and the Environmental Control Administration are under the guidance of this department.

GMPs—
A Statistician's Point of View

By CHARLES DeWITT ROBERTS

Mr. Roberts Is Assistant Professor of Statistics at the Graduate School of Business Administration of New York University.

Lest men suspect your tale untrue, keep probability in view.—John Gay

. . . in this world nothing is certain but death and taxes.—Benjamin Franklin

THE OBJECT OF THIS PAPER is to present a statistician's (and probabilist's) point of view of recent Good Manufacturing Practice (GMP) regulations. In particular, it is intended to point out the inflexibility of some of the regulations to take into account the highly developed mathematical theory of probability and statistics. In a recent article by Shupe[1], the pharmaceutical industry's point of view of recent GMPs was presented.

As a professor of statistics, I try to impress upon my students the uncertainty of almost everything: You toss a coin and call heads or tails. But as the coin is still in the air, a passing eagle swoops down, and thinking it to be food, eats it; so the outcome is neither heads nor tails. Furthermore, nothing you think you have is really yours: I called my secretary and asked, "Is this Professor Roberts' secretary?", and she replied, "No," later explaining, "Well, they couldn't talk to you since you weren't in, so it didn't matter."

Law of the Iterated Logarithm (LIL): This widely known probabilistic law is discussed mathematically by Feller[2] and is most easily described by the following example: Given a fair coin, and any number p, where p is greater than O and less than 1, then it is

[1] Shupe, "GMPs—An Industry Point of View," 24 FOOD DRUG COSMETIC LAW JOURNAL 14-16 (January, 1969).

[2] Feller, *An Introduction to Probability Theory and Its Applications*, Vol. 1, 2nd Edition 191 (1958) John Wiley & Sons.

possible to toss the coin enough times so that the fraction of heads in the past is greater than p with absolute surety. Thus, even if the coin is fair, with absolute certainty you can toss the fair coin enough times so that the fraction of heads exceeds 0.999, for example. It may take an incredibly long time to do this, to be sure, but it can be done.

Stated in another way, if you test an ineffective drug long enough, on enough patients, it will eventually, at least for a moment, look as if it is good. An unscrupulous (or misinformed) experimenter could perform an experiment sequentially until he obtained the result he wanted, and then assert that his product is "significantly better" when it really isn't.

USPWVT: Let us now consider the statement, "The lot must pass the United States Pharmacopeia's Weight Variation Test (USPWVT)[3]." In a recent article by Roberts[4], it is pointed out that "the nature of the USPWVT is such that it is possible, with almost any fairly large-sized lot, to fail the test and thereby cause recall of the entire lot. . . . If the person sampling had carefully selected the 20 tablets from the entire lot of say 1 million tablets, it is easy to see that he could surely have caused USPWVT failure of the entire lot, based only on a small fraction of the lot."

That paper points out an alternative method for fill weight variation standards which can be applied in practical situations. The method is to specify that, for example, "The lot must pass the USPWVT at least 999 times in every 1000 times the test is performed." This would eliminate the opportunity of a hostile examiner to select the tiny sample that would cause lot rejection (by the LIL property), and would require him to make inferences about the entire lot, which might be good, even if the sample were not particularly satisfactory.

Accountability: If one tosses a fair coin and bets $1 on the outcome, his expected winnings are $0. However, the outcome of $0 is impossible; he will either win $1 or lose $1, provided the eagle does not intervene. The key here is variation. It has been mused that "A statistician is a person who puts his head in a refrigerator and his feet in a stove, but on the average he feels pretty good."

[3] *The United States Pharmacopeia,* 17th Revision 926-927 (1965).

[4] Roberts, "Fill Weight Variation Release and Control of Capsules, Tablets, and Sterile Solids," 11 *Technometrics* 161-175 (1969).

To say that 100% of the product was accounted for is meaningless, if the possible errors of computation could allow the figure to vary from 50% to 150%.

The section 133.6 of the Food and Drug Administration's (FDA's) GMP for raw materials or components of the finished product requires, "an accurate statement of the weight or measure of each ingredient . . ., except that reasonable variations may be permitted . . ., provided that variations are stated in the master formula, . . . appropriate statements of theoretical weight or measure at various stages of processing and a statement of the theoretical yield."

While the FDA's statement is not completely specific, it is clear that zero variation is not required, since then no product could be made. On the other hand, reasonable accountability is required at all stages of the process, and rightfully so. At present, many (or possibly all) pharmaceutical companies do not compute a "variance" of the accountability. In a very recent paper, Roberts[5] gives a method for computing a theoretical variation of accountability.

In GMPs, we would look for the permitted limits of variation to be specified. We want to know if 1%, 5%, or 50% variation is acceptable for accountability, since the cost of production depends directly on the amount of variation that is allowable. We want to know the permitted rate of failure of the USP Weight Variation Test. For a particular lot, can the USPWVT be failed one in a hundred, a thousand, or a million times the test is performed?

Variation is a serious problem. Although the GMPs require, "In the event of any unexplained discrepancy, distribution of the batch in question and other associated batches of the drugs that may have been involved shall be prevented," while referring to labels, it is clear to the author that future FDA actions will bear this rule in mind for all types of accountability. **[The End]**

[5] Roberts, "On the Accountability Problem of the Pharmaceutical Industry," unpublished manuscript.

CCH Help on Tough New Consumer Credit Rules, Federal and State

CONSUMER CREDIT GUIDE

Creditors and their advisers have their work cut out for them. The strict new federal Truth-in-Lending rules are now in effect. Living and complying with these drastic and unfamiliar consumer credit requirements is a big order!

But it CAN BE E-A-S-Y. Join "the safe ones" by subscribing for CCH's new CONSUMER CREDIT GUIDE. It rounds up, fits together and *explains* existing, new and coming federal and state consumer credit and disclosure rules. Now, when you need all the help you can get, you'll welcome the GUIDE!

If *your* interests are affected (and a tremendous amount of money rides on how this urgent problem is handled), your contracts, practices and procedures, catalogs and advertising, employees, etc., must comply with new rules. Regulation Z, and Rulings issued under it by the Federal Reserve Board, is now a big part of this compliance picture.

Sure-Footed "Catch-Up" Help Included at No Extra Charge

To give you urgently needed guidance on all the new requirements, as a GUIDE subscriber, we'll send you immediately and at no extra cost, two ready-to-use Volumes, featuring official and explanatory coverage of the laws, regulations, and decisions within its scope. The federal Truth-in-Lending Act and the Uniform Consumer Credit Code Draft are singled out for special attention. Handy Charts and a Check List summarize federal and state requirements to keep you from overlooking anything important. Nothing is left to chance; *safeguards* come first in the GUIDE!

Dependable Biweekly Reporting Keeps You "Out Front," Ready to Act

Biweekly "GUIDE Reports" follow to keep you right up to date on new developments affecting consumer credit as they break. Oklahoma and Utah have adopted the UCCC, which will replace existing state rules in one clean sweep and may also yield statutory exempt status. New York and other states have made big changes in their consumer credit laws.

A quick-reading "summary" also goes to subscribers at no extra cost, highlighting new items and referring you to where in the "GUIDE Report" each is treated.

CONSUMER CREDIT GUIDE offers welcome help to instalment sellers and lenders, banks, mortgage houses, credit unions, lawyers and other concerned groups. Just your OK and return of the post-free card attached brings all this help to you, starting immediately.

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS of TOPICAL LAW REPORTS

420 LEXINGTON AVE. NEW YORK 10017 | 4025 W. PETERSON AVE CHICAGO 60646 | 425 13TH STREET, N. W. WASHINGTON 20004

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN REQUESTED

SECOND CLASS POSTAGE PAID
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

A COMMERCE CLEARING HOUSE PUBLICATION