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Food Drug Cosmetic Law JOURNAL

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

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

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Editorial Advisory Board

REPORTS

TO THE READER

(This is a report on the annual meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association by *Franklin M. Depew,* Chairman of the Section.)

The nineteenth annual meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association was held on January 28, at the New York Hilton Hotel in New York City. An audience of over 100 was in attendance at the all-day meeting and luncheon. *William F. Fitz-Patrick,* President of the New York State Bar Association, greeted those in attendance and congratulated the Section on its membership growth during the past few years. The Section was honored to have as its guests at the luncheon, in addition to Commissioner of Food and Drugs, *George P. Larrick, Mrs. Charles Wesley Dunn, Ralph Bernstein,* Assistant Director of New York Office, New York State Department of Agriculture and Markets; *Jerome B. Trichter,* Assistant Commissioner, Environmental Sanitation, New York City, Department of Health; *Robert E. Curran, Q.C.,* former Legal Adviser, Canadian Department of National Health and Welfare; *Augustus Gibson, M.D.,* Director, Medical Research Division, Schering Corporation; and *C. Joseph Stetler,* Vice President and General Counsel, Pharmaceutical Manufacturers Association.

Commissioner Larrick was the speaker at the luncheon and reported on the important developments during the past year in connection with administering the nation's food and drug laws. His remarks and those of the other speakers are reported in this month's JOURNAL. At the close of his opening address, *Chairman Depew* appointed a Resolutions Committee consisting of *Michael F. Markel,* Chairman, *George M. Burditt* and *F. T. Dierson.* Prior to the meeting a Nominating Committee had been appointed consisting of *William J. Condon,* Chairman, *Frank A. Duckworth,* and *George T. Scriba.*

At the conclusion of presentation of formal papers, a business meeting of the Section was convened. *Chairman Depew* pointed out that membership in the New York State Bar Association and in the Section is open to all attorneys practicing in the field regardless of whether or not they are located in the State of New York. He additionally pointed out that the best way to keep informed of the activities of the Section was by becoming a member thereof.

In the course of his address, *Mr. Burditt* had suggested that the Chairman of the Section should appoint an *ad hoc* committee consisting of federal and state officials, food technologists, consumer consultants, salesmen and

lawyers to draft and recommend to Congress an appropriate amendment of Section 403(c) of the Federal Food, Drug and Cosmetic Act requiring certain foods to be labeled as imitations. *Chairman Depew* appointed *George M. Burditt* and *Vincent A. Kleinfeld* as members of a special committee to advise the Chairman relative to the desirability and make-up of such an *ad hoc* committee.

The Resolutions Committee then proposed and after discussion the Section unanimously adopted the following Resolution:

"WHEREAS, the Food, Drug and Cosmetic Law Section of the New York State Bar Association has consistently advocated uniformity among states in food and drug and weights and measures laws, and regulations and enforcement thereof;

"WHEREAS, the National Conference on Weights and Measures is currently considering proposed amendments to the Model Law and Model Regulations governing weights and measures labeling; and

"WHEREAS, several states have recently adopted conflicting and non-uniform rules governing the size of net quantity statements on commodities in package form, which rules violate the principle of uniformity, and are detrimental to the interests of consumers and industry.

"NOW, THEREFORE, be it resolved:

"1. That the Section reaffirm its policy on uniformity and urge the application of that policy to state weights and measures laws and regulations, including those governing the size and prominence of net quantity statements on packaged commodities;

"2. That this Section offer its assistance to the National Conference on Weights and Measures and to all state weights and measures officials in furtherance of this policy;

"3. That a copy of this resolution be sent to Mr. J. Lyle Littlefield of Michigan, Chairman of the Committee on Laws and Regulations of the National Conference on Weights and Measures, and to Mr. Joe F. Lakey of Texas, Secretary of the Association of Food and Drug Officials of the United States."

Chairman Depew then asked for a report of the Nominating Committee and turned the chair over to *William J. Condon,* Chairman of the Committee. Nominations were received as follows: *Franklin M. Depew,* Chairman; *A. M. Gilbert,* Vice Chairman; *Raymond D. McMurray,* Secretary; and *Frank T. Dierson, James F. Hoge,* and *H. S. Woodruff,* as members of the Executive Committee.

There being no further nominations, upon motion duly made and seconded, the Secretary was directed to cast a unanimous ballot for the persons so nominated.

There being no further business, the meeting was thereupon adjourned.

About This Issue.—This month's issue of the JOURNAL is devoted to papers which were delivered at the annual meeting of the New York Bar Association Section on Food, Drug and Cosmetic Law. The conference's concluding paper, "The Effect of the Investigational Drug Regulations on Drug Research and Development," by *Augustus Gibson,* Director of the Medical Research Division of Schering Corporation, will be included in next month's issue.

Vol. 19, No. 2 February, 1964

Food·Drug·Cosmetic Law
Journal

Introductory Statement

By FRANKLIN M. DEPEW

Franklin M. Depew, Chairman, Section on Food, Drug and Cosmetic Law of the New York Bar Association, and President of the Food Law Institute, Presented This Statement at the Nineteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association on January 28, 1964, in New York City.

I AM DELIGHTED to extend a cordial welcome to all of you to the Nineteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association. We have prepared a program for you which we believe will be of absorbing interest to all those concerned with our food, drug and cosmetic laws.

Before introducing our speakers I wish to say a few words about important happenings in this field during the past year. First, we welcome the steps taken by the Honorable Anthony J. Celebrezze, Secretary of Health, Education and Welfare, to carry out the salient features of the recommendations contained in the Second Citizens' Advisory Report, in his recent reorganization of the FDA. Since Secretary Celebrezze announced the broad outlines of such a reorganization, George P. Larrick, Commissioner of Food and Drugs, and his staff have been quite successful in implementing the Secretary's proposals. We congratulate them on the steps taken to date and look to continuing improvement in the flow of work processes and to more efficient operation. We also take this occasion to congratulate the drug industry and the FDA staff in solving their disagreements, which threatened to become troublesome, with respect to the regulations covering labeling and advertising of prescription drugs.

Discord Caused by States' Nonuniform Labeling Regulations

I now refer to an unhappy development of the past year, which has created some discord between industry and government. This has been the action taken by various state weights and measures agencies in adopting nonuniform regulations on minimum type size and placement of the new quantity statement on the label. Industry and consumers are therefore faced with a complete lack of uniformity in state requirements which is confusing, expensive and unreasonable, and which threatens to destroy the common market of the United States in food and related products. Our Section has devoted many of its papers to the great need for uniformity in food and drug legislation. These papers have emphasized that sound and uniform state laws and enforcement are not incompatible with state sovereignty. A number of these papers were presented by officials of the Association of Food and Drug Officials of the United States. This association of state food and drug officials has endorsed uniformity as has the National Conference on Weights and Measures. However, on reviewing the records of our Section I can find no resolution by the Section on this subject. I, therefore, recommend to the Committee on Resolutions, which I am appointing for this meeting, consisting of Michael F. Markel, Chairman, and George M. Burditt and Frank T. Dierson, that they review this situation and present their recommendations for consideration at our business meeting.

Program

Our morning session will be devoted to legal and philosophical discussions of some aspects of our food and cosmetic laws by counsel who have been greatly concerned with these problems. George M. Burditt, Esq. will discuss the problems posed by the imitation provision, Raymond D. McMurray, Esq. will discuss current color additive problems, Vincent A. Kleinfeld, Esq. will discuss proposed cosmetic legislation and William J. Condon, Esq. will bring us up to date on products liability law.

Our afternoon session will be devoted to the important subject of the Drug Amendments of 1962. C. Joseph Stetler, Esq. will moderate a panel discussion on these amendments with a panel made up of Charles F. Hagan, Esq., Irving H. Jurow, Esq. and Dr. Augustus Gibson. Those concerned with this subject may be interested to know that two undergraduates of the New York University School of Law, as members of the staff of the *Law Review,* have written an extensive and comprehensive note on these amendments which appears in

38 *New York University Law Review,* No. 6 at p. 1082, December 1963. These students, Daniel D. Adams and William E. Nelson, attended a number of sessions of Professor William W. Goodrich's class on Food, Drug and Cosmetic Law at N. Y. U. as part of their preparation for writing this paper. I think this note is a good reference item for lawyers practicing in this field. The conclusion reached by the authors deserves the attention of all interested in drug law administration. It reads:

"The Drug Amendments of 1962 are capable of either promoting or injuring the public health, depending on the interpretation given to them by the FDA and the courts. The great fear of the drug industry is that the FDA because of its sensitivity to public and congressional criticism, will be overcautious in protecting the public health to the industry's detriment. Manufacturers additionally fear that courts will continue automatically to affirm any appeal from an FDA decision as soon as the FDA raises the specter of harm to health.

"The public health interest is not always on the side of restrictive regulation. In enforcing the 1962 Amendments, the FDA should consider both present and future health interests and strike a balance between them. In cases where health interests conflict with purely economic interests, the health interests should triumph. And the courts, which have traditionally been independent of public and congressional pressure, should in reviewing FDA action carefully determine whether that agency has properly balanced the competing interests."

And now I know you want to hear from our speakers, and I will promptly introduce them, first thanking them for giving of their valuable time to prepare and present these papers to us. **[The End]**

NARCOTIC CONTROL BY HEW RECOMMENDED

The President's Advisory Commission on Narcotic and Drug Abuse has recommended the transfer of the functions of the Bureau of Narcotics relating to the regulation of the legitimate manufacture and distribution of narcotic drugs to the Department of Health, Education and Welfare. The Commission also recommended the establishment of a unit within HEW to determine the safety and efficacy of and to regulate all narcotic and dangerous drugs capable of producing severe psychotoxic effects. This unit would also regulate the legitimate importation, exportation, manufacture, sale and other transfer of narcotic and dangerous drugs. The transfer of the responsibility for the investigation of the illicit traffic in dangerous drugs from HEW to the Department of Justice was among other recommendations in the report. A CCH Comment appears at ¶ 80,052 of FOOD DRUG COSMETIC LAW REPORTS.

Imitation

By GEORGE M. BURDITT

The Author Is a Member of Chadwell, Keck, Kayser, Ruggles & McLaren; Chicago.

PLAGIARISM HAS BEEN DEFINED as copying a single author. Research on the other hand is copying many authors. In Howard Milleville's excellent series of articles in *Food Processing*[1] not only has Mr. Milleville made substantial contributions to current thinking on the problem of "imitation" but also Charles Fistere,[2] Michael Markel,[3] Frank Dierson,[4] Franklin Depew,[5] Bernard Oser,[6] Wayne Hudson,[7] Bradshaw Mintener,[8] and Merrill Thompson of our office,[9] and very importantly Commissioner Larrick,[10] have expressed their thoughts. In addition, Edward Brown Williams,[11] Harvey Hensel,[12]

[1] Howard P. Milleville, "How FDA's Stand on Imitation Stifles New Product Development," *Food Processing*, October 1963, pp. 73-76; Howard P. Milleville, "When Will FDA's 'Imitation' Policy Really Be Based on Consumer Interests," *Food Processing*, November 1963, pp. 69-74; Howard P. Milleville, "How Should the FDC Act Be Amended to Solve the Imitation Controversy?" *Food Processing*, December 1963, pp. 68-69.

[2] Charles M. Fistere, "Labeling Problems Involved in 'Substitute' and 'Imitation Products,'" *Journal of Milk and Food Technology*, July, 1963, Vol. 26, No. 7, p. 214; "Comments by Industry Leaders and Legal Counsels," *Food Processing*, November 1963, p. 74 and December 1963, p. 67.

[3] Michael F. Markel, "Faulty Framework of the Present Law," *Food Processing*, December 1963, p. 66.

[4] "Comments by Industry Leaders and Legal Counsels," *Food Processing*, November 1963, p. 73 and December 1963, p. 67.

[5] "Comments by Industry Leaders and Legal Counsels," *Food Processing*, November 1963, p. 72.

[6] Cited at footnote 5, at p. 73.

[7] Cited at footnote 5, at p. 73.

[8] Cited at footnote 5, at p. 74.

[9] Cited at footnote 5, at p. 74.

[10] George P. Larrick, "To Change FDA's 'Imitation Policy' Would Require Legislation Since This Policy Is Based on the Framework of the Present Law," *Food Processing*, December 1963, p. 65.

[11] Edward Brown Williams, "Some Problems of the Food Industry Under Federal Regulatory Statutes," 18 FOOD DRUG COSMETIC LAW JOURNAL 154, March, 1963; Edward Brown Williams, "What Price Imitation?" 5 FOOD DRUG COSMETIC LAW JOURNAL 185, May, 1950; Edward Brown Williams, "New Products for Old Uses," 8 FOOD DRUG COSMETIC LAW JOURNAL 587, September, 1953.

[12] Harvey L. Hensel, "Dietary Version of a Standardized Food—Is It an Imitation?" 13 FOOD DRUG COSMETIC LAW JOURNAL 172, March, 1958.

Mr. Justice Frankfurter,[13] and last but not least, *Webster*,[14] have all been in print recently on the question of Section 403(c).[15] With so much background information available, and there is of course much more than I have mentioned here, I hope you will consider me to be a researcher rather than a plagiarist.

So much has been written and said on this subject that perhaps a good way to begin is to summarize some current thinking.

Current Thinking

(1) All commentators agree that something is wrong with Section 403(c), either inherently or in its application. It is difficult to argue with this conclusion when vegetable fat frozen dessert is "imitation ice cream" [16] but vegetable fat whipped dessert topping is not "imitation whipped cream";[17] when jam which does not comply with the standard is "imitation jam" [18] but butter which does not comply with the standard may not be marketed at all;[19] and when artificially sweetened jelly is "imitation jelly" before a standard is promulgated [20] but not after the standard is promulgated.[21]

(2) The word "imitation" has been used and abused so much that it has lost the distinctive meaning it may have had in 1938, if ever, and indeed is now clearly confusing rather than informative to consumers, particularly when used on dietary foods. For example, "imitation cheese" might be a cheap product low in fat content, or it might be a more expensive product made by a new process lowering the salt content which makes it a dietary food; "imitation sour cream" might be a cheap substitute or it might be a product with superior qualities made by a new process utilizing modern technology. The change from "imitation jelly" to "artificially sweetened jelly"

[13] *Sixty-Two Cases of Jam v. United States*, CCH Food Drug Cosmetic Law Reports ¶ 50,125.46, 340 U. S. 593 (1951).

[14] *Webster's New Collegiate Dictionary (1961 Edition)*: "Imitation . . . Simulating something superior; as, 'imitation' lace."

[15] Federal Food, Drug and Cosmetic Act, 21 U. S. C. Section 343(c), "A food shall be deemed to be misbranded . . . if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter the name of the food imitated."

[16] *United States v. 651 Cases of Chocolate Chil-Zert*, CCH Food Drug Cosmetic Law Reports ¶ 50,125.42, 114 F. Supp. 430 (DC N. Y. 1953).

[17] *Midget Products, Inc. v. Jacobsen, et al.*, 140 Cal. App. 2d 517, 295 P. 2d 542 (1956).

[18] See footnote 13.

[19] FDA advisory opinion to state officials (1960).

[20] 21 CFR Sec. 3.205 (before revocation).

[21] Definitions and Standards of Identity for Artificially Sweetened Jellies and Preserves, 21 CFR Secs. 29.4, 29.5.

was an important forward looking step in this regard. By promulgating the standard for artificially sweetened jellies and preserves, the Administration acknowledges that the word "imitation" on such a product is not nearly as informative to consumers as the words "artificially sweetened," which with specificity advise consumers precisely how the product differs from regular jam or jelly.

(3) Organoleptic similarity between two foods is essential if one of the foods is to be considered an imitation of the other,[22] but organoleptic similarity alone is not sufficient to require that one of the foods be labeled "imitation." The recent *Coffee-Rich* cases,[23] the *Dairy Queen* case,[24] and the margarine case,[25] as well as such examples as vegetable fat whipped dessert topping are sufficient to illustrate this principle.

(4) The word "imitation" connotes inferiority according to *Webster* as in common understanding and judicial precedent.[26] The problem, however, is that injecting the concept of inferiority into a determination of whether a product is an imitation necessitates a subjective judgment and subjective judgment invariably leads to differences of opinion. For example, the creamery division of a company might contend that margarine is inferior to butter whereas the fats and oils division would disagree. Or an enforcement official might contend that a standardized product which contains saccharin or cyclamate instead of sugar is inferior but a diabetic person would disagree.

These subjective differences of opinion whether at the legislative, administrative or judicial level of government or whether within industry or between consumers, it seems to me, are the basic reason for the multitude of statutes, regulations and cases—and papers such as this—on the subject of "imitation."

Perhaps our analysis of the problem would be facilitated if we try to classify the products which under judicial or administrative

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[22] *United States v. 10 Cases Bred Spred,* 49 F. 2d 87 (CA-8 1931).

[23] *Coffee-Rich, Inc. v. McDowell,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,047 (Cir. Ct. Dane County, Wis. 1963); *Coffee-Rich, Inc. v. Michigan Dept. of Agriculture,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,083 (Cir. Ct. Wayne Co., Mich. 1963); *Coffee-Rich, Inc. v. State Board of Health of Virginia,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,082 (Cir. Ct. of Richmond 1962).

[24] *Dairy Queen, Inc. v. McDowell,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 36,506.33, 260 Wis. 471, 51 N. W. 2d 34 (1952), reh'g denied 260 Wis. 471, 52 N. W. 2d 791 (1952).

[25] *Land O'Lakes Creameries, Inc. v. McNutt,* 132 F. 2d 653 (CA-8 1943).

[26] See footnote 13.

interpretation are currently required to be labeled "imitation." The similarities and differences in these classifications may help us with a possible solution.

Products Required to Be Labeled "Imitation"

(1) The first classification includes two organoleptically similar foods, one of which is nutritionally inferior to the other because it contains a less expensive ingredient or less of a more expensive ingredient or because of processing differences.

(2) The second classification includes two organoleptically similar foods which are nutritionally approximately equal but one of which contains a less expensive ingredient.

(3) The third classification includes two organoleptically similar foods one of which is nutritionally superior to the other because it contains a particular ingredient, or has been subjected to special processing, designed to meet a specific dietary need.

Under present law, whether the word "imitation" must be applied to the inferior food in the first classification depends on the subjective determination of whether the food is actually inferior, and this determination unfortunately must frequently be made by a court, legislature, or an administrator, and disagreements are inevitable. For example, a product low in fat is undoubtedly inferior for some people but superior for others. Therefore, to require that such a food be labeled "imitation" does little more than raise a red warning flag.

Whether the word "imitation" under present law must be applied to the less expensive but nutritionally equal food in the second classification again depends on a subjective determination which in turn may depend on such irrelevant factors as geography and history. Geographical influence at least on the state level is evident since cottonseed or soybean oil based products organoleptically similar to dairy products tend to lose the stigma of "imitation" in Alabama before they lose it in Wisconsin. And geography may also help explain the *Chil-Zert* case. Historical accident is evident since the question is whether margarine is imitation butter, not whether butter is imitation margarine.

Whether the word "imitation" should be applied to the nutritionally superior product in the third classification depends virtually on whether a food becomes an "imitation" if anything unusual is done to it—if it deviates in any way from what the average consumer has become accustomed to.

These classifications emphasize the inadequacies of the word "imitation" *indiscriminately* applied to one of two organoleptically similar products, usually the one which is developed after the other, whether it be more or less nutritious, more or less expensive, more or less suitable for a particular dietary need, or more or less desirable to consumers, for example, because the addition of a preservative permits longer retention of the originally similar organoleptic qualities. Such an indiscriminate use of "imitation" seems to be an outmoded approach to the problem since it implies that consumers are not really interested in seeing clearly at first glance the fundamental differences between two products and since it assumes, quite contrary to fact, that technological advance results only in the development of inferior products. Scientists may develop a new ingredient, or a new use for an old ingredient, or a new processing method, or even a new product, clearly of benefit to consumers, but because use of the ingredient or process would necessitate use of the word "imitation" on the label, the decision may well be made that further investment in the developing and marketing of the product is not justified.

Suggested Solutions

So we have a problem, and the question is how may it best be solved. Three solutions have been suggested:

(1) FDA could reconsider its present interpretations of Section 403(c), particularly as it relates to Section 403(j) the dietary foods section.

(2) Some enterprising soul could test FDA's interpretations in court.

(3) Amendments to the Act could be sought, preferably by FDA, consumers and industry jointly.

As to administrative reconsideration, we are faced with the very practical problem that Commissioner Larrick feels that "the law would have to be amended to allow us to adopt the policy advocated" [27] in Howard P. Milleville's series. And the Commissioner is probably correct: the statute does require the word "imitation" and several important cases have interpreted the statute. I wish it were otherwise, since an administrative regulation would probably be easier to draft, adopt and amend than a statutory amendment. But even if the Commissioner could be persuaded to adopt administrative changes,

[27] See footnote 10.

he cannot under any circumstances, it seems to me, go far enough to work out a comprehensive solution to the problem. Like it or not, he still has to follow *Imitation Jam* and *Chil-Zert* and undoubtedly other precedents which may not be in the best interest of consumers in 1964.

As to helping the Commissioner reconsider by court tests, go to it! FDA's interpretation was changed by the *Imitation Jam* case, among others, and may be changed again. For example, I find it hard to believe that an imitation of an administratively standardized food —jam—is legal if labeled "imitation," but that an imitation of a statutorily standardized food—butter—is illegal regardless of how labeled. FDA's ruling on this point I believe overlooks the fact that *all* standards are set by Congress, whether directly by a statute or indirectly by a regulation authorized by a statute. But in the long run, it doesn't seem to me that court tests are a very good way to hack our way out of the imitation jungle.

That leaves statutory amendment as the best solution, in my humble opinion. Amendment of Section 403(c) has several advantages:

(1) The entire problem can be considered—"Imitation Revisited." Neither changes in administrative interpretation, hampered by outmoded precedent, nor new judicial interpretations, limited to specific fact situations, can be as comprehensive.

(2) Free from the fetters of precedent, from the confusion of conflict, and relatively free from the prejudice of self-interest, a statute can be designed specifically to set the stage for: informative labeling and technological development, neither of which is accomplished by Section 403(c) as it presently stands.

(3) A statutory change could permit informative labeling whether as part of the common or usual name, for example, "low fat French dressing" or as a descriptive adjunct, for example, " a vegetable fat product for use in coffee."

(4) Consideration could be given as to whether use of the word "imitation" might not be limited to cases of "spurious foods being passed off as genuine" to quote Edward Brown Williams.[28] With Sections 403(a), 403(g), 403(j) and the food additives amendment, perhaps use of "imitation" isn't too important.

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[28] Edward Brown Williams, "New Products for Old Uses," cited at footnote 11.

(5) Finally, new legislation carefully drawn would reduce the constant risk of litigation inherent in the development of new and improved products on which the manufacturer abhors use of the word "imitation" because of its pejorative connotation.

For one commentator—at least this one—to draft a proposed amendment to Section 403(c) would be presumptuous, although I know that when I get back to the office, Judge Snyder and Merrill Thompson will accuse me of being a chicken or worse yet, an "imitation chicken." It seems to me, though, that one approach with an excellent chance of success would be for the Food, Drug and Cosmetic Law Section of the New York State Bar Association to establish a joint *ad hoc* committee composed of federal and state officials, food technologists, consumer consultants, salesmen and lawyers to draft and recommend to Congress a proposed amendment to Section 403(c). The result could be an outstanding example of the benefits derived from close cooperation of consumers, enforcement officials and industry.

[The End]

FAKE REMEDIES EXPOSED BY FDA BOOKLET

The Food and Drug Administration has issued a catalogue of fakes and swindles in the health field warning the public to beware of "secret" remedies and their sponsors.

"Worse than the financial loss is the danger that reliance on some ineffective product will cause delay in getting proper medical treatment," advises the booklet, "Your Money and Your Life." It estimates that the public spends $1 billion a year on unnecessary or falsely represented products and treatments. In addition to exposing a number of worthless devices for diagnosing and treating various diseases, the booklet also debunks baldness "cures," no-diet reducing products, wrinkle removers, sea water minerals, and many others.

The booklet also gives advice on how to tell whether a remedy is a fake. "First, is it a 'secret' remedy? If so, you can almost be certain that it is a fake. Second, does the sponsor claim he is battling the medical profession which is trying to suppress his wonderful discovery? This is one of the surest signs of quackery. Third, how did you hear about it? If the treatment was advertised or promoted in a sensational magazine or by a faith-healers' group, or by some crusading organization of laymen, be skeptical. Honest researchers do not try to stimulate interest on the part of the public until a drug is thoroughly proven and accepted by other scientists. They do not expect sick people to be guinea pigs for unproved remedies. And, finally, of course, you may ask your doctor."

The booklet may be obtained from the Superintendent of Documents, Government Printing Office, Washington 25, D. C., for 10 cents a copy, with 25 per cent discount for purchases of 100 copies or more. Single free copies are available from the Food and Drug Administration, Washington 25, D. C.

Recent Developments Under the Color Additives Amendment

By RAYMOND D. McMURRAY

Mr. McMurray Is Secretary and General Counsel of Hoffman-LaRoche, Inc.; Nutley, New Jersey.

AT THE OUTSET, let me explain that I shall have to modify, to some extent, the assigned topic, "Recent Developments Under the Color Additives Amendment." The fact is that in matters of legal interest there just are not very many recent developments.

Perhaps the most exciting event to occur recently in the color additives area is the lawsuit filed by the Toilet Goods Association (TGA) and 39 cosmetic manufacturers. This action was filed in the United States District Court for the Southern District of New York, on Friday, November 15, 1963. It was based upon the theory that the color additives regulations issued by the Food and Drug Administration far exceed the legislative authority granted the Administration by Congress. The Association and its members object first to the definition of the term "color additive" given in the regulation. Under the regulation, a "color additive" could include a finished cosmetic product containing a substance which imparts color to the human body. The Association and its members claim that to include such finished cosmetic products as lipsticks, rouge, hair dyes, eye makeup, and the like, in the definition of color additive would be tantamount to a premarket clearance requirement for each finished cosmetic. They argue that this result is not in accord with the purpose of the Color Additives Amendment and lies beyond the statutory authority.

Carrying this concept to its logical extreme, TGA theorizes that each individual cosmetic product could be termed a "color additive" and thus subject to a petition for clearance. Involved is not merely the annoyance of filling out forms, but as the cost for filing a color additive petition for a drug or cosemtic is $2,600 (and the cost of a petition for a color additive for use in foods is $3,000), it can be seen that if a manufacturer has more than a few such products, a substantial amount of money can be involved.

Further Objections to the Regulations

The second count of the Toilet Goods Association brief objects to the inclusion of diluents [1] in the definition of the term "color additive." The result seems to subject all other ingredients in an item coming within the objected-to definition of the term "color additive" to advance approval or clearance along with the actual coloring substance used therein. TGA argues that under the Act, only the coloring substance itself is intended to be covered.

The third count objects to an attempted limitation of the exemption granted to hair dyes from the operation of certain provisions of the Act. The regulations construe the term "coal tar hair dyes" to include only the dye itself, rather than the entire product. Thus, since diluents are color additives under the regulations, the hair dye product, used for coloring the human body or a part thereof, would be a color additive. Limiting the exemption solely to the dye and not including the finished product subjects it to color additive regulatory control, an anomalous result clearly not intended by the Act.

The final count of the TGA brief is an objection to the suspension of certification service if a manufacturer refuses to permit free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates by employees of FDA. TGA takes the position that FDA is extra-legally expanding its inspection privileges through the device of refusing to certify products of noncooperative manufacturers, when under the provisions of the Act itself FDA would not have access to processes and formulae.

Necessary Tests Are Expensive

As noted before, the costs of submitting a petition are high. However, even higher than the cost of the petition itself can be the cost of the tests necessary to be performed in order to submit a valid petition. Estimates on the cost of clearing a color additive have run into the hundreds of thousands of dollars.

The high cost follows the nature of the type of studies which seem to be necessary. These include chronic long-range oral toxicity tests

[1] The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body. [21 CFR Sec. 8.1(m).]

on both dogs and rats, acute oral toxicity tests utilizing two species of animals, topical tests in a number of species, subcutaneous injection tests, sensitization tests on humans, and intravenous tests in animals. Each test might be conducted for periods up to two years or more at varying dose levels in a number of different species—a complicated, involved and expensive testing protocol.

Probably due to the complexity and expense of tests necessary for the preparation of color additive petitions, the original closing date of the tests which had been set for a two and one-half year period from the date of passage of the Color Additives Amendment has been changed in progressive steps from December 1963, to January 1965, and in certain cases even later. In order to maintain the provisional listing for use of a color additive undergoing tests, however, it is now necessary that progressive reports of the studies be filed by July 1, 1964, and at six-month intervals thereafter.

Aside from the necessary activity of the cosmetic manufacturers and the TGA, developments have been sparse because being affected differently, the food and drug manufacturers and the FDA have been trying to provide for the country a properly administered color program within the confines of the present color legislation. Whatever developments there have been, have been largely behind the scenes and any given observer could not, in my opinion, presume to know all of the ramifications of the situation.

Suffice it to say, however, that real strides appear to have been made because we see, increasingly, notices in the *Federal Register* that this color or that color has been approved for sale; and not only approved for sale, but approved for use in foods and drugs at certain tolerance levels; and in some instances a statement that the requirement of certification is not necessary for the protection of the public health. I submit that this state of affairs comes a long way from the dark days of the excessive worry over the Delaney clause, the harmless *per se* doctrine, and the legislative inability of the FDA to practice its special art of wisely protecting the public health within the framework of a sensible statute permitting the exercise of its well-considered judgment.

History of the Amendment

It has truly been said that in order to understand the present, one must have a feeling for history. Thus, at the risk of using an inordinate amount of time to take this sophisticated audience back over the

years, I will try to cast a light upon the few recent developments by selecting a small bit of the history of this law for your consideration.

The concept and philosophy of the Color Additives Amendment of 1960 was, from the outset, to be quite democratic. In fact, one might have paraphrased Gertrude Stein to sum up the prevalent hope that when the legislation was finally enacted: a color is a color is a color. However, as with most concepts and many philosophies in actual practice, color additives have turned out to be more in the nature of the situation found in George Orwell's *Animal Farm* that: all colors are equal, but some colors are more equal than others.

The architects of color legislation could draw on about 100 years of recognition of the value of added color and about 75 years of attempts at guiding its use. Even so, up to 1906, when the first attempt was made at regulation there were only a few very specific pieces of color legislation. In the regulations issued under the 1906 Act, which we all know was our first try at a universal and uniform pure food and drug statute, provision was made for the use of "harmless" colors. Shortly after passage of the Act an administrative procedure was developed to safeguard food to which color had been added and a list of colors was promulgated for use, providing they were pure enough. To be "pure enough" each batch had to be tested by competent experts and found to be nontoxic and free from harmful constituents.

Safety Was Primary Concern

So the first important point we recognize is that the 1906 Act was primarily concerned with safety, although it appears that, at least in practice, certification was on a voluntary basis.

By the time 1938 rolled around and the food and drug law came in for its next major revision, there was introduced into the Act the concept of declaring an item adulterated (and hence subject to the adulteration provisions of the Act) if it contained a coal tar color other than one from a certified batch. A far-reaching change, which we have already seen to be subject to great inflation, also occurred in the 1938 Act when the government, which had borne the cost of certification under the 1906 Act, shifted this burden to the person seeking certification. There seemed to be no requirement for certification of any color except a coal tar color, but the theory of the necessity of a color being "harmless" was retained in the Act.

Safety was the prime consideration as it was under the 1906 Act, but we note that the concept of deception of the public was beginning

to be a greater concern of the FDA. Activities in this area under the 1938 Act show increasingly this concern with deception.

The rigidity of the 1938 Act which allowed for the certification of harmless colors and did not provide for any administrative procedure to set tolerances for colors shown to be toxic in varying degrees led, over the years, to an intolerable situation. Without the leeway necessary to provide for varying degrees of use of any given color, the FDA was forced, after several incidents involving the misuse and over-ingestion of certain colors, to begin to decertify some of them. As pharmacological laboratory tests became increasingly sensitive because of advances in technology, more and more colors fell under the ax of the FDA, culminating in a series of decertifications, the most notable among which were FD&C colors orange No. 1, orange No. 2, and the famous red No. 32.

Activities of Certified Color Industry Committee

A committee of certified color producers calling itself the Certified Color Industry Committee had been fighting a long and valiant rearguard action for sensible color legislation. Upon the delisting of the above-mentioned colors, the Certified Color Industry Committee went to the Second Circuit Court of Appeals on the basis that the Secretary of Health, Education and Welfare should have heard evidence on the amount of these colors which could be safely used in foods only to be told, *inter alia,* in that court's decision:

(1) That the statute did not permit tolerances for toxic colors;

(2) That although the tests proved the colors toxic, they did not establish the extent of toxocity to a certainty so as to permit the establishment of safe tolerances; and

(3) That the Secretary had no authority to establish tolerances with regard to colors.[2]

In another circuit court decision, however, the citrus industry successfully challenged the Secretary's delisting of red No. 32 to color Florida oranges based upon the relative use argument. But the United States Supreme Court, on December 15, 1958, settled the conflict when it reversed this citrus decision in the Fifth Circuit by holding, in line with the Second Circuit, that the Food, Drug and Cosmetic Act did not

[2] *Certified Color Industry Committee v. the Secretary of Health, Education and Welfare,* FOOD DRUG COSMETIC LAW REPORTS ¶ 50,191.21, 236 F. 2d 866 (CA-2 1956).

give the Secretary authority to issue tolerances to permit use of a color as "harmless" for any specific purpose when, in fact, the color was found to be injurious to test animals.[8]

FDA explained in a press release on June 15, 1960 that the

> . . . Federal Food, Drug, and Cosmetic Act provides only for the listing of coal-tar colors that are completely harmless and suitable for use in drugs and cosmetics, and does not provide for listing toxic colors for specific drugs or cosmetic uses so as to limit their total use to such small amounts that the toxicity may be disregarded. Thus a toxic color cannot be classified as a 'harmless' color under present law, no matter how little is used.

As we have all come to know, it is sometimes possible for a regulatory agency which wishes to have its law changed to show the inadequacies of the law by enforcing it assiduously. The over-enforcement in this case brought about consideration, discussion, and, finally, passage of what we know today as the Color Additives Amendment of 1960. The feeling of the time was summed up in House Report No. 1761 of the 86th Congress, Second Session, Report of the Committee on Interstate and Foreign Commerce of the House of Representatives, which accompanied H. R. 7624 as follows:

> The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which, we believe, could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health. (At pp. 892 and 893.)

The proposed revision of the law in effect followed the method first outlined by the Food Additives Amendment of 1958, by allowing the addition of colors to foods, drugs, or cosmetics in conformity with a regulation listing a maximum safe use of the material, if such a limitation was necessary for the protection of the public health and at the same time separated colors from the Food Additives provisions.

Differences in the New Law

Basic differences in the new law covering color additives were that the new provisions:

(1) Would cover all color additives, not only coal tar colors;

(2) Would cause the addition of an amount of color above a set limit to result in an adulterated food, whereas previously it was questionable whether the addition of almost any amount of certified color would be prohibited;

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[8] *Flemming v. Florida Citrus Exchange,* ¶ 50,191.22, 358 U. S. 153, 79 S. Ct. 160 FOOD DRUG COSMETIC LAW REPORTS (1958).

(3) Would now make it necessary for all color manufacturers to prove the safety of their coloring product prior to its listing for use, whereas previously FDA had to show that an item other than a coal tar color was not safe;

(4) Would extend the requirement of certification from coal tar colors to all colors, unless a regulation listing the color exempted it from this requirement;

(5) Would place the now-considerable costs of testing colors upon the shoulders of the manufacturers.

Cooperation Between Regulated Industry and Regulating Agency Is Essential

Returning to the present, the touchstone of whatever recent developments there have been must rest, now and inevitably, in cooperation between the regulated industry and the regulating agency. It may be well, quickly, to indicate with reference to the law what cooperation there might be.

In its simple, but all-encompassing definition, the law, in Section 201(t), says that a color additive includes any material which is capable of impairing color, including black, white, and intermediate grays, to any item to which it is added, including the human body. The two exceptions noted in the law provide for materials intended solely for a purpose other than coloring, or agricultural and plant chemicals which might incidentally affect the color of agricultural produce.

In essence, the Secretary is charged with monitoring the use of color in foods, drugs and cosmetics. He is given the discretionary authority to provide tolerances and to exempt from the term "color additive." Finally, he is charged with the responsibility of maintaining the integrity of listed colors under Section 706 of the Act. Under the applicable provisions of the Act, any food, drug or cosmetic is deemed to be adulterated if it bears or contains a color additive which is unsafe within the meaning of Section 706(a). Thus, the importance of the color additive provisions of the law is emphasized by subjecting any food, drug or cosmetic which contains a color additive considered "unsafe" to the multiple seizure provisions of the Act.

All of you present are certainly as capable as I am of reading the law and the regulations. I am not here to try to teach you this law. Your presence here today indicates your interest in it. I would like, however, to make a practical observation—that Congress has seen fit to set forth in considerable and, in most cases reasonable, detail the criteria for determining the safety of a color additive. The Secretary must consider:

(1) The probable exposure or consumption of an additive because of its intended use;

(2) The cumulative effect, if any, of the additive in the diet;

(3) The safety factors demonstrated by the experimental data in animals; and

(4) The availability of analytical methods for the determination of the identity and quality of:

(a) The pure dye and all intermediates and other impurities, either by itself or when admixed in a food, drug, or cosmetic, and

(b) Any substance formed in or on such article because of the use of the additive.

In setting a tolerance in line with the above considerations, the Secretary is told to concern himself with the following:

(1) He may not list the additive for use if he finds that the substance would not achieve its desired physical or technical effect when used within safe tolerances, and

(2) He may not fix the tolerance at a level higher than is necessary to accomplish the intended effect.

As an ultimate determination, the Secretary is given the authority to exempt from certification a color which need not be closely monitored because of its lack of hazard to the public health.

All of the benefits of the Color Additives Amendment can be reached through administrative processes. The most important avenue in my opinion is the color additive petition which provides the basis for listing, for setting tolerances, and for showing the extent or necessity for certification. It is important that the color additive petition be as carefully prepared as a new drug application, because it is the vehicle provided for the first sensible and, I hope, workable, color legislation we have ever had.

It is probably too early to comment on the final structure of practical color additives administration, but from this vantage point I do not view the situation with alarm. I, for one, do not believe that there can be, nor should there be, democracy among colors. It is not true that a color is a color is a color. I firmly believe that some colors are more equal than others. An administrative recognition of the fact that colors with some toxicity can live perfectly well under proper regulation with colors of little or no toxicity can and will provide the ultimate in public protection without unduly burdening private initiative. We seem to be on that road. **[The End]**

What Kind of Cosmetic Legislation?

By VINCENT A. KLEINFELD

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THE FEDERAL FOOD, DRUG, AND COSMETIC ACT is the only federal regulatory statute specifically concerned with the safety of cosmetics distributed in interstate commerce. It sets forth the circumstances under which cosmetics shall be deemed to be adulterated or misbranded, but does not require that they be tested, to the satisfaction of the Food and Drug Administration, before they are distributed in interstate commerce.

Prior to the passage of the statute, various injuries, including blindness, and even deaths, resulted from the marketing of cosmetics by a few marginal operators. These occurrences were primarily responsible for the inclusion of cosmetics in the 1938 Act. This regulation of cosmetics greatly decreased the incidence of injuries, but, as in the case of drugs and even of new drugs cleared by the FDA, some injuries have occurred. It is a fact, however, that the incidence of untoward reactions from cosmetic use has been very low, and serious harm has not been a frequent occurrence.

Whether a new amendment providing for pretesting is an absolute requirement at this time from the viewpoint of the public is a debatable point, and reasonable men may differ. If we view the situation pragmatically, nevertheless, we know that the Act now provides for the pretesting of insulin, new drugs, antibiotics, food additives, and colors, and that there is a strong demand in Congress for similar regulation of cosmetics. It would appear to be realistic, therefore, to realize, as a fact of life, that sooner or later we will have a "new cosmetic" amendment to the Act. This, as a general proposition, should not be an horrendous occurrence, for by far the great majority of those engaged in the production of cosmetics do perform the necessary pharmacological and clinical research. The real problem, in my opinion, is not whether there should be cosmetics legislation but, rather, what kind of legislation.

Amendments Preceded by Dramatic Circumstances

The statutory framework under which the FDA functions has changed radically during the quarter of a century since the enactment of the Federal Food, Drug and Cosmetic Act. In certain instances, dramatic circumstances preceded the adoption of various amendments to the law. Foremost among these was the thalidomide episode, which provided the immediate cause for enactment of the Drug Amendments of 1962. And, of course, it was the sulfanilamide tragedy which, in 1938, led to the inclusion in the statute of the provisions dealing with "new drugs." Less dramatic, perhaps, with respect to public interest, but of substantial importance so far as its impact upon industry is concerned, was the administrative construction of the law, sustained by the courts, that the "harmless *per se*" doctrine was applicable to coal-tar colors. This, in turn, provided the impetus for the 1960 Color Additive Amendments. These, extremely (and unnecessarily) far-reaching in scope, could not in reality be contested while pending in Congress, since otherwise many coal-tar colors, although actually free from hazard, would have been outlawed.

Imbalance of Controls

In 1938, but for the provisions relating to new drugs and coal-tar color certification (which were the only original licensing provisions of the statute), fundamentally the same type of control was provided for foods, drugs, cosmetics and therapeutic devices. Implicit in the kind of regulation originally exercised was comprehension that manufacturers of foods, drugs, cosmetics and devices could generally be expected to adhere to the established statutory standards, and those few who violated the law would be punished. On these bases, which have been traditional and fundamental in our political and social system, no necessity existed for any extensive degree of direct governmental control in the nature of licensing. Through this past quarter century, however, for one reason or another (in some instances perhaps for no real reason at all), various changes have taken place which have altered the type of regulation employed in the food and drug area. Today, a much greater degree of direct governmental control exists for such commodities than was the situation at the time of the passage of the Federal Food Drug and Cosmetic Act. As a result, an imbalance has developed between the type of control exercised over foods and drugs and that which is performed with respect to cosmetics and therapeutic devices.

Main Reason for Extending Controls

In large measure this disparity, of itself, now seems to form the main reason for extending further direct controls to devices and cosmetics. No really compelling need has been shown at this time for more stringent governmental regulation in the cosmetic area, such as would be the situation if an important gap existed in the coverage of the statute or if there were many serious injuries and if the incidence of reactions was high. Rather, the impetus for the greater degree of direct control appears to be predicated on the assumption that it is far simpler and neater, from the government's viewpoint, to impose licensing controls. And of course, as we know, the task of completely satisfying the demands of the executive branch of the government is an impossible one. It reminds me of the mythical Sisyphus, who was punished by Zeus by being required in Hades to roll a tremendous stone up a hill—an endless task, since every time it reached the top it would roll down again.

Main Purposes of H. R. 6788

During the last session of the present Congress, a bill, H. R. 6788, was introduced by Congressman Harris, the Chairman of the House Committee on Interstate and Foreign Commerce. This bill, endorsed by, if it is not the progeny of, the FDA, would have as one of its main purposes the elimination of the variance in the types of control which now exist. By virtue of certain provisions in the bill, however, the potential is present for the creation of further illogical disparities so that the scales will tip the other way. It is not inconceivable, based upon prior experience, that such imbalances may very well be relied upon in the not too distant future as a further goal for additional amendments in the food and drug areas. This procedure could continue in cyclic fashion until little, if any, freedom of marketing remains available to members of the regulated industries. In fact, it might proceed to the point where private interests are almost wholly eliminated in these industries and the government would hold the primary position.

It is interesting to note, in this connection, that the regulations issued under the Color Additive Amendments provide that the FDA upon request and the payment of fees, will conduct "pharmacological investigations, studies of the chemical and physical structure of the color additive, and methods of analysis of the pure color additive (including impurities) and its identification and determination in foods,

drugs, or cosmetics." The regulations relating to prescription drugs provide for censorship by the FDA under certain limited circumstances. And drug establishments, whether engaged in interstate or intrastate commerce, are required to register and are subject to federal inspection. I refuse to be trite by discussing tents and camels' noses.

The bill now pending, among other things, creates the concepts of "new cosmetic" and "new device" and subjects each category to criteria which are "similar at first glance" to those now applicable to "new drugs." The term "similar at first glance" is a calculated one, since in reality the degree of direct control exercised over cosmetics, should this bill become law, is potentially of even broader scope than that exercised over drugs. Because of this, it is possible, as I have indicated, that the imbalance now ostensibly sought to be corrected will lead, in turn, to a new variance which, in turn, will be the spur to even further legislation and control. This may well produce the cycle to which I have referred.

Absence of "Grandfather Clause"

The definition of a "new cosmetic" provided in the pending bill differs in several significant respects from the present definition of a "new drug." The most evident distinction is that there is no grandfather clause of any kind in the case of cosmetics. Every cosmetic, regardless of the period of time or extent it has been marketed, is potentially subject to "new cosmetic" classification.

Because of the absence of a grandfather clause, it is not only conceivable, but probable, that virtually every cosmetic now on the market would be subjected to new cosmetic control. In the case of drugs, the Federal Food, Drug and Cosmetic Act provides that any drug (other than those under one of the grandfather clauses), "the composition of which is not generally recognized, among experts qualified . . . to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof" is a "new drug." In the "new drug" definition, no particular concern is had with the manner in which a particular drug may become "generally recognized . . . as safe and effective." Such recognition may have come from the extremely valuable crucible of experience or from extensive clinical and pharmacological testing. The ultimate criterion is whether the drug is, in fact, "generally recognized . . . as safe and effective." (Whether it is ever possible to determine with definitiveness when a drug is generally recognized

as safe and effective, or whether the definition could withstand direct attack in a criminal prosecution because of vagueness, presents problems of another sort.)

Test of Experience Is Not Permitted

In the "new cosmetic" definition, the test of experience (which would certainly appear to be the most valid one) is not permitted. Thus, the definition provides that a cosmetic is deemed to be unsafe (and, therefore, is a new cosmetic) if its composition is such that it is not generally recognized, among qualified experts, "as having been adequately shown, through scientific investigations" to be safe for use. Under this definition, actual experience is of no legal significance. Scientific investigations alone are the sole criterion. Thus, more stringent standards are sought to be imposed upon cosmetics than are now imposed upon drugs. Is this reasonable? In my opinion it is not, and its only effect can be to lead to attempts to amend further the new drug definition to bring it into line with the new cosmetic definition.

It is not only in this respect that the "new cosmetic" definition is broader than its new drug counterpart. As stated, the status of a drug for new drug purposes is to be considered on the basis of its safety and effectiveness "for use under the conditions prescribed, recommended or suggested in its labeling." With respect to a cosmetic, however, not only is its intended use a factor in determining its "new cosmetic" status, but also "other reasonably foreseeable uses" as well. The concept of "other reasonably foreseeable uses" potentially takes into consideration uses which go beyond those "prescribed, recommended or suggested" in the labeling and advertising of the cosmetic and thus again makes the new cosmetic definition of broader application than that applicable to new drugs.

But, it may be urged, "the 'new cosmetic' definition is concerned with safety alone, whereas the new drug definition involves considerations of both safety and effectiveness." Consequently, it may be asserted that the degree of control to which cosmetics are sought to be subjected is potentially not as great as that presently involving drugs. A reply to this disingenuous position is found in another section of the bill, which precludes approval of a "new cosmetic" application if "the data before the Secretary show that the proposed labeling of such cosmetic is false or misleading in any particular . . . or that such cosmetic would otherwise be misbranded or adulterated. . . ." This provision, which is similar to one now contained in the new drug

section of the Act (as well as in the food and color additives amendments), would have the very real result of making claims relating to the effectiveness or utility of the cosmetic subject to prior clearance by the FDA. Thus, hyperbolic labeling statements that a cosmetic will lead to a "lovelier you," a "radiant appearance," an "irresistible allure" will have to be demonstrated to be absolutely correct to the satisfaction of some skeptical and hard-hearted governmental official. And, from the viewpoint of the predatory female, it is to be noted, with considerable alarm, that the FDA has already pronounced that a color additive may not be approved if its use "would promote deception of the consumer." This is also dreadful to contemplate from the viewpoint of the male, for presumably we will now have to view women without their lipsticks, hair dyes, rouges, and other weapons from their abundant armamentarium. And those innocents who believe that the "false and misleading" provision will not affect advertising should be directed to the language in the new drug application form prescribed by the FDA that "It is understood that the labeling and advertising for the drug [cosmetic] will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application."

Conclusion

These few illustrations demonstrate how the government's role would be immeasurably and unnecessarily increased in the cosmetic field if the now pending (Harris) bill were to be enacted into law. As stated at the outset of this paper, at the present time (but for the concept of pretesting and for coal-tar hair dyes), the Federal Food, Drug and Cosmetic Act substantially covers, with respect to cosmetics, all of the safety factors provided in the pending legislation. Certainly, also, far-reaching control is provided by the Color Additive Amendments and by what are (as we all well know) the extremely limited and very narrowly-drawn regulations issued by the FDA. It is well to ask, therefore, whether many of the provisions now sought to be adopted in a "new cosmetic" amendment are desirable—let alone necessary. **[The End]**

Products Liability—1963

By WILLIAM J. CONDON

This Paper Discusses Products Liability Cases Involving Food, Drugs and Cosmetics, Largely at the Manufacturer's Level, Rather Than the Retailer's Level, and Related Decisions of Significant Importance. Mr. Condon, a Member of the New York Bar, Is a Swift & Company Attorney.

THE YEAR 1963 saw a substantial increase in the number of reported cases in the area of products liability. The list of cases, grouped according to subject matter, is as follows:

Foreign Substance and Contaminated Food Cases

Fulton v. Kroger Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5005, 120 N. W. 2d 232 (S. Ct. Mich. 1963).

Athens Canning Company v. Ballard, CCH PRODUCTS LIABILITY REPORTS ¶ 5013 (Tex. Ct. Civ. App. 1963).

Safeway Stores, Inc. v. Rees, CCH PRODUCTS LIABILITY REPORTS ¶ 5046, 381 P. 2d 999 (S. Ct. Colo. 1963).

Gay v. A & P Food Stores, CCH PRODUCTS LIABILITY REPORTS ¶ 5061, 240 N. Y. S. 2d 809 (S. Ct. N. Y. 1963).

Scanlon v. Food Crafts, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5103, 193 A. 2d 610 (Conn. Cir. Ct. 1963).

Gallagher v. The Pequot Spring Water Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5140 (Conn. Cir. Ct., App. Div. 1963).

Foreign Substance Beverage Cases

Hart v. Coca-Cola Bottling Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5012, 188 N. E. 2d 817 (Ohio Ct. App. 1963).

Barefield v. La Salle Coca-Cola Bottling Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5018, 120 N. W. 2d 786 (S. Ct. Mich. 1963).

Phipps v. Carmichael, CCH PRODUCTS LIABILITY REPORTS ¶ 5052 (Tenn. Ct. App. 1963).

Dyer v. Baton Rouge Coca-Cola Bottling Company, Ltd., CCH PRODUCTS LIABILITY REPORTS ¶ 5108 (La. Ct. App. 1963).

Jarmol v. Tas-Tee Catering, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5111, 193 N. E. 2d 157 (Ohio Ct. App. 1963).

Exploding Bottle Cases

Hudnall v. Travelers Insurance Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5015, 148 So. 2d 840 (La. Ct. App. 1963).

Soper v. Enid Hotel Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5042, 383 P. 2d 7 (S. Ct. Okla. 1963).

Skipper v. Royal Bottling Company of Wilmington, CCH PRODUCTS LIABILITY REPORTS ¶ 5076, 192 A. 2d 910 (S. Ct. Del. 1963).

Manfredi v. H. C. Bohack Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5089 (N. Y. Civ. Ct. 1963).

Addeo v. Metropolitan Bottling Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5090 (S. Ct. N. Y., App. Div. 1st Dept. 1963).

Faucette v. Lucky Stores, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5100, 33 Cal. Reptr. 215 (Cal. DC App. 1963).

Abernathy v. Coca-Cola Bottling Company of Jackson, CCH PRODUCTS LIABILITY REPORTS ¶ 5112 (Mo. Ct. App. 1963).

Hutchins v. Rock Creek Ginger Ale Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5113, 194 A. 2d 305 (Mun. Ct. App., D of C 1963).

Roden v. Pepsi-Cola Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5144, 150 NYLJ No. 98, p. 14 (S. Ct. N. Y. 1963).

Drug Cases

Burke v. Bean, CCH PRODUCTS LIABILITY REPORTS ¶ 5011 (Tex. Ct. Civ. App. 1962).

Stottlemire v. Cawood & Parke, Davis Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5019, 213 F. Supp. 897 (DC D of C 1963).

Magee v. Wyeth Laboratories, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5030, 29 Cal. Rptr. 322 (Cal. DC App. 1963).

Mongin v. Hudson Central Drug Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5043 (S. Ct. N. Y. 1963).

Cosmetic Cases

Esborg v. Bailey Drug Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5001, 378 P. 2d 298 (S. Ct. Wash. 1963).

Davidson v. Wee, CCH PRODUCTS LIABILITY REPORTS ¶ 5002, 93 Ariz. 191, 379 P. 2d 744 (S. Ct. Ariz. 1963).

Spiegel v. Saks 34th St., CCH PRODUCTS LIABILITY REPORTS ¶ 5021 (Civ. Ct., City of N. Y. 1963).

Gober v. Revlon, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5024, 317 F. 2d 47 (CA-4 1963).

Benavides v. Stop & Shop, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5051, 190 N. E. 2d 894 (Mass. S. Jud. Ct. 1963).

Romero v. And'ra, CCH PRODUCTS LIABILITY REPORTS ¶ 5060, 30 Cal. Rptr. 645 (Cal. DC App. 1963).

Freedman v. Andre De Paule Beauty Salon, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5073 (Civ. Ct., City of N. Y. 1963).

Bethancourt v. Employers' Liability Assurance Corporation, CCH PRODUCTS LIABILITY REPORTS ¶ 5094 (La. Ct. App. 1963).

John A. Brown, Inc. v. Shelton, CCH PRODUCTS LIABILITY REPORTS ¶ 5116 (S. Ct. Okla. 1963).

Grau v. The Procter & Gamble Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5120, 324 F. 2d 309 (CA-5 1963).

Pinto v. Clairol, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5131, 324 F. 2d 608 (CA-6 1963).

Harrod v. Edward E. Tower Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5138 (Mass. Sup. Jud. Ct. 1963).

Tobacco Cancer Cases

R. J. Reynolds Tobacco Company v. Hudson, CCH PRODUCTS LIABILITY REPORTS ¶ 5010, 314 F. 2d 776 (CA-5 1963).

Lartigue v. R. J. Reynolds Tobacco Company et al., CCH PRODUCTS LIABILITY REPORTS ¶ 5029, 317 F. 2d 19 (CA-5 1963).

Green, Jr. v. American Tobacco Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5141 (CA-5 1963).

Animal Feed Cases

Moody v. Western Farmers Association, CCH PRODUCTS LIABILITY REPORTS ¶ 5004 (DC Ore. 1963).

Maupin v. Nutrena Mills, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5087, 385 P. 2d 504 (S. Ct. Okla. 1963).

Olano v. Rex Milling Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5110 (La. Ct. App. 1963).

Economic Poisons Cases

Ganci v. Rubino, CCH PRODUCTS LIABILITY REPORTS ¶ 5033, 5064, 241 N. Y. S. 2d 981, 40 Misc. 2d 218 (S. Ct. N. Y. 1963).

Boyl v. California Chemical Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5139, 221 F. Supp. 669 (DC Ore. 1963).

Defective Container Case

Nasoff v. Hills Supermarket, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5127, 40 Misc. 2d 417 (S. Ct. N. Y. 1963).

Just a year ago, I made reference to "the fallacy of the prediction which is the essence of Section 402 A." [1] The reference, of course, was to the new section of the Restatement of Torts. Perhaps the most significant development in 1963 was the initiation of a ground swell of activity, emanating from the shores of the Pacific Ocean, which threatens quickly to establish the accuracy, rather than the fallacy of that prediction.

Problems Arising Out of Strict Liability Doctrine

Speaking through the powerful voice of Mr. Justice Traynor, the Supreme Court of California adopted *in toto* the doctrine of strict tort liability in products cases. The case was *Greenman v. Yuba Power Products, Inc.,* 15 NEGLIGENCE CASES (2d) 35, 59 Cal. 2d 57, 377 P. 2d 897 (S. Ct. Cal. 1963). Involved was a defective home workshop power tool, which injured a user who was not the purchaser. In the course of its opinion, the court said, at pp. 62-63:

> A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being. Recognized first in the case of unwholesome food products, such liability has now been extended to a variety of other products that create as great or greater hazards if defective (citations).
>
> Although in these cases, strict liability has usually been based on the theory of an expressed or implied warranty running from the manufacturer to plaintiff, the abandonment of the requirement of a contract between them, the recognition that the liability is not assumed by agreement but imposed by Law (citations), and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products (citations) makes clear that the liability is not one governed by the law of contract warranties but by the law of strict liability in tort. Accordingly, rules defining and governing warranties that were developed to meet the needs of commercial transactions cannot properly be invoked to govern the manufacturer's liability to those injured by its defective products unless those rules also serve the purpose for which such liability is imposed.

[1] See, 18 FOOD DRUG COSMETIC LAW JOURNAL 144 (March, 1963).

This case has already been extensively cited by courts as far east as New York and it bids fair to have at least as great an effect upon products liability as the famous *Henningsen* case in New Jersey a few years ago. The doctrine has been adopted in its entirety by the Supreme Court of Missouri. (*Murrow v. Caloric Appliance Corp.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5125 (S. Ct. Mo. 1963)). And an intermediate appellate court in California has already extended the doctrine to cover a product which has no defect, as the court seemed to require in *Greenman*, but which fails to bear an appropriate warning of a danger which lurks in its normal use. (*Crane v. Sears Roebuck & Company, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5095, 32 Cal. Rptr. 754 (Cal. DC App. 1963)).

Another intermediate appellate court in California has come upon a rather peculiar problem arising out of this strict liability doctrine. In a case involving an alleged defect in a new automobile, this court held that no notice was required to be given by the plaintiff to the manufacturer. However, as between the plaintiff and the defendant dealer from whom the automobile was purchased, the court concluded that a reasonable notice was required. The result was reached by reference to the language of the sales act which is part of the statutes of California. Thus, it appears that under the new rule, a party who has privity, which used to be so desirable, now finds himself subject to greater burdens than he who is without privity. (*Vandermark v. Ford Motor Company*, CCH PRODUCTS LIABILITY REPORTS ¶ 5149 (S. Ct. N. Y. 1963)).

The doctrine of the *Greenman* case was also urged upon the Supreme Court of Nevada in the case of *Long v. Flanigan Warehouse Co.*, 382 P. 2d 399 (S. Ct. Nev. 1963). The action for breach of warranty against a remote manufacturer presented a question of first impression to the court. Nevada has the Uniform Sales Act, as do most of the jurisdictions which have abolished privity. However, the court found that the statute means what it says. Hence, this court concluded that it must decide either that there is a warranty requiring privity, or that responsibility must be based upon a strict liability in tort. Since the *Greenman* case had been decided subsequent to the trial, but prior to the appeal in the *Long* case, the Nevada court felt that it would be improper to apply this new doctrine to a case that was tried without reference to it. The court refused to make what it called a guideline decision, but preferred to wait until a case had been properly tried with reference to a rule in order to determine whether

the rule should be applicable in Nevada or not. The Court was unwilling to declare that the trial court erred in failing to conduct the trial on a theory not advanced by counsel nor at that time declared by any court to be the law.

Greenman was cited with approval and apparently wholeheartedly embraced by the New York Court of Appeals in the case of *Goldberg v. Kollsman Instrument Corp.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5058, 12 N. Y. 2d 432, 191 N. E. 2d 81 (N. Y. Ct. App. 1963). The case involved an appeal from the dismissal of warranty causes of action against an airplane manufacturer and the manufacturer of an allegedly defective altimeter arising out of the crash of an airliner in the East River. The question for decision was whether a complaint in warranty against these two manufacturers stated a good cause of action. As indicated, the New York Court adopted the strict tort liability theory which had been the basis of the holding in *Greenman*. The Court of Appeals agreed with the California Court "that the purpose of such a holding is to see to it that the costs of injuries resulting from defective products are borne by the manufacturers who put the products on the market rather than by injured persons who are powerless to protect themselves and that implicit in putting such articles on the market are representations that they will safely do the job for which they were built." The New York Court then went on to say:

> However, for the present at least, we do not think it necessary so to extend this rule as to hold liable the manufacturer (defendant Kollsman) of a component part. Adequate protection is provided for the passengers by casting in liability the airplane manufacturer which put into the market the completed aircraft.

The three judges who dissented raised some very penetrating questions concerning the court's application of what they called "enterprise liability" to the situation in this case. They disagreed with the selection made by the majority of the proper enterprise on which to impose the burden. They pointed out that the purpose of strict liability is not to regulate conduct with a view to eliminating accidents, but rather to remove the economic consequences of accidents from the victim who is unprepared to bear them and to place the risk on the enterprise in the course of whose business they arise. In the view of the dissenters, this enterprise was solely the airline, not the manufacturer of the airplane nor the manufacturer of the component part. They pointed out that the carrier immediately profited from plaintiff's custom, and was in a business which dealt directly with the public; also, the carrier was not merely a conduit

for the distribution of the manufacturer's consumer goods. On the contrary, the airline assumed the responsibility of selecting and using those goods itself as a capital asset in the conduct of a service enterprise. They added "to extend the warranty law to allow plaintiff to select a defendant from a multiplicity of enterprises in a case such as this would not comport with the rationale of enterprise liability and would only have the effect of destroying whatever rights would exist among the potential defendants by virtue of agreement among themselves." "If, as we maintain in this case, the true theory relied on by plaintiff is enterprise liability, then the rights of those from whom compensation is sought, no less than of those who seek it, 'ought not to be made to depend on the intricacies of the law of sales.' "

These three dissenting judges pointed out that the airline's liability in New York is limited to negligence. Its sole duty is due care. In light of this, it appears that the majority opinion presented an anomaly because it grants recovery to a passenger injured through a non-negligent failure of equipment but denies it to one injured through a non-negligent failure of maintenance or operation. Finally, the dissent raised the point that the airline industry is a highly regulated one. However easy it may be in a completely free economy to distribute the loss, the same is not necessarily true in a regulated industry. They pointed out that the questions raised in determining this distribution of risk or loss are the type which are within the special competence of the legislature to ascertain. For a court to assume them in order to support a theory that displaces much of the law of negligence from its ancestral environment involves an omniscience which the dissenters felt they didn't share. "For a court to apply them, not to the enterprise with which plaintiff dealt and relied upon, or to the enterprise which manufactured the alleged defective part, but to the assembler of the aircraft used by the carrier, involves a principle of selection which is purely arbitrary."

Relying upon *Kollsman Instrument,* the Appellate Division of the Supreme Court for the First Department dismissed a cause of action against a tire manufacturer when a blowout occurred on a tractor causing injury to the plaintiff. The Appellate Division apparently felt that the *Kollsman* case forever closed the avenue of recovery against the supplier of a component part.

Allergy Cases Continue

It should come as no surprise that questions concerning allergy continue to occupy a good bit of the time of our courts. This accounts in large measure for the fact that the largest category of cases which we have, over 25 per cent of the total, are concerned with cosmetics. An indication of the type of problems and the Court's handling of these problems can be seen in *Esborg v. Bailey Drug Company,* cited above. Here, in a case involving a hair tint, the Supreme Court of Washington said that first, allergy of the plaintiff is a complete defense if the plaintiff is peculiarly susceptible or unique. However, recovery by the plaintiff may be had if he is shown to be a member of a reasonably foreseeable and appreciable class or number of persons who would be similarly affected. Finally, what constitutes a reasonably foreseeable and appreciable class of persons is a question of fact to be determined by the trier of fact.

A further area which concerns the court with respect to allergy cases is the duty to warn. Hence, the United States Court of Appeals for the Fourth Circuit held that the manufacturer of a product had a duty to warn if he knew or should have known that his product would be harmful to some persons. The evidence in *Gober v. Revlon, Inc.,* cited above, disclosed only one prior complaint on the product involved. However, this, plus other considerations, led the court to say that the manufacturer had a duty to warn and its failure to discharge that duty resulted in the proper application of liability.

Partaking of the problems raised in both of these cases is the opinion of the court in *Grau v. The Proctor and Gamble Company,* cited above. Here, it appeared that the plaintiff was allergic to stannous fluoride, and as a result, suffered a severe reaction in her mouth as a result of using a stannous fluoride toothpaste. The court noted: that defendant's toothpaste is widely used and there was only one other instance of possible reaction to its use; that stannous fluoride is not a known allergen; that the allergy from which plaintiff suffered is not common to any substantial number of possible users; and that plaintiff was not aware of her allergy. From all this, the court concluded that it would be difficult to conceive of a warning which would have afforded any probability of preventing plaintiff's injury. It, therefore, affirmed the judgment on a directed verdict for the defendant.

Finally, the California District Court of Appeals in *Magee v. Wyeth Laboratories,* cited above, held that there could be no recovery against a manufacturer of a prescription drug where the administer-

ing physician had failed to heed the warnings and instructions which had been given by the manufacturer to him. The court said that a warranty does not run to one who uses the product contrary to adequate warnings. The allergic reaction of plaintiff's intestate, while rare, was provided for in the instructions to the physician. While the case does have some language concerning the application of a warranty, and the adequacy of the warnings and what constitutes a breach, basically the case properly is cited for the proposition that the failure of the physician to follow the manufacturer's instructions was an intervening proximate cause of plaintiff's injury.

Tobacco Cancer Cases

In keeping with the tenor of the times, we had three tobacco cancer cases in 1963 which were productive of four opinions. Oddly enough, all three of these cases were in the United States Court of Appeals for the Fifth Circuit. Two of them are distinguished for the amount of smoking which plaintiff did. In one, plaintiff smoked one tin of pipe tobacco and two packs of cigarettes almost every day for 33 years (*R. J. Reynolds Tobacco Company v. Hudson,* cited above). In the other, plaintiff's intestate began to smoke cigarettes when he was nine years old. He continued to smoke cigarettes and tobacco continuously for 55 years, smoking at least two packs a day. (*Lartigue v. R. J. Reynolds Tobacco Company,* cited above.) Both of these cases arose in Louisiana. The first was concerned solely with the question of when the statute of limitations on lung cancer started to run. The second was an application by the Fifth Circuit of the doctrine that it had announced a year earlier to the effect that in the case of tobacco cancer, the defendant would not be guilty of a breach of warranty where no developed human skill or foresight could have revealed the danger in the use of its products.

The third case is *Green v. American Tobacco Company,* cited above, which was discussed in this space last year.[2] You may recall that that was the case wherein the Fifth Circuit interpreted the law of Florida to be as just described, to wit, that there was no breach of warranty where no developed human skill or foresight could reveal the danger in the use of the product. After deciding that, and on rehearing, the Court of Appeals certified the question concerning Florida law to the Florida Supreme Court. This year we have two

[2] 18 FOOD DRUG COSMETIC LAW JOURNAL 141 (March, 1963).

further decisions in the case, one by the Supreme Court of Florida and another by the Fifth Circuit. The Florida Supreme Court was presented with the question:

> Does the law of Florida impose on a manufacturer and distributor of cigarettes absolute liability, as for breach of implied warranty, for death caused by using such cigarettes from 1924 or 1925 to February 1, 1956, the cancer having developed prior to February 1, 1956, and the death occurring February 25, 1958, when the defendant manufacturer and distributor could not on, or prior to February 1, 1956 by the reasonable application of human skill and foresight, have known that users of such cigarettes would be endangered by the inhalation of the main stream smoke from such cigarettes, of contracting cancer of the lungs?

In response to this question, the Florida court said "our decisions conclusively establish the principle that a manufacturer's or seller's actual knowledge or opportunity for knowledge of a defective or unwholesome condition is wholly irrelevant to his liability on the theory of implied warranty and the question certified must therefore be answered in the affirmative." The court noted in the course of its opinion that the question presented did not seek a response on the ultimate issue of liability between court and jury relating to the scope and breach of the implied warranty that a product supplied for human consumption shall be reasonably fit and wholesome for that general purpose.

On remand to the Fifth Circuit Court of Appeals, that court sent the case back to the district court for a new trial. This was done because the court felt that the jury had not made any sufficient finding on the question as to whether or not the cigarettes were reasonably fit and wholesome. It is interesting that in sending the case back, the court of appeals indicated that the jury's responses to the specific questions rendered at the first trial had become the law of the case, and, therefore, these issues were not subject to a relitigation on the retrial. The new trial may concern itself only with any issue not inconsistent with those answers.

Claims Arising Out of Factual Situations

Sometimes, the factual situations or the claims arising out of the factual situations in products liability cases are worthy of a moment's pause and consideration. Take, for example, the poor lady who encountered what appeared to be a petrified mouse in a package of brown sugar. What appears to be a petrified mouse turned out to be a rubber band, some string and a piece of cardboard. (*Fulton v.*

Kroger Company, cited above.) Or consider the plight of the poor young lady who found herself with a half-inch crewcut two weeks after the application of defendant's permanent wave lotion. This lady received $640 to reimburse her for special damages and an additional $556 for her humiliation, embarrassment and discomfort suffered during the nine months' time required by nature for her hair to grow to its previous length. (*Bethancourt v. Employers' Liability Assurance Corp.,* cited above.) And this young lady was an attractive, unmarried woman of approximately 21 years of age who, in the court's words, was "in the ardent pursuit of that nebulous attribute of the female termed beauty."

Then there was an Oklahoma lady who wondered how she would look with blond hair. She used the defendant's tint product because it could be washed out if one didn't like the result. Somehow or other, the washing didn't work, and the hair came out instead of the tint. Her shame, embarrassment and humiliation were worth exactly $4,000. Of course, there were extenuating circumstances. For example, for several days people called her on the phone to ask if she was blond or bald. In addition, her friends laughed at her and teased her to take off the head scarf which she wore as a permanent fixture for two or three months. Besides this, plaintiff, a housewife with two children, was active in club and civic work, such as the PTA and the Girl Scouts, and at the time of her injury, she was "state secretary for the Oklahoma Federation of Squaredancers." One might have been tempted to think that cosmetic damage to an attractive young single girl would be more expensive than cosmetic damage to a wife and a mother. However, this obviously reckons without the Federation of Squaredancers. (*John A. Brown, Inc. v. Shelton,* cited above.)

There is a well-known human weakness, shared by most of us, to tend to be an expert at some time or another in fields and professions other than our own. It is, therefore, pleasant to salute a federal district judge in New York who showed admirable restraint when confronted with this temptation. Discussing the issue of damages in a case which he had heard without a jury, the judge said: "Perhaps it is a fact that a placebo in the form of a huge judgment would cure this woman's obvious anxieties. It is not, however, the function of this court to practice medicine." (*Cohen v. Ford Motor Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 5014 (DC N. Y. 1963).)

As an example of the ingenuity of counsel in framing a cause of action, let me refer to you the case of *Kahn v. Chrysler Corp.,* CCH

PRODUCTS LIABILITY REPORTS ¶ 5137 (DC Tex. 1963). Plaintiff, a seven-year-old boy, drove his bicycle into the rear of a parked automobile manufactured by the defendant. He was thrown against the car and his head struck a tail fin, causing substantial injury. According to the court, the very essence of plaintiff's complaint was that the defendant owed to the plaintiff a duty to design and manufacture an automobile with which it was safe to collide. The United States District Court for the Southern District of Texas agreed that the manufacturer of an automobile has a rather substantial duty toward the public, but it said, "[T]he manufacturer has no obligation to so design his automobile that it will be safe for a child to ride his bicycle into it while the car is parked."

From time to time, we have singled out language used by some of our courts which for the sheer elegance of it made it worthy of repetition. Such is the case with the language of Judge Kosicki of the Connecticut Circuit Court deciding the case of *Scanlon v. Food Crafts, Inc.*, cited above. Plaintiff there complained that he broke a tooth when he bit into a grinder sold to him by the defendant which was, as he claimed, so hard as to be unfit. For those who may not be familiar with grinders, let met quote to you Judge Kosicki's definition thereof:

> A grinder way tersely be described as a gustatory extravaganza of regal dimensions and savor. It consists of an elongated roll or small loaf, either hard-crusted or soft, slit longitudinally and filled with an imaginative assortment of meats, condiments and vegetables. By an elidible colloquialism, the word "grinder" is accepted as descriptive of the lacerated condition of the contents of the roll; it has no anthropomorphic meaning suggestive of the grinder's own violent tendencies toward an unwary consumer.

The principal issue between the parties in the case was whether plaintiff's injury was caused by the hardness of the roll or the weakness of plaintiff's tooth. Defendant claimed that grinders normally are sold with a roll that has a crusty exterior and that the particular roll here was fit for the purpose and free of all defects. On this subject, the court had this to say:

> To the *cognoscenti,* scorning the pabulum of the soft roll, the hard roll would seem to be the only kind fit for and worthy of human consumption. No doubt it offers, among other things, to those endowed with hardy dental equipment, a welcome challenge to accomplish an ardent mastication; and thus it would seem to enhance the pleasure of eating by imparting a sense of triumph in a task nobly done. The plaintiff, however, makes no pretense to being numbered among the elect. In effect, he simply says that whether stale or not, the grinder, as to him, was too hard for consumption.

The court agreed. Whatever reservations one may have concerning the judge's determination on the issue of liability are softened

somewhat by his award of damages. Plaintiff was awarded $100 over and above his dental expenses to compensate him for his pain and suffering as well as for the permanent injury involved in the loss of a natural tooth.

There remains to discuss what may be the saddest case we have had to review for some time. (*Gallagher v. Pequot Spring Water Company,* cited above.) Plaintiff, an August bride, claims to have become ill at her wedding reception as a result of drinking grape soda which contained a foreign substance. No witness at the trial had seen the alleged substance at the time, but others at the table with plaintiff were heard to exclaim that the bottle contained a cockroach or a blood sucker. It was following these exclamations that plaintiff suffered her indisposition. At the trial level, plaintiff recovered a judgment of $2,500 which was reduced by the trial court to $1,500. The case comes to us in the form of a reversing opinion by the appellate court.

The ground for reversal and remand for a new trial was the failure of plaintiff to identify the foreign substance and to prove that it was the cause of her illness. However, it is the discussion of two elements of damage which is of interest to us.

In the first place, plaintiff contended that it was the custom in her stratum of society for the guests at a wedding reception to make gifts of money to the bridal couple during the grand march. Because of her illness, plaintiff was forced to leave before the grand march and many of the guests also left early, thereby reducing the amount of money realized through this channel. While the discussion is cryptic, the court seemed to indicate that such a loss might be sustainable on some theory of *quid pro quo.* Unfortunately, the court did not see fit to indicate what such *quid pro quo* might be.

Secondly, plaintiff complained that because of her illness, she abstained from "the joyous incidents of the nuptial night," and sought damage for loss of consortium through temporary deprivation and postponement of the connubial privilege. The court pointed out that, in Connecticut, where the case arose, consequential damages for loss of consortium, either through negligence or breach of warranty cannot be recovered by either spouse. "Such loss," said the court, "grievous though it may be, is not susceptible of judicial scrutiny and can not be redeemed in a measurable pecuniary equivalent."

On this sad note, it seems appropriate to conclude this report.

[The End]

Administrative Developments in the Food and Drug Law Field

By GEORGE P. LARRICK

The Author Is Commissioner of Food and Drugs, United States Department of Health, Education and Welfare.

WHEN SECRETARY CELEBREZZE announced the reorganization of the Food and Drug Administration last November, this was necessarily couched in general terms. While certain key people were named in the announcement, there has been, both in and out of the Food and Drug Administration, understandable interest in just how this reorganization would work out and who would be designated to operate the units such as divisions and branches within the announced bureaus and offices.

To implement the reorganization, we felt it imperative to explore every facet of each old and new unit with several objectives in mind. First and foremost was to be sure that in outlining duties and responsibilities we did not leave opportunities for administrative or regulatory problems to develop without having a specific unit responsible for dealing with them. Equally important was to be as sure as possible that we were assigning the right people to the many jobs involved in the reorganization.

This implementation took some time, but the time and thought that went into it were not wasted. The procedure followed produced ideas and suggestions from many of our people, and we incorporated all that offered good chances of improving the operation.

Now all our people know where they fit into the reorganized operation and we are able to advise inquirers which office will be responsible for various functions. Unfortunately, all our space problems are not solved (and I sometimes wonder if they ever will be), so that in all cases we are not going to be able to have all of the units of a single bureau located in the same building.

During the past two weeks our people have been phasing into their new jobs, generally doing so on a gradual basis so there will be no unfinished operations in the areas they are leaving. By next week, however, we expect to have a full-fledged going concern under the new organization, which we sincerely believe will enable us to do a better job in enforcing the statutes assigned to us and a better job in dealing with the industries involved, particularly from the standpoint of making sure they know the ground rules and have every opportunity for voluntary compliance with the several requirements of the statutes and the regulations issued thereunder.

The reorganization contemplates that we will need new blood in our top management. It will be noted that the positions which we are considering filling from the outside are: Associate Commissioner for Science; Director, Bureau of Medicine; Director, Bureau of Scientific Research; and Director, Bureau of Education and Voluntary Compliance.

Upgrading of Scientific Work Sought

While one of the major improvements which we seek from the reorganization is the up-grading of the scientific work, we think we have another dividend in the improved system for making available advice and comment to all concerned. While we have a specific branch in the Bureau of Education and Voluntary Compliance which is called "Industry Advice," certainly we will expect that its principal function will be in dealing with those who *seek* advice. We want to make abundantly clear that this is available to anyone who wants to comply with the law and has any question as to our view about how to go about doing so.

Many of you will have an opportunity to see first-hand how this reorganized FDA works out. Certainly we will appreciate any comments, suggestions, or recommendations you have as you do so.

For some time now we have been urging manufacturers to give more attention to control and other measures designed to prevent untoward incidents in the preparation, packaging, labeling, and distribution of their products. We have pointed out that in many areas the foods being commercially prepared are much more complicated and thus offer greater opportunities for something to go wrong than prevailed years ago. In our discussions, we have often equated specific food products to items being marketed by the drug industry and we pointed with pride to the types of control operations which are em-

ployed in connection with the production of many of our drug products. Lately, however, we seem to be having just too many mix-ups in drugs, ranging all the way from serious mix-ups to what might be regarded by some as minor labeling and packaging errors. All of these, however, have been serious enough to warrant getting the contaminated goods off the market immediately. Have some in the drug industry become complacent about control systems, or have they become so automated in some areas that the checks and balances which formerly prevailed are no longer being used?

Currently, as a result of the unfortunate experiences we have had with botulism, we are urging food packers to take a careful look at each one of their operations from the time the cans and the raw materials reach their establishments to see whether they have taken sufficient preventive steps to block avenues where things might go wrong. I think it is timely to offer the same kind of suggestion to the drug industry. Perhaps at least a part of this type of investigation is best conducted by those members of a firm who do not normally spend most of their time in the actual manufacturing or control operation. Certainly our inspectors are being alerted to the possibilities and, of course, will be willing to share their observations with manufacturers during every factory inspection which we make.

"Preventive Compliance" Advised

We all are familiar with the term "voluntary compliance," but perhaps we should really stress some other feature which for want of a better term might be called "preventive compliance." Of course, this doesn't mean preventing compliance, but rather, a constant alertness to the possibilities that something may go wrong—and to try to be ahead of the actual development.

This is a philosophy which we commend to you in industry because we believe it a good one, and one to which we are committed in our own day-to-day operations. We must constantly look back at procedures and policies—including regulations—that have been established with the objective of amending or cancelling them as the facts dictate. Just the other day I had a letter from a scientist who questioned the wisdom of an action we were proposing, stating that he was not aware of any untoward incident involving the chemical in question. There was no such incident, but our action was designed to keep one from happening. Should not industry follow just such a philosophy —in both principle and practice?

I had thought to discuss some facets of the drug operations arising out of the Kefauver-Harris Drug Amendments of 1962. I find, however, that so many others both in and out of FDA have done so at public meetings, that anything I might say now would be somewhat repetitious. Actually, we are convinced that the time has come when we need no longer debate the need or the worth of the law.

Constructive Suggestions Advised

We are quite pleased that in most quarters we now have a genuine recognition that when FDA publishes a notice of a proposal under the law, the accompanying invitation to comment is truly sincere. Before we publish any proposal we try to look at the matter from all sides and issue the best proposal we can. Certainly, however, we go into these matters with an open mind and we are most grateful when we get constructive suggestions. Anyone who has looked at the proposals and final publication of regulations will readily see that we have accepted any suggestions which we believe will improve the original proposals. Whenever anyone in or out of FDA believes that one of our regulations or procedures can be improved, or should be changed, we want to know about it; but we want to know the "why" as well. This invitation includes everyone in this room today. **[The End]**

STORING OF FOOD UNDER INSANITARY CONDITIONS IS CRIMINAL VIOLATION

The holding of food under insanitary conditions by a public storage warehouse after interstate shipment and before ultimate sale was a violation of Section 301(k) of the Federal Food, Drug and Cosmetic Act (FOOD DRUG COSMETIC LAW REPORTS ¶ 2171), and subjected the warehouse in which the food was stored to criminal liability, the Supreme Court of the United States has ruled in reversing the dismissal of a criminal action by the district court.

The Supreme Court found that the words "the doing of any other act" at the end of Section 301(k) referred to both adulteration and misbranding. Accordingly, it rejected the district court's conclusion that they were limited to acts of the same general nature as the preceding clause of Section 301(k), which related only to the alteration or removal of labeling. The court noted that misbranding and adulteration are wholly distinct offenses in reaching its conclusion.

The Supreme Court also rejected the argument of the warehouse that it was merely a bailee rather than a seller of the food and was not holding the food for sale within the meaning of Section 301(k). The language of Section 301(k) does not limit its application to one holding title to the goods, the Court said, and the danger to the public from insanitary storage of food is the same regardless of the proprietary status of the person storing it.—*United States v. Wiesenfeld Warehouse Company* (February 17, 1964), FOOD DRUG COSMETIC LAW REPORTS ¶ 40,098.

The Effect on the Pharmaceutical Industry of the "Effectiveness" Provisions of the 1962 Drug Amendments

By IRVING H. JUROW

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THE DRUG AMENDMENTS OF 1962[1] impose a host of new and extensive regulatory requirements on the manufacturers of medicines—both those dispensed, under the provisions of the Durham-Humphrey Amendment,[2] upon a physician's prescription,[3] as well as those sold directly, that is, over-the-counter, to the consumer.

Among the more controversial requirements are those dealing with proof of "effectiveness" of drugs.

Prior to the 1938 Food, Drug and Cosmetic Act, no provision existed for "clearance" by the federal government before drugs could be marketed. Indeed, until the sulfanilamide episode,[4] no such regulatory procedure was contemplated or proposed in the Copeland Bill during its five-year period of legislative gestation.

Following that tragic event, the bill, which eventually became the 1938 Act, was extensively amended to include what we have come to know as the "new drug" clearance procedures. But, as was indicated by the plain words of the statute, and much more clearly emphasized by the legislative history, Section 505 of the Act—the

[1] 21 USC (Supp. IV, 1962); P. L. 87-781; 76 Stat. 780.

[2] P. L. 82-215; 65 Stat. 648.

[3] 21 USC Sec. 353(b).

[4] The complete story of this incident may be found in the report of the Secretary of Agriculture to the Congress (S. Doc. 124, 75th Cong., 2d Sess. (1937)); see Dunn, *Federal Food, Drug, and Cosmetic Act,* at p. 1316, (1938).

"new drug" procedure provisions—was limited to tests and clearance for *safety*.[5]

Stimulated by the highly critical Kefauver investigation of the drug industry,[6] and propelled by the ironic repetition of tragedy in the "thalidomide" incident, the 1962 Amendments added the second basic regulatory requirement of proof of "effectiveness" to the traditional requirement of proof of "safety" as conditions precedent to governmental approval of "new drug" applications.

Pertinent Definitions

Section 201(p) of the Act, as amended by the 1962 Amendments, now defines a "new drug" as one which "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." And Section 505 of the Act, as so amended, imposes the additional requirements of proof of "effectiveness:" first, by requiring the applicant to submit investigation reports to show not only that the drug is safe for use, but also that it is "effective in use"[7]; second, by empowering the government to refuse to approve a "new drug" application if it finds "a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in [its] proposed labeling"[8]; and, third, by authorizing the government to withdraw its approval of any such "new drug" application, if it finds a similar "lack of substantial evidence" on the basis of "new information . . . evaluated together with the evidence available . . . when the application was approved."[9]

For these purposes, the term "substantial evidence" is defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it

[5] Jurow, "The 'New Drug' Law of the Federal Food, Drug and Cosmetic Act," 10 FOOD DRUG COSMETIC LAW JOURNAL 611 (September 1955).

[6] S. Rept. No. 448 (87th Cong., 1st Sess.); "Hearings on Administered Prices, Drugs," Subcommittee on Antitrust and Monopoly of Senate Committee on the Judiciary, Pts. 14-26.

[7] 21 USC Sec. 355(b).

[8] 21 USC Sec. 355(d).

[9] 21 USC Sec. 355(e).

purports or is represented to have under the conditions of use prescribed, recommended, or suggested in [its] labeling or proposed labeling. . . .[10]

This is neither the place, nor does time permit, to review and elaborate upon the various positions taken in the course of the legislative process, with respect to this proposal for adding proof of "effectiveness," by those whose vital interests were thereby affected —the medical profession, the pharmaceutical industry, the Food and Drug Administration, and lastly, but by no means the least, the consuming public. Those who seek further information are referred to the hearings on S. 1552 [11] and H. R. 11581 [12]—the Bills which eventually became the Drug Amendments of 1962—and the several reports of the Congressional Committees concerned.[13]

For good or ill,[14] these provisions are now—and at least for the time being—firmly implanted in the basic law and implemented in the current regulations of the FDA.[15]

Suffice it to say that the organized medical profession was,[16] and apparently still is,[17] strongly opposed to authorizing the FDA so to evaluate and pass upon the "effectiveness" of a "new drug," that the organized pharmaceutical industry reluctantly acquiesced in the new proposal,[18] that the governmental agency accepted this authority somewhat reluctantly,[19] and that organized consumer groups heartily endorsed it.

What does all this mean?

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[10] 21 USC Sec. 355(d).

[11] "Hearings, Drug Industry Antitrust Act," Subcommittee on Antitrust and Monopoly of Senate Committee on the Judiciary, Pts. 1-5 (1961).

[12] "Hearings, Drug Industry Act of 1962," House Committee on Interstate and Foreign Commerce (1962); see also "Hearings, Drug Industry Antitrust Act," Antitrust Subcommittee (Subcommittee No. 5) of House Committee on the Judiciary, Serial No. 32 (H. R. 6245) (1962).

[13] S. Rept. No. 1744 and Rept. 1744, Part 2, 87th Cong., 2d Sess. (1962); H. Rept. No. 2464 and Rept. 2464, Part 2, 87th Cong., 2d Sess. (1962); H. Rept. No. 2526 (Conf. Rept.), 87th Cong., 2d Sess. (1962).

[14] See, Jurow "The Legislative Picture for the Drug Industry, or 'Sulfanilamide Revisited,'" 18 *The Business Lawyer* 209, 212, November 1962.

[15] FDC Regulations, Part 130.

[16] "Hearings" cited at footnote 11, at p. 43.

[17] A. M. A. House of Delegates Resolution, December 4, 1963.

[18] "Hearings" cited at footnote 11, at p. 1997.

[19] Compare the testimony of Secretary Ribicoff, "Hearings" cited at footnote 11, at pp. 2583, 2944, with that of Secretary Flemming and Commissioner Larrick, "Hearings" cited at footnote 6, at pp. 12091, 12097, 12108 and following, and 12127.

Requirements Under New Provisions

Henceforth, under the new provisions of Section 201(p) and Section 505(b) of the Act, a drug manufacturer is required to submit to the FDA, as part of his "new drug" application, proof not only of the safety of the drug, but also of its effectiveness.[20]

Despite the fact that we lack a *statutory* definition of the term "effectiveness," we do not lack for *legislative history* which furnishes ample proof of the Congressional intent. It is abundantly clear that by "effectiveness" is meant that the drug will do that which its sponsor, the manufacturer, claims it will do—that is, the drug will do what is claimed for it.[21]

Admittedly, this may not be as simple as it sounds. Standards for "safety," which was all we had to establish under the "new drug" provisions of the law before 1962, are readily available. Basically objective in nature, "safety" may be more readily resolved, and the translation from animal results to human prediction appears to be generally accepted. "Effectiveness," however, implicitly involves elements of subjectivity and, in far more cases, will require judgments —even opinions—and the translation from animal to human evaluations will be far more difficult. Especially will this be true in those instances in which the disease state is not present in the animal or where the ailment is affected by subjective, psychosomatic or symptomatic factors.

The legislative history also establishes that the applicant need not satisfy any requirement of "relative efficacy," that is, that the "new drug" is more effective than other therapeutic agents for the same purposes.[22] All he need prove, as has been said, is that the "new drug" will do what he says it will do; not that it will do so, as well as, or better than, other drugs. Indeed, it would appear that the statutory standard of "effectiveness" may be satisfied even though the "new drug" does what is claimed for it less effectively than other therapeutic agents.

How will the applicant for approval of a "new drug" application satisfy the requirements of "effectiveness"? The statute requires the

[20] For an appreciation of the effect of this new requirement, compare the form of "new drug" application required by the FDA before and after the 1962 Amendments (Form FD-356, Rev. 1961; Form FD-356, 1963).

[21] S. Rept. No. 1744, cited at footnote 13, at p. 16.

[22] "Hearings" cited at footnote 11, at pp. 2585, 2945; S. Rept. No. 1744, cited at footnote 13, at p. 16.

administrative agency to approve a "new drug" application unless it finds, on the basis of the information furnished by the applicant in its "new drug" application, and upon any other information before the agency relating to the drug, that there is a "lack of substantial evidence" that the drug will have the effect claimed for it "in the proposed labeling." It is to be noted that the statute does not require a finding that there is "substantial evidence" that the drug will have the effect claimed. Rather, the statute requires only a finding that there is a "lack" of substantial evidence to that effect. The difference may be significant, particularly in terms of judicial review. For thereby the Congress intended to permit and to require the approval of a "new drug" application where the evidence in favor of "effectiveness" consisted even of a minority view of the medical profession, so that "a voice crying in the wilderness" could and would be heard.[23] I would assume that this requirement is both quantitative and qualitative.

"Substantial evidence" is defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling."

This does not require the applicant to establish his case for "effectiveness" by demonstrating unanimity or near unanimity of medical opinion,[24] nor does it mean that his burden is to do so by a "preponderance" of the evidence.[25] He will satisfy his burden of proof by demonstrating that a responsible segment of the profession attests thereto.[26]

Despite its tautness, the statutory definition of "substantial evidence" bristles with uncertainties and opens a "Pandora's Box" of questions. What is "adequate"; what is "well-controlled"; who are

[23] See, S. Rept. No. 1744, cited at footnote 13, at p. 16; see also, S. Rept. 1744, Part 2, at p. 6.

[24] Obviously, if he can make such a showing, he need file no "new drug" application under Section 505 unless required so to do because of the applicability of Clause (2) in Section 201(p), namely, that, despite general recognition of its safety and effectiveness, the drug has not been used "to a material extent" or "for a material time" otherwise than in investigations.

[25] "Hearings" cited at footnote 11, at p. 2945; see also, S. Rept. No. 1744, at p. 16 and S. Rept. No. 1744, Part 2, cited at footnote 13, at page 6.

[26] S. Rept. No. 1744, cited at footnote 13, at page 16.

"experts"; what "qualifications" must they possess; what quantum and quality of "scientific training," of "experience"; when are their conclusions "fairly" and "responsibly" arrived at?

In the hands of administrators conscious of their public responsibility, free from preconceived judgments in evaluating the admittedly imperfect science of medicine, and exercising a degree of discretion consistent with the public welfare, there should be little cause for concern as to the application of these standards. But, if it be otherwise, we may find ourselves reminded of the colloquy between Alice and Humpty Dumpty. "When *I* use a word," said Humpty Dumpty, "it means just what I choose it to mean—neither more nor less."

Requirement of Effectiveness Not New

Reflection will demonstrate that the requirement of "effectiveness" is not really and essentially new in the administration of the Federal Food, Drug and Cosmetic Act. It is new only in the sense that it now has statutory sanction and the FDA now possesses *express* power and authority to pass upon it in the earliest stage, that is, in its "new drug" clearance procedures, and again in a later stage through the suspension or withdrawal provisions.

For even prior to the 1962 Amendments, the law, in its broad application, did not countenance the distribution of "ineffective" drugs. Admittedly, the FDA had the power to require, and did require, a showing of "effectiveness" as that quality of the drug was reflected in the determination whether the drug was *safe* for use. The FDA could, and did, reject a "new drug" application when, in the context of "safety," the drug's effectiveness did not sufficiently outweigh the risks and toxic results so as to justify a finding that the drug was "safe" for use.[27] The objective of the new requirement is to broaden the application of the test of "effectiveness" to circumstances perhaps not as circumscribed as those where only "safety" is involved. True, as has been said, this judgment being related to "safety" affected only the public health aspect; "efficacy," as an economic factor, was therefore unaffected.

But the FDA also had the power and authority, and frequently effectively exercised it, to attack claims of effectiveness by proceeding under the seizure sanctions for misbranding.[28] The law books are full with cases attesting to this substantial method for driving worth-

[27] S. Rept. No. 1744, cited at footnote 13, at pp. 15 and following.

[28] S. Rept. No. 1744, cited at footnote 13, at p. 17.

less drugs from the market. In this fashion, both the public health and the economic aspects of the law could be vindicated. This procedure, it is true, does pose a somewhat different legal issue than is now imposed under the "new drug" procedure; but under both issues the substantial question is raised of the efficacy or "effectiveness" of the drug. Under the "misbranding" procedure, the burden of going forward with action and the burden of proof in the proceeding were both upon the government. Under the present law, as provided in Section 505, both burdens must now be borne by the manufacturer of the drug.

The accusation that pervaded the Congressional hearings, both investigatory and legislative, that pharmaceutical companies were marketing worthless drugs, and that the FDA was helpless to do anything about it, was decidedly inaccurate in both premises. Thus, the amplification of the FDA's authority is not due to the absence of power to proceed against ineffective drugs, but rather to authorize the exercise of that power at the initial stage, that is, *before* marketing, and also to shift the burden of proof to the applicant.[29]

In this context, it is probably safe to say that the effect on the drug industry of these new requirements will not be awesome in its consequences. They will not have the dire effects that some have predicted; nor will they, on the other hand, be easy of acceptance and satisfaction as others have blithely assumed.

Reliable manufacturers produced and distributed drugs which, in their considered judgments, were not only safe but were also effective for the purposes intended. No reputable manufacturer knowingly marketed a worthless, ineffective drug; self-interest surely dictated otherwise. If his own sense of responsibility and pride in his reputation for quality and integrity were not sufficient, surely the triple-pronged sanctions of the Federal Food, Drug and Cosmetic Act and the Damoclean sword of "product liability" were adequate threats to impel any reputable producer to assure himself of the validity of his "effectiveness" claims.

Why then should the pharmaceutical industry have hesitated to accept governmental authority to pass upon the "effectiveness" of its drugs? Without elaborating upon the theme, it seems clear that any extension of government authority in the regulation of commerce and industry poses a threat of autocracy and, until assured that its

[29] S. Rept. No. 1744, cited at footnote 13, at p. 16.

exercise will be reasonable and practical, the citizen must remain concerned.

Substantial Burden of New Drug Application

Thus, the essential difference, before and after the 1962 Amendments, is that a manufacturer may not now market a "new drug" product unless and until he has fully satisfied the FDA that it is both safe and effective—in accordance with the standards laid down in the statute—and has obtained the government's affirmative approval to do so. A "before" and "after" comparison of Form FD-356—the "new drug" application—reveals the substantial burden this imposes. The 1961 version was almost Spartan in its simplicity; the 1963 revision, despite the fact that its new text is essentially to provide material for proof of "effectiveness," is dramatically more complex.[30] Together with the new regulations governing "new drug" procedures, and the related ones applicable to investigational drugs, they call for the production of a vast amount of material and information to the FDA before one can obtain the essential governmental "license" to market.[31]

There is no doubt that the industry will be called upon to do ever so much more work, both in quantity and quality, than in prior years, not merely to satisfy the new law but to satisfy it in light of the current scientific explosion. This will mean more time, more money, more people, more skills—all of which will surely not add up to lower prices for drugs.

There are additional complications. Now that the FDA is required to "approve" the "new drug" application, as distinguished from allowing it to become "effective," greater care and greater conservatism will undoubtedly prevail. Since there is now more reason for the public to assume that an "approved" "new drug" has the *imprimatur* of the government, it is only logical to expect greater caution on the part of the regulatory agency. Hopefully, these new powers will not be employed in the espousal of individualistic concepts of medical practice, or of economic theories.

What has been said about the procedures for the introduction of "new drugs" applies also to the new provisions for the withdrawal of an approved "new drug" application under Section 505(e) of the Act. The Administration must proceed along the same lines and be gov-

[30] FDC Reg. 130.4(c).

[31] After 25 years, the Federal Food, Drug and Cosmetic Act has now, indeed, become a "licensing" statute. See, Jurow, cited at footnote 5, at p. 614.

erned by the same standards. However, the withdrawal procedure may not be instituted unless and until the FDA has "new information," in addition to that contained in the original "new drug" application, to support its finding that a "lack of substantial evidence" exists.

Of what this "new information" consists, and how this provision will be applied, must await further clarification on the part of the regulatory agency. But one would assume that this "new information" should be of equal probative value as that required of the applicant to justify his claim of "effectiveness."

Since Section 201(p) was amended to provide the test of "effectiveness," and became effective upon enactment, provision had to be made for drugs on the market, or subject to "new drug" applications theretofore made effective, in order not to precipitously condemn those unable to satisfy the new statutory test.

As to the effect of these new provisions on subsisting "new drug" applications, that is, those cleared prior to October 1962, and on drugs in commercial distribution prior to that date, rights described as "grandfather" rights, obtain. My co-panelist, Mr. Hagan, will shed light on that somewhat esoteric subject. **[The End]**

PESTICIDE BILL PASSED BY HOUSE

A bill to amend the Federal Insecticide, Fungicide and Rodenticide Act by repealing the provision permitting the registration of pesticides under protest, permitting the federal registration number to be shown on the label of pesticides, and requiring it to be shown if the Secretary of Agriculture so provides was passed by the House of Representatives on February 17, 1964.

Technically, the House acted on S. 1605, the bill passed by the Senate. However, the language of H. R. 9739 was substituted for the Senate text before passage. Accordingly, the bill must now be returned to the Senate for acceptance or rejection of differences between S. 1605 and the House text. The text of S. 1605 as passed by the Senate and pertinent excerpts from Senate Report No. 573 appear at ¶ 40,070 of FOOD DRUG COSMETIC LAW REPORTS. The House bill deletes the provision allowing the Secretary of Agriculture to submit the matter to an advisory committee after denial of registration, adds a provision assessing the costs of the advisory committee against the government if the committee recommends in favor of the petitioner, sets a limit of 90 days after the hearing for the Secretary to reach a decision, and provides that all data submitted to the Secretary or the advisory committee in connection with the petition shall be considered confidential. The differences between S. 1605 as passed by the Senate and H. R. 9739 are discussed at ¶ 40,095 of FOOD DRUG COSMETIC LAW REPORTS.

Grandfather Protection Under the Drug Amendments of 1962

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MY SUBJECT IS, broadly, the so-called "grandfather" clauses which as to certain drugs, exempt from or postpone the operative date of the "effectiveness" provisions of the Drug Amendments of 1962.

The grandfather provisions are in the 1962 law, of course, because of its various provisions dealing with effectiveness, particularly the amendment of Section 201(p) which changed the definition of "new drug" from one "not generally recognized as safe" to one "not generally recognized as safe *and effective*" for labeled uses, the amendment of Section 505(e) allowing the Food and Drug Administration to withdraw approval of a new drug application (NDA) for lack of "substantial evidence" that the drug will have its intended effect, and the amendment of Section 507(a) which brought all previously uncertified antibiotics for human use under the certification procedure thereby subjecting them to such efficacy requirements as are authorized by Section 507(a) and (b).

If it were not for the grandfather clauses, the change in the "new drug" definition would have made it unlawful, immediately upon enactment of this new law, to ship any drug for which *no* NDA was in effect, unless it was generally recognized as safe and effective. Secondly, as to those new drugs which had effective NDA's, FDA could have at once commenced a proceeding to withdraw NDA clearance for any such drug as to which FDA had new information which, coupled with the evidence available to them when the NDA was cleared, supported a finding that there was a lack of substantial evidence that the drug would have its intended effect.

In order to preclude the first of these dire possibilities, and to postpone the time at which the second possibility might become a

reality, Section 107(c)(3) and (4) was made a part of the Drug Amendments of 1962.

Similarly, if it were not for the grandfather provisions in Section 507(h), FDA could have refused to issue monographs providing for the certification of previously uncertified antibiotic drugs which had been cleared through the new drug procedure, if the individuals who now reviewed the effectiveness data were not satisfied with it. Since antibiotics are generally employed in treating serious diseases, their effectiveness is intimately related to their safety and, hence, when FDA cleared those drugs under the new drug procedure this amounted to acceptance of their effectiveness. It could have been most troublesome if the individuals at FDA who would now review the effectiveness data for these drugs were able to substitute their judgments on effectiveness for those made by their predecessors, particularly since the antibiotics certification provisions of the Act (were it not for Section 507(h)) would have contained no standard for judging effectiveness.

The "Two Year" Grandfather Provision

Section 107(c)(3) provides, in Subsection (A), that as to any drug with respect to which an NDA was deemed approved (meaning previously made "effective") on October 9, 1962, the amendment to the definition of the term "new drug" in Section 201(p) and the amendments to Section 505(b) and (d) insofar as they relate to "effectiveness," do not apply to such drug when intended only for use under conditions recommended in labeling "covered by" such "approved" NDA. It is important (for reasons which will be discussed later) to note that there is no fixed duration to the grandfather rights with regard to Sections 201(p) and 505(b) and (d). This protection persists unless and until the NDA is withdrawn or suspended pursuant to Section 505(e).

Section 107(c)(3) goes on to provide, in Subsection (B) that FDA *cannot* bring a proceeding under the revised Section 505(e) to withdraw approval of the NDA for such drug on grounds of lack of substantial evidence of effectiveness until either October 10, 1964 *or* the date on which approval of the NDA is withdrawn or suspended on grounds other than effectiveness, whichever occurs first. Incidentally, I don't understand what was intended to be accomplished by the reference to a date of withdrawal of an NDA on grounds other than effectiveness, but since October 10, 1964 is not very far away, it doesn't seem worthwhile to comment further on this.

It would appear that there is one factual situation as to which the application of the grandfather provision we have just discussed seems clear. I refer to the situation where a drug on October 9, 1962 (the day before enactment of the new law) was a new drug, and for which there was outstanding an approved (meaning an "effective") NDA.

It seems clear that until October 10, 1964, FDA has no authority to commence a proceeding to withdraw approval of such NDA on "effectiveness" grounds with regard to conditions of use recommended in labeling covered by such NDA. Such drugs, in effect, have grandfather protection from the efficacy provisions of the new law for two years from its enactment.

Suppose, however, a company *now,* or at any time before FDA issues a final order withdrawing approval of such NDA or NDA's, wishes to market for the first time a new drug identical in formulation and claims to a drug as to which one or more other companies have "two year" grandfather protection under this provision. Would such drug made by the newcomer have the same grandfather rights, so as to be entitled to obtain an approved NDA without submitting substantial evidence of efficacy? The answer to this question depends on whether Section 107(c)(3) when it speaks of "any drug with respect to which an application is deemed approved" means to refer only to companies who had received effective NDA's for that drug, or whether it means that so long as one company obtained an effective NDA, the drug itself is covered, and anyone who later sells it is included.

The latter interpretation is inconsistent with the principle that new drug clearance is "personal" to the holder of the NDA and not possessed by the drug *per se,* which principle has been adopted by both industry and FDA since the birth of the new drug procedure in 1938, and yet there are indications that this is the interpretation which FDA has recently been following. I suggest, however, that FDA's narrow construction of the scope of the "forever" grandfather protection (which will be discussed next) probably necessitated their adopting this interpretation. I am, of course, pleased that this interpretation has benefited some drug manufacturers. At the same time the inconsistency between this interpretation and the long recognized "personal" nature of a new drug clearance is troublesome.

We have been speaking of drugs for which NDA approval is now sought and which are "identical" in formulation and claims with a

drug or drugs which received NDA clearance prior to October 10, 1962. The next logical question is to what extent can such a drug be less than "identical" and still, under what appears to be FDA's interpretation, be the beneficiary of the two year grandfather rights possessed by the older drug or drugs. I suspect that FDA would say that if the respects in which the new drug is not identical with the older drug or drugs are not material from the point of view of safety and effectiveness, the new drug would have the benefit of this grandfather protection. I leave it to you to judge what guidelines would prevail in determining "materiality" in such circumstances.

The "Forever" Grandfather Provision

The second grandfather provision (Section 107(c)(4)) makes the change in the definition of "new drug" under the 1962 law forever inapplicable to any drug which on October 9, 1962 met three criteria: (1) was then in use or sale in United States, (2) was then not a new drug, and finally (3) was then not "covered by" an effective application. As we will see, this third criteria muddies the interpretative waters considerably.

There is, however, one factual situation where the application of this provision also appears clear. I refer to the situation with regard to those drugs which were "old drugs" on October 9, 1962 and as to which no one ever received an effective NDA. This would be the pre-1938 drugs and those marketed after 1938 without an NDA being required by anyone. It is clear that such drugs are forever protected from the effectiveness provisions, unless this protection is lost for reasons which we will discuss later.

Here again, suppose someone now wishes to market for the first time a drug identical in formulation and claims to a drug already on the market which has this grandfather protection, or one which is less than identical but in respects not material with regard to safety or effectiveness. Let us assume the drug is *not* generally recognized as effective and, hence, is a new drug. I would assume that FDA would consider that the newcomer's drug has the "forever" grandfather protection under these circumstances. Since we are now discussing drugs for which no one received NDA clearance, such an interpretation would not be inconsistent with the personal nature of NDA clearance, and would seem desirable both to FDA and industry.

Old Drugs Which Formerly Were New Drugs

It would seem that we have now exhausted the factual situations involving nonantibiotic drugs where the scope and effect of the grandfather provisions are even relatively clear. What are left for discussion, of course, are the host of drugs which were "old drugs" on October 9, 1962 but which had earlier been new drugs and subject to effective NDA's for at least some manufacturers.

Let's consider first whether such drugs *as a class* meet the three criteria set forth in Section 107(c)(4) so as to be entitled to the "forever" grandfather protection. Since these drugs were on sale prior to October 10, 1962, and where not then "new drugs" they meet the first two criteria. It is very difficult to answer whether they meet the third criterion because its meaning is not clear. This third criterion is that the drug on October 9, 1962 was not "covered by" an effective NDA.

One theory is that *no* drug which was an "old drug" on October 9, 1962 was then "covered by" an effective application, and hence, that *all* these old drugs meet the third criterion. There are two problems with applying this theory under the new law to all such old drugs. First, it would seem to render the third criterion mere *surplusage* since the second criterion is that the drug had to be an old drug. As we know, courts generally try to find some meaning for statutory provisions rather than to consider them surplusage. The second problem with this theory arises out of the statement by the managers of the House bill which appears in the October 3, 1962 Conference Report. That statement is to the effect that the "forever" grandfather protection applies only to drugs that have *never been subject* to the new drug procedure.

On the other hand, the theory that such drugs remained "covered by" the NDA's which they obtained earlier is beset with at least as many difficulties. It just doesn't seem to make any sense to argue that such drugs remained "covered by" their earlier NDA clearance when the manufacturing procedure, formulation, claims, and so forth, could have been (and often were) changed without the necessity of submitting a supplemental NDA unless the change was such that it caused the drug to become again a new drug, and when any newcomer could market the same drug without any NDA clearance. Indeed, FDA's own regulations (see Section 130.9(e) and the last sentence in the paragraph in parenthesis which follows paragraph number 8 in

the new drug application Form FD-356-Rev. 1963) seem clearly to recognize that once a drug becomes an old drug no supplemental NDA is required for changes in it or its labeling unless such changes are such as to cause it again to become a new drug.

On balance, however, it is difficult to be too optimistic about the chances for a successful argument that *all* drugs formerly subject to NDA's, but which had become old drugs prior to passage of the new law, are entitled to the "forever" grandfather. It seems to me that the best chance for a successful argument on this point ties in to the question of whether a company which marketed a drug for the first time when it was an old drug, even though other companies earlier had obtained NDA's for the same drug, is entitled to the "forever" grandfather protection. If the old drug, as to the newcomer, is entitled to such protection, there is certainly room for a strong argument that Congress could not have intended the degree of grandfather protection to depend on the accident of how early a particular company marketed a drug, particularly when the companies who marketed the drug the earliest, when still a new drug, and who did the required animal and clinical testing, would wind up with the least grandfather protection. Such a result would be ludicrous.

Applying the three criteria of Section 107(c)(4) to a drug first marketed by a company after it ceased to be a new drug, and hence without new drug clearance, it would seem that the drug as to that company meets all three criteria, and hence should have "forever" grandfather protection.

A further argument in favor of "forever" grandfather protection for such a drug can be made by considering what its status is if it does not have this "forever" protection. It seems to me that it would then either have no grandfather protection at all, which would seem a difficult construction for FDA to sell a court, or that it has the Section 107(c)(3) protection. But, if it has this latter protection, and FDA believes there is not substantial evidence of efficacy for the drug, FDA has no right to summarily declare that the drug has become a new drug and consequently cannot be sold any longer until covered by an approved NDA. It has no such right because, as mentioned earlier, drugs covered by Section 107(c)(3) are not subject to Section 201(p) or Section 505(b) and (d) unless and until the NDA is withdrawn pursuant to Section 505(e). Thus the *only right* FDA is given under this section is to suspend approved applications after October 9, *1964. But how can you suspend an NDA for a drug*

which never received an effective NDA? What would be the effect of suspension of a nonexistent NDA?

Representatives of FDA have expressed the view that if one manufacturer received an effective NDA, and others later manufactured the same drug as an old drug without NDA clearance, all are, by some phenomena that I do not understand, "covered by" an effective application of the first manufacturer. Presumably, this interpretation applies even though the manufacturing and testing procedures and facilities, the formulation and the claims for the drugs of the other companies are not entirely the same as provided for in the earlier NDA.

I don't know what FDA would say if the first manufacturer had withdrawn his application. Would this fortuitous circumstance affect the extent of grandfather protection of the other manufacturers? Or suppose that there had been two manufacturers which had received NDA clearance, but only one of them had withdrawn it's NDA when the drug became an old drug. Would the grandfather rights of all those which later marketed the drug as an old drug depend on the rights of the earlier manufacturer who had withdrawn the NDA, or on the other manufacturer, assuming that there would be a difference?

Furthermore, the concept that new drug clearance by one manufacturer affects the rights of subsequent manufacturers is inconsistent with the established doctrine that new drug clearance is *personal* to the applicant, and does not embrace the drug *per se*. Parenthetically, I might mention that FDA's position that new drug clearances are *not* personal insofar as grandfather protection is concerned would seem diametrically in conflict with their continuing interpretation that new drug clearance constitutes only a personal prior sanction under the grandfather clause (Section 201(s)(3) in the Food Additives Amendment), and is not a sanction for the drug *per se*.

Section 201(s)(3), in effect, exempts from the Food Additives Amendment "*any substance* used in accordance with a sanction or approval" granted under the Food, Drug and Cosmetic Act, among others. Even though this exemption, by its terms, seems clearly to apply to "substances" per se, FDA's position is that because of the personal nature of NDA's, the sanction resulting from NDA clearance is personal and does not embrace the substance per se. It is difficult for me to understand how that interpretation can stand side by side with the one we have been discussing without the inconsistency being obvious.

If, as I believe, a company which marketed an old drug before October 10, 1962 without an NDA, has the benefit of the "forever" grandfather protection even though others earlier had obtained effective NDA's for the same drug, it would seem, as before mentioned, that this would provide a fairly strong basis for arguing that Congress could not have intended to give more limited grandfather protection to those who began marketing the same drug when it was a new drug, but rather intended that all such old drugs receive the same "forever" protection.

Notwithstanding the strength of these arguments, it is most difficult to predict their chances for over-all success in view of the third criterion of Section 107(c)(4) and its legislative history. It is conceivable that the eventual result will be that some old drugs previously cleared under the new drug procedure will be found to have "forever" grandfather protection and others will not.

These drugs can be separated into three categories: (1) Those which, when they became old drugs, had their NDA's formally withdrawn by their manufacturers; (2) Those as to which FDA advised their manufacturers in writing that they had become old drugs; and (3) Those as to which neither of the above things occurred.

It seems untenable to argue that a drug in category (1) remained "covered by" its NDA. The chances that they have "forever" grandfather protection would appear to be quite good. The number of drugs in category (2), of course, is very large. While drugs in this category present a much closer question, a convincing argument can be made that they did not remain "covered by" their NDA's. As mentioned earlier, it just doesn't seem to make sense to argue that such drugs remained covered by their NDA's when even FDA agreed they were no longer new drugs.

If you were arguing a case involving the extent of grandfather protection of a drug in class (2), it would seem that your position would be strengthened by asserting that, of these three categories, only drugs in category (3) fail to possess the "forever" grandfather protection. By such an assertion the third criterion of Section 107(c)(4) would apply to drugs in category (3), and hence this criteria would not be surplusage. There is even a logical reason why Congress may have wished to treat this (3) category of old drugs different from the first two, namely, the fact that there is no precise means for determining what drugs fall into the (3) category whereas those falling into the first two categories can be ascertained from

correspondence between FDA and the manufacturer. You could argue that Congress did not intend there to be endless argument as to what drugs had become "old drugs" prior to October 9, 1962, and hence Congress limited the "forever" grandfather protection to those in the first two categories.

This argument admittedly is not overwhelming but neither, in my judgment, is any argument that I have heard made to support the position that drugs in category (2) do not have "forever" grandfather protection. My conclusion on this argument is simply that it has possibilities.

Loss of Grandfather Protection

Under Section 107(c)(4), the "forever" grandfather protection applies only when the drug is intended "solely" for use under conditions recommended in its labeling as of October 9, 1962. This might mean that any change in recommended conditions of use would result in the drug "losing" its grandfather protection. Consequently, when continuation of grandfather rights is important to a particular drug, it would seem prudent to avoid any change in the recommended conditions of use. If FDA should assert that such a loss had occurred, it would be interesting to consider whether the grandfather protection could be reclaimed simply by discontinuing the changed recommendations for use.

It is not clear whether, or to what extent, the formulation of such a drug could be changed without loss of grandfather protection. Here again, I would hope FDA's position would be that if the change was not material with regard to the safety or effectiveness of the drug, it would not affect its grandfather rights.

As to the "two year" grandfather protection, if a supplement is submitted to an NDA proposing a change in conditions of use, it seems to me that it is entirely clear that FDA has no authority to use that as a basis for challenging previously cleared claims on the ground of lack of substantial evidence of efficacy. Section 107(c)(3) itself is entirely clear on the point and, in addition, the Senate Judiciary Committee Report, dated August 21, 1962, supports the view that only any changed conditions of use are to be evaluated as to efficacy. That report, on page 7, states:

> . . . [A] drug which is on the market and has gone through the new drug procedure would not have to be resubmitted for clearance of existing label claims with respect to effectiveness of the drug unless approval of the NDA is withdrawn or suspended under the Act, or *unless an amendment or supplement to the effective*

new drug application is filed (in which event only the changed labeling would be re-evaluated).

There are no statutory guidelines as to what other changes can be made with respect to a new drug, without resulting in FDA having the right to challenge previously cleared claims on grounds of lack of substantial evidence of efficacy.

The Antibiotic Grandfather Clause

The grandfather provision as to antibiotics in the new law (Section 507(h)) applies only to those which became subject to certification as the result of the new law and which previously had been cleared under the new drug procedure. It has two parts.

The first part provides that those drugs which previously received new drug clearance (providing such clearance had not been withdrawn) may obtain certification or exemption from certification without FDA making an affirmative finding of the efficacy of such drugs.

The second part, in effect, gives to such drugs, after certification, the same "two year" grandfather protection as new drugs possess under Section 107(c)(3). By this I mean that denial of further certification on ground of lack of substantial evidence of efficacy cannot be accomplished until after October 9, 1964. Furthermore, any action by the Secretary to deny further certification would be subject to the administrative and judicial procedures specified in Section 507(f) of the Act.

In closing, let me make the obvious remark that the grandfather provisions do not leave FDA without a remedy as to claims for effectiveness that are false or misleading. Under Section 502(a) such a claim renders the drug misbranded and enables FDA to proceed by seizure, injunction and/or criminal proceeding. **[The End]**

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