VOL. 20, NO. 4 APRIL 1965

# Food Drug Cosmetic Law JOURNAL

Concluding Papers Presented at the Food Standards Symposium

Decision Making in the Food and Drug Administration . . GEORGE P. LARRICK

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

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; 3 years, $49; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

April, 1965
Volume 20 • Number 4

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

# FOOD DRUG COSMETIC LAW JOURNAL

## Table of Contents ..... APRIL, 1965




VOLUME 20 NUMBER 4

# FOOD DRUG COSMETIC LAW JOURNAL

## Editorial Advisory Board



---

# REPORTS

## TO THE READER

**Foods Standards Symposium.** — A symposium on "The Legal Basis and Regulatory Use of Food Standards," was held in Washington, D. C. on December 1, 1964. In the March issue, papers from the morning session were presented. Included in this April issue are papers which were delivered at the afternoon panel discussion, "Do FDA's Present Food Standards and Standard Making Policy Best Serve the Consumer?"

*Malcolm R. Stephens,* Assistant Commissioner for Regulations, FDA, in the first article, suggests giving manufacturers more flexibility in using optional ingredients while holding them to more rigid labeling requirements. In the second article beginning on page 184, *O. L. Kline,* Assistant Commissioner for Science Resources, FDA, points out the need for scientific study in several aspects of food standard making. *H. Thomas Austern,* of the Washington, D. C. law firm of Covington & Burling, and a member of the Lawyers Advisory Committee, The Food Law Institute, suggests possible improvements in food standardization in his article beginning on page 188. *Paul E. Ramstad,* Director of Grocery Products Quality Controls, General Mills, Inc., and a member of the Food and Nutrition Board, National Academy of Sciences, is the author of the article beginning on page 193. He suggests that standards should be "buying" rather than "processing" oriented.

**Charles Wesley Dunn Food and Drug Lecture.** — *Commissioner George P. Larrick* of the Food and Drug Administration delivered the 1965 Charles Wesley Dunn Food and Drug Lecture at Harvard University. His lecture on "Decision Making in the Food and Drug Administration" begins on page 197.

**Twentieth Annual Meeting of The Section on Food, Drug & Cosmetic Law of The New York State Bar Association.**—This meeting was held in New York City on January 26, 1965. A paper by *C. A. Morrell,* Director of the Food and Drug Directorate, Department of National Health and Welfare of Canada, which begins on page 208, discusses recent developments in Canadian Food and Drug Law. "Compliance with the New IND and NDA Regulations" is discussed in the article by *Raymond D. McMurray* of New York City, beginning on page 215. *Sidney H. Willig,* an Attorney with Sterling Drug Co., Inc., writes about the role of the medical detailer in relation to the New Drug Amendments in the article beginning on page 221. Recent developments with respect to product liability law are reviewed in an article by *William J. Condon,* an attorney for Swift & Co. His discussion, beginning on page 228, is concluded with a list of product liability cases for 1964.

**Latin-American Food Code.**—In August of 1964 the Latin-American Food Code Council published the *Second Edition of the Latin-American Food Code.* A brief summary of changes and improvements in this new edition starts on page 238. An English translation of the topics in the index is included.

Vol 20, No. 4 April, 1965

Food·Drug·Cosmetic Law
Journal

# Do FDA's Present Food Standards and Standard Making Policy Best Serve the Consumer?

Comments by MALCOLM R. STEPHENS, Panelist

"Do FDA's Present Food Standards and Standard Making Policy Best Serve the Consumer?" Was the Subject of the Afternoon Panel Discussion at the Symposium on The Legal Basis and Regulatory Use of Food Standards, in Washington, D. C. Papers Delivered at the Morning Session Were Contained in the March Issue. Mr. Stephens Is Assistant Commissioner for Regulations, FDA.

The necessity for standards of identity for food products is an economic one. Satisfactory enforcement of the food provisions of the existing law or of this bill cannot occur unless legal food standards are established. To the consumer and to the enforcing agency it is immaterial whether these standards are provided through legislative or through executive channels. There is a definite preference by food producers for the latter method because of its greater flexibility and the readiness with which new conditions and new developments could be met and dealt with. Food manufacturers are not objecting to the provisions of the bill which authorize, by regulation, the formulation and promulgation of standards of identity for food products. Their support of this provision is the outgrowth of an extended experience with advisory, and therefore unenforceable, standards only. To both the consumer and the trade, few food provisions transcend in importance those providing for standards of identity. . . . .

If it is impossible—and that cannot be gainsaid—for the Congress to address itself to the enactment of measures which would set up standards for food products with that particularity, precision, and detail required in the determination of standards of identity for the various items of food, what more equitable or proper formula for the determination of such standards could be devised than that set forth in this measure?[1]

[1] Statement of W. G. Campbell, Chief of the Food and Drug Administration, Department of Agriculture, analyzing the provisions of Amended Bill S. 5, Pages 1231—1232, "Federal Food, Drug, and Cosmetic Act—A Statement of Its Legislative Record," Charles Wesley Dunn.

THIS WAS THE CASE made nearly 30 years ago for authority to promulgate food standards through the administrative process. The principles enunciated by Mr. Campbell in that statement have, over this quarter of a century of trial been proved to be sound. These principles are as sound in practice today as they were then as a philosophy.

Based on the best information we can gather, these convictions are shared by the great majority of consumers and food manufacturers.

Since the standard making authority was given to the Food and Drug Administration (FDA), food standards have been promulgated for an impressive list of food commodities that play a major role in the daily diet of the American consumer. To name a few and in no sense of attempting to rate their importance, but as a reminder to you of their dietary role, I mention standards for such staple articles as canned fruits, vegetables, fishery products, cheeses and a number of other dairy products, olemargarine, cereal products, fruit preserves and jellies and egg products. We find no evidence that consumers would wish to dispense with them. We are told by thoughtful leadership in the regulated industry that it would not wish to return to the days when their chances of surviving the vicissitudes of unscrupulous competition in the food industry were as good but no better than the odds of our winning court cases based on advisory standards.

This is not to say, however, that existing standards cannot be improved upon or that present policies cannot be shifted to give better implementation to the objective of the law to promote honesty and fair dealing in the interest of the consumer.

## Goals for Improved Standards

The two primary drives in the standards area today are that of the consumer for more informative labeling on the standardized article and that of the food manufacturer for more freedom in his choice of optional ingredients—freedom from the so-called "recipe making" approach and its alleged stifling effects on progress in the food industry.

Are the respective goals of these groups incompatible? We think not; on the contrary we think that they may be mutually dependent upon each other.

The inherent and legal right of the consumer to know the composition of the food he eats applies just as much to a standardized food

as to a proprietary food. Also, the need to know is very real with the individual confronted with allergy problems. Whether from this standpoint or on the basis of his right to know, we are receiving more and more expressions from consumers that they believe a standard will promote honesty and fair dealing only if *all* the optional ingredients are declared on the label. In fact some feel strongly that the philosophy of the law that the composition of standardized foods is known and understood by virtue of the promulgation process is most unrealistic and that the labeling exemption in the law for standardized foods should be stricken. While we are not certain it is desirable to go that far, the consumer's opinions must be carefully considered. To those who would ignore the consumer's views, we believe some good advice is contained in the words of Thomas Jefferson, "If we think them not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them but to inform their discretion by education."

Today's consumer is the first to acknowledge a pressing need for dynamic programs designed to bring to him an understanding of our food supply. If one wishes to dramatize this need he has only to recall the use of such expressions as "time honored standards employed by the housewife," "the well-established standard of the home," and "common law standards" in the legislative history of section 401 and then take note of the myriad of complex, functional chemicals, perhaps never heard of, certainly not understood, by most consumers, that have been added to standardized foods in recent times. This is the setting in which today's consumer is saying, "Irrespective of the state of my knowledge of foods, I wish to at least know of their presence in the food supply and to be able to elect a choice of whether or not I purchase foods containing them."

The FDA is doing a great deal to satisfy this educational need with its stepped up consumer education programs. We think much more could be done by industry to help the consumer solve his dilemma, undoubtedly with resultant benefits to the responsible element of the industry. As you fully appreciate, nutritional quackery flowers and flourishes on the consumer's lack of understanding of his food supply.

Those of you who follow the standard making process have seen that in response to the consumers' wishes we have moved from a

policy of requiring declaration only of the characterizing optional ingredients to one of requiring the declaration of more and more of the optional ingredients and at the same time shifting the long-standing requirement that any optional ingredient required to be declared shall be shown directly associated with the name, to permitting non-characterizing ingredients that are now being required to be declared to be placed on the main panel or panels in a prominent and conspicuous fashion.

Now, as to the freeing of the standard making process from the "recipe making" approach with which we are charged. In a recent paper presented at the meeting of the Institute of Food Technologists we noted we did not know how much weight to give to the charge and its alleged impact on the food industry and we still do not. We do know that as long as twenty years ago it was urged upon an Appeals Court that if the Court upheld the FDA position in excluding unauthorized ingredients from food standards this would prevent the development of new foods and "lay a dead hand on progress."[2]

When one takes into account the dramatic evolution and growth in the food industry during the last twenty years we think there is an ample basis to question the soundness of that prediction and perhaps cause us to continue to wonder whether today's predictions are based more on fancy than fact.

We do think, however, it is sound as we move in the direction of meeting the consumer demands for more and more ingredient declarations that we should be able to provide in standards more freedom of choice for the use of optional ingredients so long as the consumers who purchase such foods under their standardized name can have assurance that they will get what they may reasonably expect to receive when purchasing them. Any freedom of choice beyond this point would make the whole standard making process a futility. The problem in a nutshell is whether it is in the public interest to give the manufacturer additional flexibility on optional ingredients, while holding him to more rigid labeling requirements and all the while surround the process with sufficient safeguards to maintain the identity of the standardized article. We think so.

**[The End]**

---

[2] *Libby, McNeill and Libby v. United States* (148 F. 2d 71).

## Comments by O. L. KLINE

Dr. Kline Is Assistant Commissioner for Science Resources, Food and Drug Administration.

IN THE DEVELOPMENT of a food standard, under the Food, Drug and Cosmetic Act, a number of scientific aspects must be taken into account. This audience does not need to be reminded of the state of food technology in 1938 at the time of the passage of the present act. The development of technological use of chemical compounds in the processing of foods as we know it today was in its beginnings. The number of optional ingredients discussed and proposed in the hearing on flour in 1940 was relatively small. We had just begun to consider the problems of addition of individual vitamins and minerals to foods. It was in the standard for flour that the pattern for vitamin and mineral enrichment was formulated. Today, with important advances in the science of food technology, and the great increase in the number and variety of foods, each processed for the greater convenience of the purchaser, we must deal with emerging problems on a sound scientific basis.

### Science and Food Standards

Scientists and scientific information have from the beginning of formulation of food standards, had an active part in the overall considerations. The administrative decisions as to whether a proposed provision or component, either required or optional, meets the test of "promoting honesty and fair dealing in the interest of the consumer," must take into consideration the scientific facts that are pertinent.

In evaluating any proposal for a food standard, an important consideration is the safety of the components and constituents proposed, particularly those that are chemical compounds, or chemically processed food constituents. For those substances that are not classed as "generally recognized as safe," and are food additives, then the food additive section of the law applies. The pattern for establishing safety for food additives is well known to most of you. Upon receipt and evaluation of sufficient data to demonstrate safety, a regulation is published describing the safe use for which the food additive is proposed. It has been customary to develop with our pharmacologists and food chemists, the protocols for animal and other laboratory experiments designed to demonstrate safety. You are familiar, of course, with the kinds of experimentation required in the study of such

substances as the emulsifiers. Long-term animal tests demonstrated the possible chronic toxicity of these substances. On the basis of such tests, we could decide upon the levels of these substances that are without hazard when they are used as food components. Just recently, consideration was given to the question of safety of the addition of calcium salts to canned potato. Calcium salts are added for the purpose of producing a firmness of the potato. It was important to make certain that with a reasonable intake of the food, the amount of calcium salts consumed would not exceed a reasonable proportion of the normal daily intake of calcium. The proposed use was such that the probable intake would fall well within an acceptable range.

A second consideration which the scientist must give to the review of the acceptability of components of a food standard is that of determining whether or not the constituent will accomplish the desired purpose. A food constituent which provides energy and nutrients, of course, to the extent that it does so, accomplishes the desired purpose. Those ingredients that are added for a technological purpose, are useful only if they perform the desired function. Here the scientist reviews not only the likelihood of the accomplishment, but also the amounts that may be needed for the purpose described. It has not been uncommon that from a scientific standpoint, we have recommended reduction in the permitted level of the constituent requested upon learning that amounts less than that requested will adequately perform the desired purpose. It is within the authority derived from the food additive section of the law for us to limit in the published regulation, the amount of an additive permitted. In the food standard area, we have another example where the use of calcium salts for producing firmness in the canned potato clearly required only one-half the amount requested. Here, in the interest of promoting honesty and fair dealing to the consumer, we have limited the amount to be used.

A third consideration is the selection of appropriate methods for determining the presence or absence of the components included in the composition of the food being standardized. This may be of particular importance in dealing with optional ingredients which are added on the volition of the manufacturer. Suitable methodology is essential to a sound and effective regulatory program which will insure to the consumer the product offered by the labeling. Good methods are also an important protection of the best interests of the manufacturer himself. We are frequently called upon to test proposed

methods for their adequacy, sensitivity, and specificity. It is in the subject of methodology that we have developed a particular expertise in our research program.

## Nutritional Values in Standardized Foods

A further concern with which our scientists must deal is the whole question relating to the nutritional value of the food being standardized. In such an evaluation, we must look at each of the constituents to determine what effect one or another might have upon the stability of the nutrient value of the food during processing, storage, or distribution. For example, copper salts are known to be destructive to ascorbic acid. Bisulfite readily causes the decomposition of thiamine. We look further at the composition of the food from the standpoint of its digestion, absorption, and utilization for nutrient purposes. Sequestering agents, if present in the diet in excessive amounts, may reduce important metal ions essential in nutrition. In promoting honesty and fair dealing in the interest of consumers, we are mindful that it may be misleading to the purchaser to call attention to the inclusion of nutrients that would have no significant effect either upon the nutritional value of the food itself, or upon the nutritional state of the consumer. For example, from studies made by our own scientific staff and from opinions developed from authorities in the nutritional scientific community, we are convinced that the diet consumed in this country is more than adequate in its protein content and protein quality. Even though the addition of specific amino acids might improve the protein quality of the single food to be standardized, there has been no basis for concluding that this improvement of the single food would be of value to the consumer when it is a part of the ordinary diet used in this country. Under these conditions, to include amino acids in a standardized food would imply and suggest nutritional superiority which we believe clearly misleads the purchaser who is unable to evaluate for himself these nutritional relationships.

## Measurement of Subjective Factors

If one observes the list of standards that have been promulgated under the authority of section 401, it becomes apparent that a great many more standards of identity have been established than have standards of quality or standards of fill of container. This is due in no small degree to a lack of adequate scientific methods for measuring factors of quality and for determining when a proper fill of con-

tainer has been achieved. Many of the characteristics that contribute quality to a food are essentially subjective in nature, such as flavor, texture, and eye appeal. A very modest beginning was made many years ago in attempting to measure some of these factors. Examples are the alcohol insoluble solids test in canned peas for measuring mealiness, the measurement of color in canned tomatoes in terms of Munsell color values, and hardness in canned peaches with a penetration pressure test. A great deal remains to be done to develop methods that will measure and report in objective, reproducible values the characteristics that the tongue and the eye evaluate as desirable or undesirable quality. The prospects for developing such methods seem much brighter today than they did a few years ago. Recent advances in gas chromatography, paper and thin layer chromatography, infrared spectroscopy, and many other new techniques now offer the promise that soon the tools will be available to identify and measure quality in the many diverse foods for which quality standards would be appropriate with the degree of objectivity and reliability necessary to implement the statute.

An analogous situation exists for standards of fill of container. It is of course relatively easy to measure the extent to which a can, a bottle, or a box is filled with food, but such a measurement is not enough if the product consists in part of the principal food and in part of a necessary but less valuable packing medium. This of course is the case with most of our canned foods. The problem is further complicated by the fact that usually the principal component changes shape, volume, and texture during heat processing. Better scientific methodology is needed to establish a correlation between the fill of the container after processing and shipment with the degree of fill that actually existed at the time the can was packed and sealed.

Many dry foods packed in cartons and boxes shake down and contract in total volume during the handling that accompanies shipment and distribution. This frequently results in packages that appear to have been poorly filled, but which really were not. More scientific information is needed here, both to enable the manufacturer to pack in such a way as to minimize such shrinkage and to enable FDA to evaluate such shrinkage and make due, but not unnecessary, allowances for it in prescribing and enforcing standards of fill.

Another aspect of fill that needs scientific study on our part is the extent to which liners, dividers, and buffers are needed in packaging such products as candy, nuts, and similar foods. In many products now on the market such non-food materials occupy a very substantial

portion of the volume of the container. They are usually justified by the manufacturer on the grounds that they are necessary to prevent undue breakage or abrasion of the products. Some scientific study, possibly of a more or less empirical nature, appears to be needed here.

Certainly one may predict that as scientific research develops more complicated technology in formulating, processing and packaging foods, correspondingly greater scientific study must go into developing necessary standards for them. I believe it is clear that we are making important progress in the use of scientific and technological developments in the promulgation of food standards. Continued cooperation with industry scientists and full use of the scientific accomplishments that improve food processing and distribution are essential to a successful program. **[The End]**

## Comments by H. THOMAS AUSTERN, Panelist

**Mr. Austern, of the Washington, D. C. Law Firm of Covington & Burling, Is a Member of the Lawyers Advisory Committee, The Food Law Institute.**

IN THE FULL SPECTRUM of total Food and Drug Administration (FDA) activity, food standards have been somewhat of an Orphan Annie. The waif has been neglected in favor of new drugs, pesticides, food additives, color additives, and hazardous substances—as well as for an abiding absorption with Congressional hearings.[1]

That is not criticism, but realism.

Niggardly budgets have limited the FDA staff. Those new laws each had time limits. To implement them taxed both the FDA staff and the size of the *Federal Register*. And economic regulation—food standards, as Mr. Stephens has said, being economic—always must, and should, yield priority to health protection.

Since early 1963, however, Orphan Annie has been doing better. With more money, there has been more staff and prompter action. Petitions get published before they get old and cold. The back-log is being cleared up. Hearings are being held.[2] They are mercifully shorter, and the issues are often sharpened. Even more, there is an

[1] See Austern, "Drug Regulation and the Public Health," 19 FOOD DRUG COSMETIC LAW JOURNAL 259, 269-271 (May, 1964).

[2] Hearings were held during 1964 on the listing of guar gum as an optional ingredient in Cold-Pack Cheese Food, 29 *Federal Register* 297 (January 11, 1964), and on various aspects of the Standard of Identity for Breaded Shrimp, 28 *Federal Register* 13940 (December 21,

*(Continued on next page.)*

administrative receptivity to new ideas, and a frank re-examination of some encrusted old ones.[3]

Many think a new wind is rising to give fresh momentum to the food standards boat. Into that new wind, I would like briefly today to launch some five small kites. They may never get off the ground. They may get quickly shot down. Or they may be too insubstantial to stay aloft.

## Suggestions for Further Improvements

*First,* let us stop arguing, at least for awhile, about whether and how to amend section 401 of the Act. There is, I suggest, enough scope in the present Act to avoid inflexibility, and to answer those polemics that standards stymie technological development, or shackle a standardized food against improvement, or confine it in an administrative straitjacket.

The "welcome mat" is now out for amendments. If the Hale Amendment[4] is effectively used, and there is adequate staffing, these amendments can be both promptly published and made effective. Experimental marketing by temporary permit is also available to test consumer acceptance of new ingredients.[5]

None of us likes the permit system to be used to exact labeling changes—unrelated to the new experimental ingredient—that FDA does not otherwise enforce. To convert the permit into a label preclearance requirement, on points not concerned with the new ingredient, is an undesirable clog.

By the same token, to require a showing that the consumer has a nutritional need for a new optional ingredient, rather than to permit her to have the option to get it if she desires, converts standardization into dietary licensing. It opens the door to critics of the entire process. It was thought that that quaint heresy had been largely dissipated.

---

*(Footnote 2 continued.)*
1963). Findings of Fact and Proposed Orders have been published within a reasonably short period of time. 29 *Federal Register* 13973, 18175 (October 9 and December 22, 1964).

[3] See Stephens, "Food Standards and the FDA" *(FDA mimeo.* May 26, 1964).

[4] See Act, Secs. 401 and 701(e), as amended by 68 Stat. 54 (April 15, 1954), and 70 Stat. 919 (August 1, 1956), FOOD DRUG COSMETIC LAW REPORTS ¶ 51,051 and ¶ 2617.

[5] See 21 C. F. R. Sec. 10.5, FOOD DRUG COSMETIC LAW REPORTS ¶ 51,305.

Paramountly, everything that could be accomplished by tinkering with section 401 can be administratively achieved. The so-called "breaded shrimp" concept offers a splendid way to do so.[6]

It may not work for all products. Perhaps the line can be drawn between basic foods, like eggs, canned pears, or orange juice, and what are essentially fabricated foods.

As to fabricated foods, the present law permits wide administrative latitude in applying that "breaded shrimp" concept. Never forget that two standardized foods can be combined, under proper labeling, without amending either standard.[7] If you want to pack canned peaches and chocolate together, I know of nothing to stop you.

The real point perhaps is that food standards do not have to standardize everything in the product. You can fix the quantity of cherries in cherry pie without standardizing the crust ingredients. You can provide a home for the pie that is deficient in cherries by a quality standard without first tying up all of the pie ingredients in an identity standard.

You can standardize the required level of peanuts in peanut butter, and still leave a manufacturer free to see if the consumer might like mustard or even pickle added to it.[8]

Doing so, of course, leans heavily on labeling, and does not equate physical similitude with "purports to be."[9] This approach is not new or radical, and is indeed reflected in present standards—as shown by separate standards for light cream and heavy cream, or bread and enriched bread. The time has come for standard makers to be fully aware that we have a literate population who can read.

Even more important, you can do all of that kind of standard-making under the present law.

The recent arguments about imitation foods, in my view, are not tied up with section 401. That controversy about the applicability

[6] As originally proposed, the "Definitions and Standards of Identity for Frozen Raw Breaded and Lightly Breaded Shrimp" contained a list of the specific breading ingredients that would be permitted. 26 *Federal Register* 2722 (March 31, 1961). As finally promulgated, however, it permits any "suitable" substances to be used as a breading ingredient as long as it meets the requirements of the Food Additives Amendment to the Act. 28 *Federal Register* 4556 (May 7, 1963); 29 *Federal Register* 18175 (December 22, 1964).

[7] See 21 C. F. R. Sec. 1.10(a), Food Drug Cosmetic Law Reports ¶ 3310.

[8] Compare the recently proposed "Definitions and Standard of Identity for Peanut Butter," 29 *Federal Register* 15173 (November 10, 1964).

[9] Act, Sec. 403(g), Food Drug Cosmetic Law Reports ¶ 51,071.

of the imitation label to new products may or may not be vastly exaggerated, but with the developing administrative flexibility on food standards it can gather no support in this area.

As a final tail on this first kite, I suggest that standard making for all food products is neither ordained nor required. The need for a standard must still be demonstrated. If that need is challenged, it must be proved by solid facts of record.

*Second,* I agree that periodic updating of standards would be highly desirable. Updating, however, should not be prescribed by formal and rigid statutory time limits. An egg will long remain an egg. Here, again, flexibility must be maintained, and what is needed can best be met by money and staff in the FDA.

Where updating is most needed is where, unhappily, the standard is constructed not as an objective measurement of the finished product, but as a manufacturing direction. A standard describing a food in terms of how-it-is-made, rapidly gets out of date. That leads to my next ball of string.

*Third,* manufacturing standards ought to be avoided.

Obviously, imports cannot be inspected where the regulation talks about how the product is made, and not about what it is. And where you can make the identical food product in different ways, the consumer interest is not really served by label differentiation that has no relation to her eating, taste, or preference.

I have become increasingly convinced that a standard expressed in terms of "how-to-make-it" usually conceals a lack of any reasonable method to enforce it.

*Fourth,* food standards would be vastly improved by the incorporation of up-to-date statistical techniques in their formulation and enforcement. These widely used and modern statistical methods are useful in many important ways.

Without dilating on who and what is the statutory personification of the consumer, I am satisfied that the best way of learning about her or him is by a soundly designed statistical sample survey, free of bias, and properly executed.

Next, where data are available, a correct statistical analysis of overall industry practices affords a better basis for the definition

of a food. The law, it must be remembered, requires that a standard be a definition of identity and not wholly a new concept.[10]

For fill of container standards, experience also suggests that sound statistical techniques are well nigh essential. More important, the use of statistical sequential sampling will yield both reasonable standards and better enforcement methods.

*Fifth,* and finally, standards that cannot be enforced are legal ghosts. Even worse, as Mr. Stephens pointed out last May, they "do little for the consumer and make the honest firm the helpless and easy prey of the unscrupulous."[11]

Let us admit it. There are standards on the books that specify required percentages of ingredients, where the methods prescribed do not permit enforcement within 20% of the required minima. There are fill standards that are purely precatory—prayerful directives to do the best one can.

In other areas, analytical methods have now become refined and are sensitive enough to permit measurements to parts per billion. New techniques, employing radioactive detection or gas chromatography, are more and more available. These should be applied to food standards.

It is perhaps on enforcement that the strings to my five kites get tangled together. If future standards are administratively limited to basic ingredients, and do not try to encompass every minor optional ingredient, they will be more readily enforceable. If present standards are up-dated to include the newer testing techniques, they will be truly enforceable. If manufacturing or how-to-make-it formulations are avoided, standards will be enforceable even on imported products. If moderen statistical techniques are deployed for standard formulation and for sampling, enforcement will be both reasonable and more effective.

What I have suggested may be too hopeful—perhaps even Utopian. Yet I believe that initiative and cooperation by the regulated industries, an ever open-minded administrative attitude, enough budget, and much hard work, will yield those desirable objectives.

Whether they will, as the question posed for this panel asks, be the "best" I do not know. I am confident they will be better.

**[The End]**

---

[10] See Austern, "The Formulation of Mandatory Food Standards," 2 FOOD DRUG COSMETIC LAW JOURNAL 532, 552-553 (1947).

[11] Stephens, "Food Standards and the FDA" (*FDA mimeo.* May 26, 1964).

## Comments by PAUL E. RAMSTAD, Panelist

**Dr. Ramstad Is Director, Grocery Products Quality Controls, General Mills, Inc., and a Member of the Food and Nutrition Board, National Academy of Sciences.**

SECTION 401 OF THE FOOD, DRUG AND COSMETIC ACT OF 1938 authorizes Food and Drug Administration (FDA) promulgation of standards whenever, in the judgment of the Secretary, these will "promote honesty and fair dealing in the interest of consumers."

While the intent of standards is that of serving consumer interests, it is also clearly evident that standards may serve useful purposes both for the FDA and the food industry. Standards can simplify a regulatory agency's task by defining what is proper and automatically making everything else unacceptable. Standards can also serve to regulate the nature of competition within the industry.

Certainly the term, "interest of consumers," is one that may be defined in various ways. In my own definition, it would include the right of consumers to select from a variety of foods to meet different food preferences and nutritional needs, and it would also include the consumers' right to receive the benefits of technological progress in food processing as they do in other areas of modern living such as transportation, housing, textiles, etc.

The 1938 Act made it possible to eliminate, at least partially, any ingredients from food whose safety was not clearly established, and it simplified the regulatory function, since anything which did not conform to an established standard automatically became a clear-cut violation.

### Standard Making—Its Effects on Research

After some of the standards which were promulgated under this authority had been in existence for a time, concern arose among food scientists that standard making might have the unfortunate effect of inhibiting research that might be directed toward product improvement simply because changing a standard might prove to be impossible or, at best, time-consuming and expensive.

As a result of this widespread feeling and concern on the part of the scientific community interested in foods, the Food and Nutrition Board of the National Research Council appointed in 1951 a Com-

mittee on Definitions and Standards of Identity of Foods to study the problem. The committee membership was made up of individuals from government, universities, and industry. In addition, other individuals from these areas accepted the committee's invitation to present their viewpoints and to offer constructive suggestions.

After study of the matter, the committee concluded that there was a valid basis for the claim that definitions and standards of identity of foods had the effect of discouraging research effort on standardized products; instead, industry preferred to direct research expenditures into non-standardized products. It seemed to the committee that the standards served a necessary and desirable purpose but that better standards would result if there were more pre-hearings, and informal communication between industry and FDA, if the standard amending process could be made easier, and if means for establishing safety could be accomplished outside the standard making process.

In 1953, the Food and Nutrition Board adopted the recommendation of the committee that the board, for the purpose of expediting food standards hearings, go on record as favoring:

(a) the exclusion from food standards hearings of matters relating to the determination of safety of new, intentional chemical additives for use in foods, provided, however, that other adequate procedure is first established for the testing and prior approval of such ingredients;

(b) provision for the issuance or amendment of food standards without hearings in cases in which no protest arises following due public announcement of such proposals.

Today, both of these recommendations have been implemented through the Hale Amendment of 1954, the Food Additives Amendment of 1958, and the Color Additives Amendment of 1960. Furthermore, in the past decade there has been a vast increase in food research and development activities. As a result, the variety of foods available to consumers is greater than before, and more foods receive more processing before reaching the consumer. However, the standard making process has not kept pace with the new developments in the food industry.

There may be more justification for standard definitions of the basic commodities which are ingredients of other foods than to attempt standardization of products which are complex mixtures, some of which may appeal to the majority of consumers but most of which may serve only a limited minority.

## Need for Periodic Review of Standards

When a food standard is found to be serving either the purpose of, one, providing economic protection to a segment of industry or, two, providing a guaranteed nutritive contribution to the diet, there is the likelihood that either the need for or the accomplishment of these objectives may change with time. Recognizing this, such standards should be reviewed periodically to ascertain whether they should be revised or eliminated.

Standards are, after all, a form of specification. Many kinds of specifications can be and, indeed, are written. A single product may be described with several types of specifications, each serving a different and specific purpose.

A manufacturer needs to use specifications for processing to guide him in making consistently a product with the same ingredients, formula, and processing conditions.

On the other hand, a buyer needs a specification to describe what he desires and against which to check the acceptability of the product which is offered to him. A processing specification is not designed to be a purchasing guide. A purchasing specification should define and demand performance in terms of intended use.

In the food industry, both processing and purchasing specifications are used, and, unfortunately, sometimes they are confused. Writing good specifications is more demanding and difficult than most people realize. Note: I said *good,* not *tough* or *tight* specifications. The latter are easy to devise. There are those who have the impression that a specification that is hard to meet or can only be met at high cost provides assurance of getting that which one needs. This is not always true.

In industry, the real advantage of using performance specifications for purchasing purposes is in order to gain the benefit of process improvement which can be beneficial to manufacturer and buyer, alike.

I believe FDA standards will best serve the consumer interest if they are "buying" rather than "processing" oriented. Good standards should describe the minimum quality and performance the consumer has a right to expect. They should describe details of processing only to the extent that public health considerations may require this. They do not need to provide rigid recipes with every detail of ingredients and proportions included.

A review of present FDA definitions and standards of identity for foods will show that they vary in the amount of processing detail which is included and in the latitude of choice permitted a manufacturer. Examples of such differences have already been cited by other speakers.

Perhaps with the background of long experience now possessed by both FDA and industry and with the protection afforded by amendments to the 1938 Act, old standards can be revised and new ones promulgated in a manner which will make them more consistent in philosophy and detail and, in so doing, better serve the consumers' interest. **[The End]**

## SECOND INTERNATIONAL CONGRESS OF FOOD SCIENCE AND TECHNOLOGY TO BE HELD

The Second International Congress of Food Science and Technology will be held in Warsaw, Poland, August 22—27, 1966. Topics to be discussed at the plenary sessions include plans for the formation of an international union of national scientific and technical societies or bodies which deal with food science and technology, and programs of action for such a union. Discussions will also cover other topics of international interest i.e. "New Protein Sources and Their Utilization;" "Chemical and Biochemical Changes in Food;" "Modern Technological Aspects of Food Processing, Manufacture and Preservation;" "Advances in Food Engineering;" "Technical Problems of Producing Wholesome Foods;" "Assessment of Food Quality;" "Modern Trends in the Academic Training of Food Scientists and Technologists;" "Economic, Nutritional and Sociological Aspects of Food Processing, Manufacture and Consumption."

Special invited papers as well as selected, freely contributed research papers will be presented at the plenary sessions.

Titles and abstracts for freely contributed research papers must be in the hands of the Secretariat on or before November 1, 1965. Anyone interested should submit papers before this deadline to: Executive Committee Secretariat; Hon. Secretary: A. Borys, M.Sc.; Instytut Przemyslu Miesnego; Warszawa 12, UL. Rakowiecka 36, Poland. Freely contributed papers must deal only with previously unpublished material.

The official languages of the Congress will be English, French, German, and Russian.

# Decision Making in the Food and Drug Administration

By GEORGE P. LARRICK

Commissioner Larrick of the Food and Drug Administration Presented This Paper for the Charles Wesley Dunn Food and Drug Lecture, Harvard University in Cambridge, Massachusetts, on February 2, 1965.

BEFORE DISCUSSING DECISION MAKING which is the subject assigned to me, it seems advisable to present a brief picture of the job of the Food and Drug Administration (FDA).

We are charged with the administration of five federal laws, most important of which is the Food, Drug and Cosmetic Act of 1938 which has been amended a number of times. The others are the Hazardous Substances Labeling Act, the Filled Milk Act, the Import Milk Act, and the Tea Act.

I will discuss principally our work under the first of these acts.

The Federal Hazardous Substances Labeling Act of 1960 provides for precautionary and warning labels for hazardous substances which may be used in and about the household.

The Filled Milk Act prohibits interstate and foreign commerce in products made in imitation or semblance of milk or cream, if they include any dairy product plus a fat other than milk fat.

The Import Milk Act provides that milk or cream may not be imported into the United States until we have issued a permit to the shipper.

The Tea Act calls for the examination of every importation of tea on a fee basis to determine whether it complies with certain specifications required by the statute.

The authority for administration of these statutes is vested in the Secretary of Health, Education, and Welfare. With one exception, he is authorized to and has delegated this authority to the Commissioner of Food and Drugs.

## Responsibilities of FDA

Thus, coming to the most important of the laws we enforce, the Federal Food, Drug and Cosmetic Act, we have responsibility for the preclearance of or licensing of new drugs and antibiotics, pesticide residues in or on foods, food additives in processed foods, including materials used for packaging, the establishment of a variety of regulations and food standards, and, of course, compliance.

Our activities in these areas call for three important foundations. These are adequate legislation; adequate appropriations, including equipment and facilities to enable us to do the job; and third, and in my opinion of paramount importance, an adequate staff of competent personnel. We must have personnel of the caliber and competence, with experience and knowledge of the various scientific and other disciplines, that are essential to competent decision making in the important areas covered by the statutes. This we do have!

One of my earliest introductions into the decision-making process in this field came over thirty years ago when, as a junior member of the FDA staff, I was privileged to participate in many conferences attended by Dr. Rexford G. Tugwell, then Assistant Secretary of Agriculture; Professor Dave Cavers; former Commissioner Walter G. Campbell; and others. At that time decisions were being made as to what should be included in a new Food, Drug and Cosmetic Act to update the obsolete law of 1906.

Equally important were decisions as to how these proposed changes in the law should be sold to the political administration in office, and, of course, to the Congress.

This decision making progressed constructively and intensively between 1933 and 1938. It resulted in the enactment of the Federal Food, Drug and Cosmetic Act which is the foundation of the federal law under which we operate today.

Decisions under the 1906 Act largely revolved around the question of whether a particular lot of food or drugs should be subjected to federal seizure and whether firms or individuals should be prosecuted under the criminal sections of that law.

Beginning in 1938, the administrative approach began to undergo a long-range change. Preventive enforcement began to find its place along with punitive enforcement. This was due in large measure to three factors. One was the preclearance or licensing approach pioneered by the new-drug provisions of the 1938 law. The

second was the response of the industries involved who expressed their genuine interest in finding out what would be required to comply. And third, there was the increased penalty for violation.

Since that time we have increasingly sought to foster voluntary compliance. We now have a separate bureau whose functions are directed to this end.

The new-drug approval provision of the Federal Food, Drug and Cosmetic Act was inaugurated in 1938 following the notorious elixir of sulfanilamide incident. In that case, a manufacturer, having no obligation to come to FDA, marketed a fine drug, sulfanilamide, in a very poisonous solvent which resulted in the deaths of over 100 patients. That incident led to the requirement that all new drugs must be precleared for safety before they could be sold.

This was followed by a requirement for preclearance for both safety and efficacy of batches of five classes of antibiotics.

These requirements worked well. Some 15 years later in 1962, the Kefauver-Harris Drug Amendments extended the requirement for preclearance in the new-drug field to a showing of efficacy of the drug, and required batch certification of all antibiotics offered for human use.

Decision making in this area of whether to allow a new drug to be marketed has presented very knotty problems, and this will be readily understood when it is recognized that very few drugs are "safe" in the absolute sense of the word, because if they are to do the job they are supposed to do, they will almost invariably have side effects and there will be those who cannot tolerate the particular drug at all.

Thus, the decision making process in this area may be regarded as a three-step operation:

Step One: Determine the benefit to be derived from the drug;

Step Two: Determine the risk;

Step Three: Weigh the benefit against the risk and decide whether it is in the public interest to approve the drug for marketing or to withdraw approval if the product is already on the market.

## Checks on Drugs After Approval

It is perhaps surprising to some that we must keep close checks on drugs after we have gone through the very meticulous study of

their earlier testing, including not only animal studies but extensive clinical trials on humans. Experience has shown, however, that as a drug is marketed for use by thousands of physicians on millions of patients, some untoward results may show up which were not observed during the careful, but necessarily limited, clinical trials before the drug was marketed. Taking into account that these adverse effects may show up only in a few patients, we always have the statistical likelihood that they would not have been uncovered during the initial trials. Additionally, we must recognize that, like lawyers, physicians are not all of the same degree of competence.

While the initial clinical trials are necessarily conducted by physicians who are expected to have the most experience and training in this area, once the drug gets on the market it is available to physicians of varying skills and abilities for use in patients with a multitude of disease processes, many occurring concurrently, and in patients incorrectly diagnosed or inadequately tested by accepted laboratory procedures.

Thus, we have a situation that neither the doctor who has had the misfortune to encounter one of the serious reactions from a drug, nor the physician who has saved a hundred lives with that same drug without untoward incident, is in a position to make a comprehensive judgment.

The FDA makes these judgments by recruiting physicians, pharmacologists, chemists, bacteriologists, and other scientists skilled in making the individual decisions. and by giving them the training needed to make recommendations involving the broader picture of the relative merits of a drug for all of society.

It is possible to make these recommendations on a basis of evaluation of an accumulated body of data, with their recommendations subjected to administrative review which takes into account the applicability of existing law. Then, and only then, can the FDA arrive at an institutional decision.

We have regulations which require manufacturers to inform us of any adverse reactions which are reported to them after the drug is placed on the market, and additionally, we have arrangements with some 500 hospitals to report adverse reactions believed to have been caused by drugs. The American Medical Association (AMA) has similar arrangements with physicians generally. We share and monitor this material, and, on occasion, we have found that a drug

cleared by us is resulting in unforeseen difficulties as it is used in medical practice.

While we have thus found it necessary to remove drugs from the market after they received our approval, there are times when our decision is that the drug is so valuable that, when improved cautionary labeling and warnings are brought to the attention of all prescribing physicians, the drug should be kept on the market in spite of its dangers.

One such incident involved the very important antibiotic, chloramphenicol. It was found that this sometimes caused serious blood disorders which led to fatalities, and we received much urging that the drug be removed from the market. After consideration of all the data, we concluded, with the advice of an expert group selected by the National Research Council of the National Academy of Sciences, that the drug should not be removed from the market, but that its labeling should be sharply revised to make it plain that it does have real possibilities of harm, and should not be used for treatment of infections which respond to other, safer, anti-infective agents.

## Action to Suspend Approval

I mentioned earlier that there was one item of authority in the law which the Secretary may not delegate to the Commissioner. This involves the right to take summary action to suspend the approval of a new-drug application where an imminent hazard to the public health is involved in the distribution of the drug.

Even here, however, it is the responsibility of the FDA to acquire facts upon which to make a decision to recommend appropriate action to the Secretary.

## Rule Making

In each area involving new drugs, pesticides, food additives, and others where rule making is involved, before we reach the question of making decisions on individual cases, there must be rules as to what shall be submitted to be used as a base for making these decisions. FDA has issued regulations which outline to all concerned what is necessary in any submission.

This delineation of the kinds of information which should be submitted, such as data on toxicology, chemistry, nutrition, and microbiological effects of a proposed additive, is an attempt to help those

who wish authority to use substances covered by the statute. This is usually supplemented by discussions between industry scientists and FDA scientists as to the kinds of preliminary testing that should be undertaken with a specific substance.

There are many differences of opinion among scientists. We often attempt to resolve such differences by presenting the matter to a specially selected group of scientists, just as we did in the case of the chloramphenicol which I mentioned earlier. For example, two recent committees which we appointed were most helpful to us in handling problems involving an antipain drug that had been on the market for a great many years, and a new problem involving the possible hazard of a small quantity of penicillin which was a contaminant in other drugs manufactured in the same plants as the penicillin.

In individual cases it is encouraging that FDA and industry scientists can usually work out technical problems to a satisfactory conclusion. This has been possible because in each instance our people, in reviewing petitions, have been able to delineate not only what additional information is needed, but also a sound reason for calling for it. Also, in many cases our scientists have been helpful in outlining ways by which the needed data may be acquired.

A recent example of this involved a petition under the Food Additives Amendment for authorization to use certain petroleum waxes as packaging materials and as coatings for some fruits and vegetables. It is well known that some of the petroleum products are contaminated with polycyclic aromatics some of which have been shown to be carcinogenic. It is, therefore, essential that any wax which we authorize for use be free of such harmful impurities.

Out of a great many waxes available, the industry selected a limited number which were believed, on the basis of chemical composition, to be of a grade suitable for these uses, and then arranged for a very good study of these selected waxes at the University of Chicago. In addition to extensive chemical work, this involved lifetime animal feeding studies.

Our people kept in close touch with this work over a period of years. At its completion, we reviewed all the accumulated data submitted to us in a petition which demonstrated, to the satisfaction of our scientists, that certain waxes, free of hazardous contaminants, were otherwise acceptable for the uses proposed.

We would have gone ahead and issued a regulation, but one question remained, "How would we be able to test a wax, represented as one of the acceptable items, and be sure that it was an authorized wax?"

We do not issue regulations authorizing additives to our food supply unless we have an acceptable means of enforcement. This led to more months of intensive research, not only on the part of the industry scientists, but by FDA chemists as well, with the happy solution that finally tests were devised which could be applied to the waxes being marketed. These would detect the presence of any of the harmful materials which might be present even in most minute amounts. Then we went ahead and issued the regulation.

## Safeguards in the Law

We call attention to the safeguards in the law which provide ways by which those who disagree with us may appeal our decisions in one way or another. These involve various procedures, such as in the case of new drugs where those who disagree may call for a hearing on the issues, with appeal to the courts, if they are not satisfied with the outcome of the hearing. In the case of proposals to establish pesticide tolerances, or authorizations for the use of color additives, an aggrieved party may call for consideration of the issues by a committee of scientists from a panel nominated by the National Research Council of the National Academy of Sciences, with appeal to the courts, if the results are not acceptable. These procedures have been used from time to time.

We still have a long way to go in fully implementing the preclearance requirements of the Color Additive Amendments of 1960, because of the large amount of long-term toxicological tests on animals which has been required. Already, however, we are engaged in a legal action brought in the federal courts by the toilet goods industry, which takes sharp exception to a regulation reflecting a decision we made dealing with the scope of the preclearance requirement.

It is interesting that the Food Additives Amendment of 1958 does not provide for the aggrieved party to call for a National Academy of Sciences committee, but he may call for a public hearing with subsequent appeal to the courts. However, in the time that this law has been in effect during which we have issued over 300 regulations involving some 2,000 substances proposed for use as human food additives, animal food additives, authorization for packaging and equip-

ment items, and a few radiation treatments, no one whose application has been denied by the FDA has yet carried his objections to a public hearing.

## Legal Action Involving Violations

This brings us to another important decision-making activity of FDA, which involves questions of the inauguration of legal actions where significant violations are encountered. This is not a hit-or-miss operation but rather is a carefully planned program. Since we cannot give equal attention to all of the products subject to the laws we enforce, we program the work of our 18 field district laboratories to give attention to those categories which, in the opinion of our scientific and administrative experts, are of the most importance to the consumer from the standpoint of health, public decency, and pocketbook protection.

Sometimes it is an extensive task to acquire enough information to appraise the importance of a particular program. An example is how extensive should our sampling of raw fruits and vegetables be to check on nonpermitted or excessive amounts of pesticide residues? Until July 1962, we were able to analyze less than 7,000 shipments per year. We knew that this was inadequate, considering that there are about two and one-half million such shipments per year. Starting in 1962, we arbitrarily set as our goal 1% of these shipments, or 25,000 samples. But we are not sure that this is proper coverage, so now we are engaged in a comprehensive statistical study of the results of the past two years to see whether the percentage of violations justifies a change in the number and manner of selection of the samples.

We have just inaugurated a new approach through the appointment of a council of 18 distinguished individuals from outside of the federal government to advise us in the areas of planning and operational problems. While the group has had but one meeting—primarily to get a picture of FDA—we expect the members to be a very great help in overall planning.

In our programs we outline the kinds of violations which we believe are of sufficient magnitude to warrant legal actions, either by seizure of the offending goods, prosecution of those responsible for the violations, injunction to prevent further violations, or a combination of these three sanctions.

It is obviously impossible to anticipate all of the possibilities and kinds of violations which may be uncovered, so we maintain in

Washington a staff of experts to evaluate the results of our field investigations and examinations and to recommend decisions as to whether, considering all of the facts, a particular situation warrants legal action, and if so, which one, or combination of the three sanctions.

There is little difficulty in determining that a lot of rat-infested food or a shipment of a manufactured tomato product made from rotten tomatoes should be seized.

In administering those sections of the statute that deal with economic frauds or cheats, however, there are a great many judgmental factors which must be applied, such as a determination of the seriousness of the violation to the consumer and the likelihood that we can present convincing testimony should the case be contested.

There is a provision in the law which prohibits deceptive packaging. Initially, we brought a great many cases in this area resulting, we are glad to say, in general correction of the most serious practices complained of. After a while, however, as closer questions arose we began to get contests of our legal actions. After we had lost three cases in a row, we had to completely re-evaluate our regulatory approach in this area.

Perhaps even more difficult is the decision making on the question of whether a criminal action should be instituted. We do not subscribe to a philosophy that every violation of any magnitude should be followed by a criminal action. In fact, the statute makes it plain that there is no obligation to institute such action in the case of minor violations, where it is believed that a warning will suffice. Even in the case of some apparently major violations, we take into account all the circumstances under which the violation took place. In the interest of good administration, we will have cases where the violation is a major one and there would be no question in our minds about the evidence, but we do not institute criminal action because we are convinced that those responsible had done what we would regard as a reasonable job in endeavoring to comply with the statute. Also difficult in this area is the question of whom to bring the action against. In a great many cases the illegal shipments are made by corporations, and we must determine whether any individuals should be personally charged. As might be expected, our decisions in this area are frequently a matter of controversy, and perhaps are responsible for more contests of our legal actions than we would have if we

brought them solely against corporations. We believe, however, that our obligations are such that once we are convinced that an individual should be named as a defendant and we have what we believe to be the evidence to convict him, we should not forego prosecution of the individual merely to avoid a court contest.

I do not propose to give you many figures, but perhaps you will be interested in just a few details of legal actions during the past fiscal year. Under the Federal Food, Drug and Cosmetic Act and the Hazardous Substances Labeling Act combined, we instituted 1,288 seizures, 205 prosecutions, and 22 injunctions. During that period, there were 215 terminated prosecutions, with fines totaling $144,155. The highest fine was $7,000 in a case involving storage of food under filthy conditions. There were also 35 jail sentences, ranging from one hour to seven years.

## Limitations of the Law

In all of our decision-making activities, we take into account the limitations of the statute involved. The Food and Drug Division of the Office of the General Counsel, under the able direction of Mr. William W. Goodrich, makes itself available for consideration of any question of a legal nature which arises in our decision making in all areas of our responsibility.

The FDA does not believe that the existence of a law or the enforcement activities of FDA alone could result in the breadth and depth of consumer protection to which the people of this country are entitled. Rather, we are committed to the view that we must encourage and have voluntary compliance on the part of the great majority of the industries regulated by the statutes we enforce.

We seek to be of assistance to those who want to comply with the law and in this effort we are faced with very important decision-making responsibilities.

For example, as we see a trend heading towards what we believe to be a significant conflict with the terms of the law, we have tried to be helpful through the issuance of formal policy decisions published in the *Federal Register*. Some of the most difficult of these to deal with have involved matters where we believe industry trends are resulting in labeling which is false and misleading to the consumer. Here, of course, we are often in the area of opinion. We seek from our scientists the best advice we can get as to the merits, or lack of them, of the particular type of labeling claims involved, and

frequently, we get a scientific report showing that there is no unanimity of scientific view. We, therefore, have the responsibility to weigh the pros and cons, and where we conclude that the implications of the labeling used by some is not supported by the weight of the scientific evidence, even though there were those who feel there might be something to the claims being made, we issue a policy statement announcing our position.

As might be expected, we find that the decision making in the FDA results in lawsuits with those who disagree with our interpretation as applied to specific products. We have always welcomed the opportunity to get the opinions of not only the district courts, but the appellate courts and the Supreme Court as well. These court decisions are, in the main, what have guided us through the years.

The laws which we enforce are not perfect, and we have no hesitation in recommending, through appropriate channels, to the Congress that amendments be enacted where we believe this is in the public interest.

Currently, our legislative program does call for consideration of a number of improvements in the Food, Drug and Cosmetic Act, and we are hopeful these will be considered favorably by the Congress. We are, however, committed to a program of doing the best job of consumer protection we can with the law and facilities made available to us so that we can continue to have the cleanest, safest, and most reliable food, drug and cosmetic supply of any country of the world.

## Summary

In summary, then, the decision process in the FDA is based on a combination of science, administration, and law.

When possible, facts are assembled from all the involved scientific disciplines which lead to a demonstrable fact as an unassailable basis for the decision.

When, as usual, demonstrable scientific fact must be liberally supplemented by technical opinion, then we seek to assemble the most mature scientific judgments available. These are then subjected to scrutiny by the administrative and legal disciplines.

The institutional decision thus arrived at is then announced in the various ways to which I have referred. After this, the democratic process of court review is available to those aggrieved. **[The End]**

# Some Recent Developments in the Canadian Food and Drug Law

By C. A. MORRELL

The Author Presented This Paper at the Twentieth Annual Meeting of The Section on Food, Drug & Cosmetic Law of The New York State Bar Association. Dr. Morrell Is Director of the Food and Drug Directorate, Department of National Health and Welfare, Ottawa, Canada. Succeeding Papers in This Issue Were Presented at the Same Meeting.

THERE HAVE BEEN TWO RECENT AMENDMENTS to the regulations under the Food and Drugs Act of Canada which may be of particular interest to you. These are the new regulations concerning food additives and the addition of vitamins to foods. I will describe the most significant changes in general terms and discuss them briefly. A complete understanding of the new regulations would require a detailed study.

## Food Additives

The control of additives to foods is based on section 4 (a) of the Food and Drugs Act of Canada which says that "No person shall sell an article of food that has in or upon it any poisonous or harmful substance." This section also provided a basis for the regulations governing the tolerances for pesticide residues in or on foods and for those limiting the use of colors and preservatives in foods which have existed for a number of years.

The new food additive regulations were approved and adopted by means of an Order in Council by the Government of Canada on September 23, 1964. Until that time there had been no specific regulations governing intentional food additives with the exception of colors and preservatives. The use of food additives had been controlled indirectly in so far as standardized foods are concerned, because the standards for such foods listed all permissible ingredients in foods. Whenever the use of a food additive in a standardized food

was requested, the manufacturer was required to produce satisfactory evidence that its use in that particular food was neither harmful nor likely to result in deception of the purchaser or consumer. If such evidence was produced, the standard was amended by Order in Council to permit the use of the additive in a stated amount.

There was, however, no such obstacle to the addition of food additives to unstandardized foods. In such cases it was the responsibility of the Food and Drug Directorate of Canada to prove in court if necessary, that the use of the additive would result in the food being harmful or likely to deceive the consumer.

We believed that we would be in a better position to prevent the possibility of harmful effects if we had specific requirements in the Food and Drug Regulations that would, in effect, require manufacturers to produce in the future, evidence of safety and no deception before a food additive could be used in a food. The authority to make such regulations is given in section 24 (1) (b) (iii) and (iv) of the Food and Drugs Act of Canada which states, in part, that:

> The Governor in Council may make regulations for carrying the purposes and provisions of this act into effect, and in particular . . . may make regulations . . . respecting the sale or condition of sale of any food or the use of any substance as an ingredient in any food . . . to prevent the consumer or purchaser thereof from being deceived or misled as to its quantity, character, value, composition, merit or safety or to prevent injury to the health of the consumer.

Drafts of the proposed regulations were discussed with industry over a period of three years during which time a great amount of data on which to base decisions as to the acceptability of each compound was accumulated. The new regulations, including a list of acceptable compounds, are now in force.

These regulations define a food additive as follows:

B.01.001

(d) "food additive" means any substance, including any source of radiation, the use of which results, or may reasonably be expected to result in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include:

(i) any nutritive material that is used, recognized, or commonly sold as an article or ingredient of food,

(ii) vitamins, mineral nutrients and amino acids,

(iii) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives,

(iv) pesticides,

(v) food packaging materials and components thereof, and

(vi) drugs recommended for administration to animals that may be consumed as food.

In subparagraph (i) nutritive material recognized or commonly sold as an article of food is excluded as a food additive, for example, sugar, starch, salt, etc. Vitamins are dealt with elsewhere. Spices are not likely to harm the normal consumer in the amounts used but if subsequent information shows otherwise it will be possible to handle them by specifically prohibiting their use in foods as is now done for coumarin and safrole. The carry-over of residues of veterinary drugs in animals for foods is now controlled by requiring manufacturers to demonstrate that no residues remain in the meat (or eggs) when used as food.

Along with the regulation which prescribes the names and permissible uses of food additives (section B.16.100) there were a number of consequent amendments. Two of these prescribe what may be used as food additives in standardized and unstandardized foods (B.01.042 and B.01.043) by referring to those additives and the amounts given in the tables to section B.16.100 as the only ones that may be used.

Standardized foods are now specifically designated as such. The tables listing permissible food additives specify the purpose for which a food additive is used and in the case of a standardized food, the names of the foods in which they can be used. There is also a general requirement about the purity of food additives (B.01.045). Where a finite limit for the amount of an additive in a food is not given, the regulations state that the amount shall not exceed the amount required to accomplish the purpose intended, in other words "good manufacturing practice" must be employed (B.01.044).

Provision is made for the addition to or changes in the usage of food additives in section B.16.002 which reads as follows:

B.16.002. A request that a food additive be added to or a change made in the Tables following section B.16.100 shall be accompanied by a submission to the Minister in a form, manner and content satisfactory to him and shall include:

(a) a description of the food additive, including its chemical name and the name under which it is proposed to be sold, its method of manufacture, its chemical and physical properties, its composition and its specifications and, where that information is not available, a detailed explanation;

(b) a statement of the amount of the food additive proposed for use, and the purpose for which it is proposed, together with all directions, recommendations and suggestions for use;

(c) where necessary, in the opinion of the Director, an acceptable method of analysis suitable for regulatory purposes that will determine the amount of the food additive and of any substance resulting from the use of the food additive in the finished food;

(d) data establishing that the food additive will have the intended physical or other technical effect;

(e) detailed reports of tests made to establish the safety of the food additive under the conditions of use recommended;

(f) data to indicate the residues that may remain in or upon the finished food when the food additive is used in accordance with good manufacturing practice;

(g) a proposed maximum limit for residues of the food additive in or upon the finished food;

(h) specimens of the labelling proposed for the food additive; and

(i) a sample of the food additive in the form in which it is proposed to be used in foods, a sample of the active ingredient, and, on request a sample of food containing the food additive.

B.16.003. The Minister shall, within ninety days after the filing of a submission in accordance with section B.16.002, notify the person filing the submission whether or not it is his intention to recommend to the Governor in Council that the said food additive be so listed and the detail of any listing to be recommended.

The regulations I have described are similar to the Food Additive Amendments to the United States Food, Drug and Cosmetic Act but there are some differences as I understand the requirements of the United States law. I will mention a few. Under the Canadian regulations, all food additives that may be used will be placed on the permitted lists in section B.16.100. If a substance does not appear on this list for a specific purpose it may not be used. We have no wording that would permit the use of substances "generally recognized as safe" (GRAS). Furthermore, there are no substances permitted use only because of prior acceptance. All substances permitted must be listed.

We hope these regulations will provide for a systematic and reasonable control of additives used in foods sold in Canada.

## The Addition of Vitamins, Minerals or Amino Acids to Foods

Section 5 (1) of the Food and Drugs Act of Canada states that:

No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

This is the principal section in the act from which authority is derived to prescribe regulations to prevent consumers from being misled as to the value or merit of a food. It also supplements section 4 of the act to which I have already referred, in authorizing some protection as to the safety of foods.

Addition of certain vitamins to foods has been permitted in Canada for nearly a quarter of a century. Vitamins A, D and C, and the B vitamins, thiamine, riboflavin and niacin, may be added to foods within specified limits. Pyridoxine may be added to foods used solely for children under two years of age. The minimum and maximum amounts of vitamins that may be added were selected to bear a relationship to the daily requirements for the vitamins. The lower limits represent approximately 75 per cent of the daily requirements and the upper limits, one or two times the daily requirement depending on the vitamin.

Until a few years ago, vitamins were added to foods primarily for nutritional reasons. For example, the addition of thiamine, riboflavin, niacin, iron and calcium to flour in Canada came about because of definite evidence of widespread vitamin deficiencies in Newfoundland. A medical survey following the addition of these vitamins and minerals to flour and bread showed that there was a general improvement in the nutritional status of Newfoundlanders although it was not possible to state how much of the improvement was due to the use of the flour and bread as the general economic situation in that province had improved in the meantime.

A second and more recent example of filling a nutritional need of a significant portion of the population by permitting the addition of a vitamin to a specific food, is the addition of vitamin C to evaporated milk. In recent years there have been persistent reports from public health officers that there was evidence of a considerable amount of infantile scurvy in the out ports of Newfoundland and among the Indians and Eskimos in the Canadian north. Because of the widespread use of evaporated milk for infant feeding in those areas and of the suitability of evaporated milk as a carrier for vitamin C, the standard for evaporated milk was changed to permit the addition of that vitamin and a minimum concentration of the vitamin C was prescribed. It is too soon to determine whether the objective of this action has been accomplished.

Addition of vitamins to certain other staple foods has some nutritional basis. It seems logical to permit, for example, the addition of vitamin A to margarine which replaces butter.

During the past few years, there has been an increasing trend towards the addition of vitamins to foods for promotional purposes, without regard for nutritional needs. We now have apple drink with

added vitamin D, cereals with added vitamin D and gelatin desserts with added B vitamins. The addition of vitamins to soft drinks and candy seriously interferes with proper nutritional education.

There appears to be no harm from consuming large amounts of water soluble vitamins since the excess is excreted in the urine. (Many Canadians have, as a result, a very expensive urine!) While toxic reactions to vitamin A have been reported, they are not likely to result from amounts consumed in foods. With vitamin D the story is different since an intake as low as 2,000 International Units per day has been reported to retard the growth of infants. This is only five times the daily requirement. A survey has shown recently that it is quite possible to obtain 4,000 International Units daily by consuming a variety of foods containing added vitamin D. Indiscriminate additions of vitamin D to foods may, indeed, constitute a hazard to health. The very great majority of Canadians are sufficiently well nourished and will not benefit from vitamins indiscriminately added to foods.

The same reasoning can be applied to the addition of minerals and amino acids to foods and in addition, it can be said that the amounts of these substances now added are trivial in many cases and could have little if any value to the consumer in any event.

After consultation with nutritionists and medical specialists, a draft regulation was prepared to control the addition of vitamins, minerals and amino acids to foods. The proposed regulations were presented to the food industry in August, 1963, in one of our *Trade Information Letters*. It was pointed out that foods containing added vitamins, minerals or amino acids, would meet the requirements of the proposed regulations if existing standards provided for their addition, for example, fortified flour and bread, iodized table salt, fortified apple juice, etc. In addition, a list of unstandardized foods already containing added vitamins, minerals or amino acids, which would be acceptable under the proposed regulations was supplied. After discussion with industry, somewhat modified regulations were sent to the Minister and became law on September 23, 1964.

These regulations are as follows:

D.03.010. No person shall sell a food to which a vitamin, mineral or amino acid has been added unless

(a) the section prescribing the standard for that food in Part B of these Regulations provides for the addition of that vitamin, mineral or amino acid;

(b) in the case of a food for which a standard is not prescribed in Part B, a table in section B.16.100 provides for the addition of that vitamin, mineral or amino acid to that food; or

(c) that vitamin, mineral or amino acid is listed opposite that food in the following Table:

*Foods to Which Vitamins, Minerals and Amino Acids May Be Added*

| *Food* | *Vitamin, Mineral or Amino Acid* |
|---|---|
| 1. Breakfast cereals | Thiamine, riboflavin, niacin, iron |
| 2. Fruit drinks, nectars and fruit drink bases | Ascorbic acid |
| 3. Infant cereals | Thiamine, riboflavin, niacin, iron, calcium, phosphorus, iodine |
| 4. Margarine and margarine-like products | Vitamin A, provitamin A, vitamin D |
| 5. Alimentary pastes | Thiamine, riboflavin, niacin, iron |
| 6. Prepared infant formulae | Ascorbic acid, vitamin A, vitamin D, thiamine, riboflavin, niacin, pyridoxine, iron, iodine, calcium, phosphorus |
| 7. Chocolate or malt beverage mixes and bases | Thiamine, riboflavin, niacin |
| 8. Specialty meat substitutes for vegetarians | Lysine |

D.03.011. Section D.03.010 does not apply to foods recommended for special dietary use that are not advertised to the general public.

Manufacturers were advised that requests for changes in the table given in section D.03.010 would be considered upon receipt by the Director of evidence indicating:

(a) the need by the general public for an increased intake of the specified vitamin, mineral or amino acid, or that the product has replaced a food which normally provides to the general public a significant proportion of the dietary requirement for the specified vitamin, mineral or amino acid,

(b) the food in question is a suitable vehicle of distribution of the vitamin, mineral or amino acid because it is widely and regularly consumed, or because the added vitamin, mineral or amino acid is needed to replace loss which occurs during processing when good manufacturing practices are followed, and

(c) the stability in the food of the vitamin, mineral or amino acid.

Finally it should be emphasized that the above regulations do not prohibit the addition of vitamins, minerals or amino acids to foods if it can be shown there is a public health need for the addition. Consumers are not in a position to judge the validity of nutritional claims made for foods nor the value of such additions in terms of their health.

**[The End]**

# Compliance with the New "Investigational New Drug" and "New Drug Application" Regulations

By RAYMOND D. McMURRAY

Mr. McMurray Was Formerly Secretary and General Counsel of Hoffman-LaRoche, Inc. in Nutley, New Jersey.

AN INTERESTING RECENT PHENOMENON has been the rash of photos appearing in the pharmaceutical trade press depicting the monumental size of New Drug Application (NDA) submissions. Usually the photo depicts several columns of bound data next to which is a young lady to give both beauty and perspective to the message.

Those of us who have been associated with the pharmaceutical industry for a number of years can remember when an NDA was of manageable size and, more importantly, contained a manageable amount of meaningful data. In recent years, largely because of the Drug Amendments of 1962 which drastically changed the law, including the new drug provisions, aided by a newly acquired zealousness on the part of Food and Drug Administration (FDA) personnel, submitters of NDA's have been subjected to attitudes of suspicion and delay never dreamed possible in the years before Senator Kefauver.

Although FDA has in the past denied that there has been a slowdown and, of course, vehemently objects to charges of a conscious dragging of feet, there can be no doubt that there has in fact been a virtual halt to NDA approvals. A candid and refreshing recognition of certain administrative problems leading to great delays has finally been officially recorded by Dr. Ralph Smith, in his address to the 1964 Joint National Conference of the Food and Drug Administration and The Food Law Institute held in Washington, D. C. on November 30, 1964.[1] Although Dr. Smith ascribes the delays to the

[1] Ralph G. Smith, "Comments on New and Investigational Drugs," 20 FOOD DRUG COSMETIC LAW JOURNAL 82 (February, 1965).

fact that increases of staff have not kept pace with increases in work load, industry feels that even given such increase many delays have been unnecessary.

Fortunately, there is no need to argue the merits here. The fact that there is now open discussion between industry and the FDA about the problem goes a long way toward its solution. The need for cordial intercommunication, which had become so strained and formal in recent years, is being reestablished, to the benefit of all concerned.

There is little argument with the proposition that some of the Drug Amendments of 1962 were necessary and indeed long overdue. In addition some of the NDA provisions have a good deal of merit. Most notable among the changes are the Investigational New Drug (IND) requirements and the need for efficacy data in the NDA.

On this subject, incidentally, it is well to keep in mind FDA's statement that they will not use the efficacy provisions of the law to engage in a program of approval based upon comparative efficacy. This is an area of diligence which should constantly be before the sponsor and his attorney. It is a human tendency to compare and to act upon comparison—but we must require that each new drug be evaluated on its own merit, measured against the disease entity which it attacks rather than upon the relative merits of drugs useful in treating the same disease entity.

Even though we may recognize that there have been ruffled feathers and hurt feelings on either side of the regulatory fence due to the prolonged Kefauver hearings we should see some relief in sight. Differences of the past cannot control present activities as these are only background against which we must now exercise our particular practice. It behooves those of us who advise clients who must submit NDA's to recognize not only the full import of the changes in the law but also the requirements of the regulations which implement that law. I would not presume to stand here today to read the law to you nor would I attempt to set forth in any great detail the regulations. I do, however, recommend to you a careful reading of the entire section 505 of the Federal Food, Drug and Cosmetic Act and the regulations appertaining thereto, namely, 21 CFR Section 130 in its entirety.[2]

[2] 21 CFR, Sec. 130, FOOD DRUG COSMETIC LAW REPORTS ¶ 71,301—¶ 71,379.

## Investigational New Drug Form

Any discussion of NDA's subject to the effective date of the 1962 Amendments must of necessity concern itself with a new official form, namely, the IND or "Notice of Claimed Investigational Exemption for a New Drug," otherwise known as a Form FD-1571. This form allows the FDA to monitor investigational compounds long prior to the submission of an NDA. Former practice was that unless it heard about a new drug compound through the "grapevine" the FDA had no knowledge of its investigational use until the formal filing of the NDA.

Form 1571, the IND, and its accompanying forms 1572 and 1573 give FDA a regulatory tool which if properly used can indeed be a major contribution to the public welfare. In essence, the IND is a statement by the new drug sponsor that in his opinion, which opinion he knows will be tested by FDA scrutiny, sufficient work has been done in the chemistry and pharmacy laboratories and in the pharmacology department of the sponsor (or experts to whom this work has been referred by the sponsor) to provide the necessary information for taking the drug into the clinic.

The first use of a new drug compound in man has always been an exacting and sophisticated procedure requiring the highest scientific and medical skill. It also requires that fine sense of morality and intellectual honesty which must place human values above material gain. In the past our leading pharmaceutical companies have competently engaged in the fine art of human pharmacology without the ever-presence of the regulating body. Now in the full glare of public attention they must continue this activity, ever mindful of the watchful eye of FDA.

This partnership should be welcomed because, I believe, as the practice is refined it can prevent the unfortunate occurrence of duplicating toxic reactions and the unnecessary multiplication of the expenditure of competitive dollars in the pursuit of a worthless drug entity.

It must be granted that the new situation requires the placing of absolute trust in the motives and integrity of those who administer the law. Time will provide the background against which the value of this trust will be judged. It is hoped that with the increasing funds available to it FDA can attract and sustain physicians and scientists of the highest calibre.

## Use of New Drugs in Humans

Each of you at one time or another will be asked the question by your client: "May I now go into the clinic with this new drug entity?" There will be, to support an answer to this question, a gathering of documents reflecting chemical, pharmaceutical and pharmacological studies. You will be asked to evaluate and to recommend the next course of action.

The caveat which must be inherent in this highly specialized scientific field is to recognize that this decision is not a legal one. Nothing in the lawyer's background or training can equip him to decide, based upon such evidence presented, that it is now time to attempt to use the drug in humans. This is a decision for a scientifically trained and responsible member of the sponsor firm (or the sponsor himself). The decision requires full knowledge of the activity of the compound, its chemistry, its activity and reactions in animals, the relation of an established LD-50 to the probable toxicity in humans, an educated guess as to the probable human activity, including therapeutic and toxic doses, side reactions and contraindications likely to be encountered by the clinical investigator, and, finally, a willingness to make a difficult decision and to act upon it.

All of the above is necessary because in its wisdom Congress provided for the filing of an IND but not for its approval by FDA. Within the total framework of the new drug procedure currently applicable a new drug cannot be marketed without an approved NDA but investigators can use it in humans without governmental sanction. Additionally, although the IND is filed chances are it will not be reviewed prior to the first clinical use of the new drug compound. Therefore, as in the past, your client must be right in its decision to enter the clinic but now there is the added burden of preproving that it is right, and of placing on the public record all of the evidence for the decision.

The risk of course is that FDA may at a later date carefully review the IND, decide that the sponsor is prematurely in the clinic and either through newspaper or other well-known FDA publicity devices destroy the sponsor's image to protect its own. The quiet discontinuance of a study by a sponsor who in the past might consider his new drug to be unsafe or not effective may not be currently possible because of the IND requirements. In this regard I commend you especially to a careful reading of the requirements of Form FD-1571 as

set forth in 21 U.S.C. 130.3 and the accompanying forms 1572 and 1573 also set forth in that section.[3]

## Understanding the Law and Human Judgment

The touchstone of compliance with any law or regulation is understanding it. Difficulty arises with those regulations in which qualitative or quantitative judgment is involved. We are faced with seemingly explicit regulations, replete with official forms and needed guidelines. Thus misunderstanding is greatly minimized. We are, however, confronted with the proper handling of potentially toxic materials in a manner beneficial to the public health and welfare.

We can see from the chart[4] exactly how an IND report will be handled and exactly how an NDA report will be handled. We know to whom these documents will go and the scientific disciplines which will be used in their evaluation. *But*, whatever the material filed, whatever the data show, whatever is claimed for the drug, in the final analysis human judgment will come to bear upon it. This human judgment, even though supplemented by all the gadgetry modern science can marshall is still the ultimate in this most important stage of drug development.

Human judgment will differ. Exasperating delays have and will continue to take place, plaguing sponsors and upsetting carefully made future plans. For their part, FDA personnel will be increasingly wary of a wide variety of spectres from teratogenicity of the new compound to its effect upon elderly patients.

Efficacy is a vague standard. Evaluation of clinical studies can as easily be misapplied by an over-strict FDA as they can by an eager sponsor. Safety generally is measurable in some tangible degree and its evaluation has had a long history. The rules have become well established. In order to establish the new rules for the evaluation of efficacy the road ahead will be difficult for both the regulated and the regulator. It is hoped, as men and women of good will, they will rapidly acclimate to it, for the benefit of us all.

## Summary for Compliance

A summary then of compliance with IND and NDA regulations would go something like this:

---

[3] 21 U.S.C. 130.3, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 71,303.

[4] "Flow Chart on Procedures for Processing IND and NDA Filings: From FDA Memo," *The Pink Sheet*, November 30, 1964.

1. Be thoroughly familiar with all the requirements of the forms 1571, 1572 and 1573—these are the backbone of the IND procedure.

2. Comply fully with every reasonable FDA demand.

3. Pay strict attention to the considered judgment of the sponsor's scientific personnel (or consultants).

4. When, and only when, the scientists concerned with toxicology and pharmacology are satisfied that they have done all there is to do *and* qualified medical researchers have agreed, go to the clinic.

Here is your first hurdle of judgment. It is difficult in the abstract and more difficult because there is no government "partnership" as yet. The decision belongs to the sponsor and needs to be taken decisively—one way or the other. It is clearly a decision of science, not of law.

5. Once in the clinic the amassing of data should proceed—looking toward the filing of an acceptable NDA. Here, even the NDA form cannot substitute for proper judgment. All reasonable avenues of safety and efficacy in humans must be explored, ideally with intelligent and unbiased concern.

Here is the second hurdle of judgment. But now it becomes an *inter partes* judgment. It will not be ultimately made without exploration and persuasion, sometimes painful, always challenging. Sooner or later, if the drug has demonstrated promise, the NDA will be approved and sale may commence—a justification for thorough preparation under the law and regulations.

Pragmatic advice to the sponsor and his attorney: Act with restraint and patience and trust that FDA will act with helpfulness and wisdom. **[The End]**

## CORN PRODUCTS CHAIRMAN TO HEAD FOOD LAW INSTITUTE

Alexander M. McFarlane was elected chairman of the Food Law Institute in March, 1965. Mr. McFarlane, chairman of Corn Products Company, succeeds William T. Brady.

The Food Law Institute provides information on food and drug laws through publications, industry-government conferences and instruction at leading university graduate, law and medical schools. Founded in 1949, the Institute is supported by the food, drug and related industries. Its trustees include leaders of industry as well as federal and state food and drug officials.

# The Medical Detailer and the New Drug Amendments of 1962

By SIDNEY H. WILLIG

Mr. Willig Is an Attorney with Sterling Drug Co., Inc.

THERE ARE APPROXIMATELY 20,000 medical detailers or pharmaceutical representatives acting as field agents for the ethical pharmaceutical industry at the present time. The preponderant majority of these are pharmacy or premedical college graduates, trained and retrained for this work.

In their contact activities these men perform a public service, beyond their mere promotional presentations, in that they help overcome the difficulties that today's busy physician has, in keeping up with newer product developments. There is no question that their employment objective is to sell product specification, but at the same time they offer to their physician contacts, general informative service with regard to new trends, beliefs, and techniques in medicine. For example, the detailer, promoting a new antibacterial cannot help but review the latest ideas in bacteriology which may well serve the physician in many ways. The man who comes to the doctor with a new antihypertensive drug is trained in its anatomical, cardiovascular implications, and indeed trained to contrast it to other media and other methods versus hypertension. Obviously, then, his presentation is not without informative value to the doctor regardless of the detailman's own normal sales bias.

I have commented on this briefly since it is not truly within the scope of this article. I have done so, however, because of the general misconceptions that fuzz the thinking of the general public as to the detailman's activities. Even within his own company, research, legal and marketing staff may know him only vaguely as a sales tool. I believe the only way to get a fair picture of his activities is to "live" them for a while, something I fortunately was enabled to do some years

ago. I have consistently found that my legal brethren in pharmaceutical companies, my friends among state and federal food and drug and pharmacy officialdom and even practicing pharmacists often have dangerously inaccurate views as to this professional's place in public health care.

## Oral Promotional Statements

At the present time the Food and Drug Administration (FDA) has recognized that the promotional statements made by a medical detailer to a physician or other professional contact are not readily categorized as label, labeling, or advertising, for a drug product.

Although there were a few who felt that the New Drug Amendments of 1962 would extend FDA control over oral promotional statements through the changes made in the subsections of section 502 of the Federal Food, Drug and Cosmetic Act as interpreted by its effectuating regulations, William W. Goodrich, Esquire, Assistant General Counsel, Food and Drug Division, Department of Health, Education and Welfare, among others, (*New York University Law Review*, Volume 38:1082, p. 1124) has expressed a contrary view.

On the other hand the detailer's oral presentation is subject to section 502 (f)(1)[1] inasmuch as his mention of uses not covered by the approved new drug application, or not established as safe and effective for that drug, would be actionable.

Courts, in considering whether charges are within the scope of the Act have supported the FDA's position that wherever a false claim in terms of effectiveness or safety is made for a drug by any advertisement or promotional means, directions for use of the article in its label or labeling are inadequate and that therefore the drug is misbranded.

In addition, any oral statements which tend to show actual labeling as being incomplete, false, or misleading, in the case of new drugs, is a potential basis for action under section 505 (e),[2] to suspend it.

These considerations are in no way a modification of the detailer's role as agent in the delivery of labeling materials which may accom-

[1] See Act, Sec. 502 (f)(1), FOOD DRUG COSMETIC LAW REPORTS ¶ 228.

[2] See Act, Sec. 505 (e) as amended by 76 Stat. 780 (October 10, 1962), FOOD DRUG COSMETIC LAW REPORTS ¶ 260.

pany his verbal statements to a physician during an interview. Such materials call for complete and affirmative disclosure.

## Company Responsible for Fair Exposition

Regardless of statutory applicability, there are numerous judicial precedents which hold the company responsible through its detailer for a fair exposition of his subject. Where there is no warning of hazards communicated, or the detailer seeks to discourage the physician's attention to them as they concern the product for which specification is sought, both agent and principal may be liable in tort, *(Thomas v. Winchester,* 6 N.Y. 397). Action might also be predicated on product liability. In either event the courts may regard the physician as an agent for the ultimate patient-consumer of the drug. Detailmen, therefore, are instructed that any information received by a practitioner, that could lead him to validly claim it caused him to prescribe, should be accompanied by full disclosure to prevent any subsequent charge of deceit *(Wechsler v. Hoffman-La Roche,* 99 N.Y.S 2nd 588; *Carmen v. Eli Lilly and Co.,* 109 Ind. App. 76). Labeling which is presented during the interview is a normal part of such full disclosure. Its insufficiency may invite plaintiff's suit, since statutory negligence translated into negligence per se, helps make out a prima facie case for the complainant.

The use of out-dated literature, or other detailing pieces not presently in compliance, is unsatisfactory, and may be actionable as a misbranding. This will require diligence in keeping abreast of changes in package inserts and product brochures that will probably result from the application of paragraph 130.35 of the regulations and forthcoming needs to substantiate effectiveness or modify labeling after October 9, 1964.

Where advertising material presently defined within the regulations pursuant to section 502 (n),[3] is utilized by the company or its representative to accompany the product, (or sample thereof), and is used to serve the function of describing the nature and usage of the drug, some problem may be created. FDA officials, supported by the courts, in some instances, have pointed out that such advertising would be labeling. As such, it might be deficient per se, and deficient for the detailman's purposes, since labeling requires full disclosure and advertising requires brief summarization.

[3] See Act, Sec. 502 (n) as amended by 76 Stat. 780 (October 10, 1962), FOOD DRUG COSMETIC LAW REPORTS ¶ 238.

One overall concept that derives from the advertising regulations lends itself well to preparation for the detailing presentation. That is the idea of the balanced presentation and the brief summary. Since time is a dimension of detailing that is not considered in the same manner in the advertisement, obviously this concept must be a flexible one, and the use of labeling material can be made to apportion such balance.

Some other standards, that reason would apply, hold the detailer responsible for a description of the product and ingredients in the same terms as those which appear in the labeling.

He must not adopt or use for either the drug or ingredients a fanciful name that differs at all from the approved labeling, or that may mislead the listener because it sounds like the name of a different drug or ingredient.

He may not promote inert or inactive ingredients to create any impression of value greater than their true functional role in the formulation.

Considering for a moment further the distinction outlined in paragraph 1.105 of the regulations, it is clearly stated that the most stringent information requirements, "full disclosure" labeling in accordance with paragraphs 1.104 and 1.106 (b)(c), apply to brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogs, house organs, literature reprints and similar pieces of printed matter concerning a drug, which are disseminated in any manner by or on behalf of the product manufacturer.

A physician, who is not an agent of a drug's sponsor, may laud a drug and describe its nature and usage in terms based on his scientific appraisal of it. This, even though, his statements are other than the accepted claims for safety and effectiveness which are part of the new drug application. However, a reprint of such a manuscript, or its verbal equivalent may not be adopted by the distributor of the drug or his agent for promotional dissemination to other practitioners.

Carefully consider proper use of a journal or exhibit reprint, therefore. The danger signal should sound for detailer agent, and company principal, where such article, though otherwise adoptable for use by the drug's sponsor, violates paragraph 1.105. It does this when it exceeds claims or dosages cleared in the new drug or certification application procedures, or nullifies contraindications, toxicities, or other cautionary advice conceded and required to be noted.

This in no way limits the scientist's right to publish the results of his study or experience in exactly the language he deems proper. It merely clarifies the fact that this prerogative may not be transferred to a drug's sponsor for commercial purposes.

As part of the scientific reporting service which is customary to his calling, the detailer may call such an article to a doctor's attention and give him information as to its source and availability. An oral disclaimer, however, should precede or accompany the reference, clearly indicating that the article does not reflect the manufacturer's claim for the safety and effectiveness of his product. Complete disclosure should accompany it to the physician if and when he requests it.

Preferably, detailmen should not write letters to practitioners. Aside from reprints, correspondence with physicians that discuss a newer use, or an uncleared use of a drug, should be confined to reportorial material. Therefore, it should be clearly indicated within the letter that the manufacturer is not recommending such use at this time. Failure to do so might comprise a recommendation that would expose the firm to liability. After the correspondent receives the report with the disclaimer, his use of the drug for any but its approved claims is experimental therapy on his part, for which he assumes liability.

## Investigational Drugs and Detailman's Responsibilities

With this we come to another important area within the New Drug Amendments that affects the legal responsibilities of the detailman as a general agent for his employer. Section 505 (i) of the Act[4] and the regulations which cover investigational drugs must be implemented. Depending upon the actual responsibilities delegated to him, and new duties that may be assumed thereunder, the detailman's overall effort should be at least to help the company maintain the investigational exemption it has created by filing the form FD 1571.

This can be done by being certain that no claims are made that indicate that the safety and effectiveness of the drug have been established for its uses prior to the time it becomes an approved new drug.

The detailman should report to appropriate persons or to his manager any abuses of distribution or usage with regard to the new

[4] See Act, Sec. 505 (i) as amended by 76 Stat. 780 (October 10, 1962), FOOD DRUG COSMETIC LAW REPORTS ¶ 264.

drug. This information should come to him through his regular observations in conjunction with his activities, or perhaps by alert reconnoitering, but never by prying, questioning or general nosiness, unless instructed otherwise.

The detailman can assist by making certain that he promptly reports in confidence to his company when he sees investigationally labeled drugs in traffic, storage, or use, after such product is a commercial product. In the event his company is aware of this and the labeling has a proper purpose, then nothing more need be done. If, however, this is material that should have been returned—it is important that his company know of this, to avoid a misbranding violation.

Still another important consideration for the detailman in everyday compliance with the New Drug Amendments, is his heightened responsibilities as agent of his employer in adverse reaction reporting. Although the regulations at first set out to cover these legal requirements with investigational drugs and with drugs of very recently "approved new drug status," through recent ancillary regulations, older drugs are covered.

Therefore, within each company, some standard reporting system has been set up to receive and consider reports from the field. In the initial handling of these, on the speed and thoroughness of the reporting may hang the life or death of a product.

As to the newer inspection authority of the present act, we have noted since the temporary set-back in the *Cardiff* case *(United States v. Cardiff,* 344 U. S. 174, 73 S. Ct. 189 (U. S. Sup. Ct. 1952)), a growth of FDA prerogatives both real and assumed. Their powers with regard to inspection of factories, warehouses, establishments and vehicles, and most especially with regard to prescription drugs, are carefully delineated. An unwarranted excess through caprice, or whim or poor judgment endangers the exercise of authority that is needed or desirable at this time.

Historically, it would seem that in the exercise of the police power on various governmental levels, the failure to provide for a search warrant and the flouting of the Fourth Amendment can be used by FDA more effectively against a corporation than the detailman. The latter who has a more personal set of rights to protect with the Fourth and Fifth Amendments could easily emphasize that these amendments were created to combat the "police powers" exerted by authoritarian governments.

Yet, the detailer must approach this matter with clean hands. He must always conduct himself within the law if he is to avoid the possibility of trouble for himself and his company. Very often, among the infrequent occasions where an FDA inspector has contacted a detailer in his rounds, the officer tries to get the detailer off balance by first catching him in an offense. For instance, impersonating a hospital employee of whatever category, a pharmacist, another detailman, the FDA inspector will ask for a sample of a legend drug. Local inspectors will frequently seek to catch the detailer in illegal diversion of sample material within a drug store, or try to find improper "clean-out" of samples, literature or drug materials into the street.

While dwelling on some of the newer legal requirements for detailman observance, it is good to re-emphasize some of the older ones. These have enlarged importance because of the New Drug Amendments of 1962.

Misbranding violations do not stem solely from labeling problems we have previously considered. Sections 503 and 505 are complementary to section 502. Hence, misbranding may come from mispresentation of legended materials, sample or stock, to those unqualified under state law to receive them such as nurses, hospital attendants, etc. Likewise, any such distribution by the detailman may not be outside of his normal agent relationship with his employer, nor beyond the scope of the established pattern of his employment. Neither may a drug bearing the prescription legend, whether commercial or experimental, be sent to other than a licensed medical practitioner who must be privileged to prescribe and dispense within the state in which he practices. So that, if a legend drug is sent or given to a podiatrist in a state where he may not prescribe or dispense such drug, nor be its recipient except as a patient pursuant to prescription, it is a misbranding.

This does not interfere with the right to ship appropriately labeled material to individuals who qualify for receipt of the drug by meeting the descriptions in the regulations and signing the required accompanying forms.

Compliance with the New Drug Amendments and the entire act should not pose any difficulty for the average medical detailer who conscientiously prepares for, and applies himself, to his job. Actually, the detailman's legal responsibilities fit properly and exactly into the every day modus operandi of his procedures as instructed by his principal. **[The End]**

# Developments with Respect to Product Liability Law

By WILLIAM J. CONDON

Mr. Condon Is an Attorney with Swift & Company.

IN OUR REPORT ON THE DEVELOPMENTS IN 1963, delivered last year,[1] we made reference to the first cases applying by name the concept of strict liability in tort. During 1964, section 402A of Restatement of Torts 2nd, which enunciates the doctrine of strict tort liability, has been cited with approval by courts from all sections of the country. The doctrine is clearly established on a firm foundation at this time and is obviously spreading at a very rapid rate. Indeed, the most interesting cases in this area in 1964 involved efforts by courts to determine the applicability of the doctrine to special situations.

## Trend Toward Extension of Liability for Products

For example, in California, where the doctrine had its first expression in *Greenman v. Yuba Power Products, Inc.*,[2] discussed last year,[1] a court has held that strict liability does not apply to a claim for failure to warn of the dangerous side effects of a drug, otherwise safe and properly made. *(Love v. Wolf*)*

The Minnesota Court, accepting the tort theory, concluded that contributory negligence is a defense to a warranty action in so far as consequential damages are concerned. In that court's view, this is the logical conclusion to be arrived at from the application of the tort principle. *(Gardner v. Coca-Cola Bottling Co. of Minnesota, et al.*)* On the other hand, California, where the tort doctrine is in full flower, holds that contributory negligence is not a defense to an action based on implied warranty. (*Vassallo v. Sabatte Land Co.**)

[1] William J. Condon, "Products Liability—1963," 19 FOOD DRUG COSMETIC LAW JOURNAL 93 (February, 1964).

[2] *Greenman v. Yuba Power Products, Inc.*, 15 NEGLIGENCE CASES (2d) 35, 59 Cal. 2d 57, 377 P. 2d 897 (1963).

* See cases cited at conclusion of article.

The framers of section 402A relied heavily upon the New Jersey case of *Henningsen v. Bloomfield Motors, Inc.*,[3] to support the strict liability theory. It will be recalled that this is the case wherein the New Jersey Supreme Court abolished the privity requirement in an action involving personal injuries arising out of the sale of a defective automobile. The New Jersey Appellate Division, in construing *Henningsen,* found it to have a somewhat narrower impact than is frequently ascribed to it. In *Santor v. A. & M. Karagheusian Inc.*,[4] the court held (1) that *Henningsen* did not abolish the requirement of privity of contract in a breach of warranty action for loss of bargain only, and (2) that *Henningsen* is restricted to the marketing of a product whose defect in manufacture resulted, and foreseeably so, in personal injuries to a member of the family of the purchaser.

In the light of this very definite trend toward extension of liability for products, the holding of a Florida appellate court comes as something of a surprise. The case involved a claim for serious injuries from the side effects of a drug product purchased from the defendant retail druggist. The action, based on breach of implied warranty was brought by the purchaser, so that there was no question of lack of privity. Nonetheless, the court dismissed the complaint for failure to state a cause of action. The court held that no action for breach of implied warranty will lie against a retail druggist for injuries sustained as a result of the nature of the drug, as opposed to any foreign matter on impurities in it, which has been approved for sale by federal authorities acting pursuant to federal law, and which has been dispensed upon the prescription of a physician. *(McLeod v. W. S. Merrell Co., et al.*)*

1964 produced several cases construing the uniform commercial code as it affects products liability. The Pennsylvania Court, for example, held that an action for breach of implied warranty alleging personal injury of the plaintiff is governed by the four year Statute of Limitations contained in the code rather than the two year personal injury statute governing actions in Pennsylvania generally.[5] Pennsylvania also decided that the warranties in the code are not available to an infant injured by a defective vaporizer where the purchaser was

---

[3] *Henningsen v. Bloomfield Motors, Inc.*, 32 N. J. 358 (1960).

[4] *Santor v. A. & M. Karagheusian Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5193.

* See cases cited at conclusion of article.

[5] *Gardiner v. Philadelphia Gas Works*, CCH PRODUCTS LIABILITY REPORTER ¶ 5163, (1964) 413 Pa. 415, 197 A. 2d 612.

a relative who did not live in the same household with the injured plaintiff. The Pennsylvania courts are apparently unprepared to carry privity beyond the precise language of the statute, to wit, "to any natural person who is in the family or household of his buyer or who is a guest in his home."[6]

In Connecticut, it was held that the warranties provided by the Uniform Commercial Code do not extend to products used upon a customer in a beauty salon in the course of a beauty treatment. The rationale of the decision is that the transaction in the beauty salon is essentially a service and not a sale, and the warranties under the code do not attach to a service. *(Epstein v. Gianmattasio.*)*

Finally, the Massachusetts court held that a fishbone in fish chowder does not give rise to an action for breach of warranty under the Uniform Commercial Code. *(Webster v. Blue Ship Tea Room.*)*

## "Duty to Warn" Cases

Another area of the law which is still in the developmental stage is to be found in the so-called "duty to warn" cases. These involve the responsibility of a manufacturer of a product with dangerous propensities or one which tends to elicit untoward reactions in some of its hosts to warn of the dangers and his liability if he fails to do so or if the warning which he gives is inadequate. Two cases decided in 1964 graphically illustrate two different approaches which courts may take to this problem.

In *Charles Pfizer & Co., Inc. v. Branch,** the plaintiff injected two calves with a product manufactured and sold by the defendant for the purpose of being injected into animals to prevent infection. The calves suffered a severe reaction and died within a short time. There was a warning on the label to the effect that if the cattle showed a reaction to the product its use should be discontinued. There was evidence at the trial that it was well-known in the industry that some cattle would suffer a severe reaction to this product and that unless a specific antidote was administered promptly, cattle so affected would probably die. In view of this evidence, the Texas Court of Civil Appeals held that the defendant's warning was inadequate since it failed to mention the possibility of the severe reaction and the antidote

[6] *Miller v. Preitz,* CCH PRODUCTS LIABILITY REPORTS ¶ 5242, Pennsylvania Court of Common Pleas.

* See cases cited at conclusion of article.

which was necessary in the event such should take place. However, there was testimony by the plaintiff that he had used this product for 8 years without any unpleasant experience and that in all that time he had never read the warning which defendant had on its label. Accordingly, defendant argued that, even if it be found negligent for failure to print an adequate warning on the label, such negligence was not the proximate cause of the plaintiff's damage because the plaintiff had not read the label anyway. This argument seems to have considerable merit. Nevertheless, the court held defendant liable and said that, on the evidence, the trial court could have concluded that if a proper warning had been on the label, the plaintiff would have heard of it at some time during his eight years' experience and would have been aware of the antidote and could have thus prevented his injury.

In contrast to this, consider the attitude of the Appellate Division of the Supreme Court of New York in *Kaempfe v. Lehn & Fink Products Corp.** Testimony at the trial established that plaintiff had suffered an allergic reaction to the aluminum sulphate ingredient in the defendant's spray deodorant. The label on the can bore the statement "contains aluminum sulphate." This was the first time that plaintiff had displayed any allergic tendencies to any products. The essence of plaintiff's claim was that, although defendant knew that a certain number of people are allergic to aluminum sulphate, it failed to give any warning of that fact on its label and, therefore, was negligent. The Appellate Division reversed a judgment in favor of plaintiff and dismissed her complaint. It held that, since plaintiff had never suffered an allergy before, and since there was no evidence of the existence of any test which might be made for an allergic sensitivity, any special warning printed on the label would have been useless and ineffective. Accordingly, said the court, "the defendant should not be held negligent in failing to give a warning which would have served no purpose."

## "Tobacco Cancer" Cases

1964 produced two developments in the tobacco cancer area. In *Ross v. Philip Morris & Co., Ltd.,** the United States Court of Appeals for the Eighth Circuit affirmed a judgment on a jury verdict for the defendant. The crucial issue in the case was the validity under Missouri law of the identical instruction to the jury which has been the subject of our discussions in prior years. The trial court had instructed the jury, *inter alia,* as follows:

* See cases cited at conclusion of article.

A manufacturer of products, such as cigarettes, which are offered for sale to the public in the original package, for human use or consumption, impliedly warrants that its products are reasonably wholesome or fit for the purpose for which they are sold, but such implied warranty does not cover substances in the manufactured product, the harmful effects of which no developed human skill or foresight can afford knowledge.

Noting that Missouri has joined the liberal trend toward allowing recovery from the manufacturer for breach of warranty in the case of knowable defects, the court nevertheless reached the conclusion that Missouri would not go further and hold the manufacturer as an absolute insurer—"without regard to 'reasonableness' and without regard to 'developed human skill or foresight!' "

Another chapter has been unfolded in the case of *Green v. American Tobacco Company.** You will recall that this case was tried in the United States District Court for the Southern District of Florida, appealed to the Court of Appeals for the 5th Circuit, then to the Supreme Court of Florida for a clarifying opinion on Florida law, back to the Court of Appeals and back to the District Court for a retrial on the limited issue of reasonable fitness. This trial was held and the case given to the jury on November 27, 1964. After deliberating for one hour and thirty minutes, the jury came back with a verdict for the defendant. On this trial, the issues of the defendant's knowledge or developed skill and foresight were removed from the jury and, for all practical purposes, the only issue which the jury had to consider was whether or not defendant's cigarettes were reasonably fit for use as cigarettes. Indeed, when the case was presented to the jury, the question was not confined to defendant's cigarettes, but properly encompassed cigarettes of any brand. It will be interesting to see whether this case, which could provide, among other things, a rather complete procedure course for lawyers, will terminate at this point or will develop further interesting insights into the law.

## Function of Privity in Field of Negligence

Amidst all the furor created by the tendency of courts to abolish the privity requirement in breach of warranty cases, we are apt to lose sight of the fact that privity has a function, albeit somewhat limited, in the field of negligence. We are reminded of that function by the Appellate Court of Illinois in the case of *Gibbs v. Proctor & Gamble Manufacturing Company.** Plaintiff alleged that she contracted a contact dermatitis as a result of using a detergent manufactured by

* See cases cited at conclusion of article.

the defendant and charged that the defendant was negligent in its manufacturing and in its testing procedures. The evidence in the case presented the Appellate Court with many problems of proof. Nevertheless, the court held, among other things, that plaintiff had no standing to bring this action in negligence because she was not in privity with the defendant and there was no showing that the product involved was inherently dangerous or imminently dangerous to life or limb if negligently manufactured.

In the interests of imparting an aura of reality to these reports, we have, from time to time, reviewed the factual patterns in some of these cases apart from any legal considerations, so that we might provide the casual observer with an appreciation of what a products liability case is made. Consider, for example, the unfortunate young lady who became ill when she saw what looked to her like the torso and tail of a decomposed mouse in a soft drink bottle from which she had been drinking. Later in the day, as she recounted the horrible experience to her mother, her symptoms of illness, shaking and paleness, returned once again. The next day, still feeling ill, she went to see her lawyer. Thereafter, her symptoms still persisting, she sought out her doctor. He assured her that she had suffered no toxic or other physical injury from her experience. However, her symptoms of emotional distress persisted. These were considerable. She was unable to sleep. When she did drop off to sleep, however, she dreamed of mice. She was unable to drink nontranslucent liquids. She developed an intense fear of mice. After two weeks of this, she consulted a psychiatrist who found very definite evidence of emotional distress causally related to her experience with the soft drink. He concluded, however, that she did not need psychotherapy to remove these symptoms, but rather that they would alleviate in time. Unfortunately, we are not advised whether her $2,500 recovery provided the kind of therapy that these symptoms needed or whether they still persist. (*Ritter v. Coca-Cola Company.**)

For anyone who is interested in the culinary arts, we strongly recommend a careful reading of the case of *Webster v. Blue Ship Tea Room,** wherein the Massachusetts Supreme Judicial Court sets out several tempting recipes for fish chowder, including one by Daniel Webster, a namesake but no relation to the plaintiff. The issue in the case was whether or not the presence of a fish bone in fish chowder constituted a breach of warranty. As stated above, the court con-

* See cases cited at conclusion of article.

cluded that it did not. In reaching this conclusion, the court found it necessary to review several recipes for fish chowder, and particularly the manner of preparing and cutting the fish. In its brief, defendant urged the court to rule in such fashion that no chef is forced "to reduce the pieces of fish in the chowder to minuscule size in an effort to ascertain if they contained any pieces of bone." The defendant's brief went on to say "in so ruling, the court will not only uphold its reputation for legal knowledge and acumen, but will, as loyal sons of Massachusetts, save our world-renowned fish chowder from degenerating into an insipid broth containing the mere essence of its former stature as a culinary masterpiece." Having reached its conclusion, the court noted that it took some comfort from a similar decision by a federal court in California, but, since that court is also situated on a coast, perhaps that was to be expected. What impressed the court most was the holding by the Supreme Court of Ohio that a bit of oyster shell in an order of fried oysters was to be expected and, therefore, not a breach of warranty. If it appeared in this light to a court in the Mid-West, surely nothing less could be expected of the Supreme Judicial Court of Massachusetts.

It might be profitable to consider the applicability of products liability principles to an entirely different type of product. As an example, the Utah Court was confronted with a case of breach of warranty which involved a stallion purchased for breeding purposes whose every effort on behalf of his new owner resulted in failure. With apologies to Erle Stanley Gardner, we might properly label this "The Case of the Sterile Stallion." The defendant urged that he had sold the horse in good faith believing him to be fertile. The court agreed that there was no reason to doubt the seller's good faith and went on to say "In all likelihood this was also true of the horse." However, this being a breach of warranty action, good faith is not an issue and the plaintiff was allowed to prevail in his action for rescission.[7]

All in all, 1964 proved to be another significant year in this area of the law. We have little doubt that many more interesting developments lie ahead.

## PRODUCT LIABILITY DEVELOPMENTS 1964

The list of cases for 1964, grouped according to subject matter, is as follows:

[7] *Ericksen v. Poulsen*, CCH PRODUCTS LIABILITY REPORTER ¶ 5186, Utah.

## Foreign Substance and Contaminated Food Cases

*Harpur v. Martin's Local, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5161 (N.Y. Sup. Ct., App. Term, 1st Dept.)

*Gustafson v. Gate City Co-op Creamery*, CCH PRODUCTS LIABILITY REPORTS ¶ 5174 (S. Dakota)

*Webster v. Blue Ship Tea Room, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5225 (Mass.)

*Wagner v. Mars, Inc., et al.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5284 (Dist. Ct. App., Fla.)

*Sneed v. Clay Beaverson*, CCH PRODUCTS LIABILITY REPORTS ¶ 5298 (Okla.)

*Calumet Cheese Co., Inc. v. Chas. Pfizer & Co., Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5301 (Wis.)

## Foreign Substance Beverage Cases

*Williams v. Quaker State Coca-Cola Bottling Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5154 (Ct. Common Pleas, Pa.)

*Pierson v. The Borden Company*, CCH PRODUCTS LIABILITY REPORTS ¶ 5215 (La. Ct. Appl.)

*Ritter v. Coca-Cola Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5250 (Wisc.)

*Welch v. Coca-Cola Bottler's Association*, CCH PRODUCTS LIABILITY REPORTS ¶ 5300 (Ct. Civ. App. Tex.)

*Dr. Pepper Bottling Co. v. Scruggs*, CCH PRODUCTS LIABILITY REPORTS ¶ 5316 (Tenn. App.)

## Bursting Bottle Cases

*Atlanta Coca-Cola Bottling Co. v. Burke*, CCH PRODUCTS LIABILITY REPORTS ¶ 5187 (N. Y. Sup. Ct. Spec. Term)

*Savoie v. F. & M. Schaefer Brewing Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5187 (N. Y. Sup. Ct. Spec. Term)

*Gabriel v. Royal Products Division of Washington Products, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5209 (La. Ct. App.)

## Drug Cases

*Ball v. Mallinkrodt Chemical Works et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5166 (Ct. App., Tenn.)

*Chas. Pfizer & Co., Inc. v. Branch,* CCH PRODUCTS LIABILITY REPORTS ¶ 5170 (Tex. Ct. Civ. App.)

*Goldblatt v. William S. Merrell Co.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5173 (N. Y. Sup. Ct. Spec. Term)

*Love v. Wolf,* CCH PRODUCTS LIABILITY REPORTS ¶ 5247 (Calif. Dist. Ct. App.)

*DiBelardino v. Lemmon Pharmacal Co. et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5258 (Pa. Ct. Common Pleas)

*Philbrick v. Weinberger,* CCH PRODUCTS LIABILITY REPORTS ¶ 5290 (Calif. Dist. Ct. App.)

*Bennett v. Richardson-Merrell, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5303 (U.S.D.C., E. D., Ill.)

*McLeod v. W. S. Merrell Co. et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5318 (Fla. Dist. Ct. App.)

## Cosmetic Cases

*Young v. Clairol, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5168 (U.S.D.C., E. C. Pa.)

*Epstein v. Giannatasio,* CCH PRODUCTS LIABILITY REPORTS ¶ 5182 (Conn. Common Pleas)

*Bayhi v. S. H. Kress & Co.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5197 (La. Ct. App.)

*John A. Brown Co., Inc. v. Shelton,* CCH PRODUCTS LIABILITY REPORTS ¶ 5241 (Okla.)

*Hardman v. Helene Curtis Industries, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5249 (Ill. App.)

*Kaempfe v. Lehn & Fink Products Corp. et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5254 (N.Y. Sup. Ct. App. Div. 1st Dept.)

*Spiegel v. Saks 34th Street et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5255 (N.Y. Sup. Ct. App. Term)

*Wrenn v. Vincent et Vincent of Langley, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5272 (Md.)

*Howard v. Avon Products, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5294 (Colo.)

*Ptomey v. Sayers,* CCH PRODUCTS LIABILITY REPORTS ¶ 5305 (Super. Ct. Del.)

## Animal Feed Cases

*Green v. Ralston Purina Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 5190 (Missouri)

*Atlanta Tallon Company, Inc. v. John W. Eskelman & Sons, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5310 (Ga. Ct. App.)

## Defective Container Cases

*Kotiadis v. Gristede Bros., Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5180 (N.Y. Sup. Ct. App. Div. 1st Dept.)

*Gardner v. Coca-Cola Bottling Co. of Minnesota,* CCH PRODUCTS LIABILITY REPORTS ¶ 5195 (Minn.)

*Yentzer v. Taylor Wine Co., Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5223 (Pa.)

*Vassallo v. Sabatte Land Company, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5229 (Calif. Dist. Ct. App.)

*Huggins v. John Morrell & Co.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5239 (Ohio)

*James v. Childs et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5293 (La. Ct. App.)

*Foley v. Weaver Drugs, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5331 (Florida)

## Tobacco Cancer Cases

*Ross v. Philip Morris & Co., Ltd.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5184 (C. A. 8)

*Green v. American Tobacco Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 5341 (U.S.D.C., S. D. Fla.)

## Detergent Case

*Gibbs v. Procter & Gamble Mfg. Co. et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5312 (Ill. App.) **[The End]**

# The Latin-American Food Code

## Second Edition—1964

In August of 1964 the Latin-American Food Code Council published the Second Edition of the *Latin-American Food Code* under the mandate which it received from the VIII Latin-American Chemical Congress in Buenos Aires by a Resolution unanimously adopted on September 18, 1962. This Resolution also confirmed the transformation of the Permanent Latin-American Food Code Committee into a "Latin-American Food Council" (Consejo Latinoamericano de Alimentos) under the chairmanship of Dr. Carlos A. Grau, who was authorized specifically to represent the Council in all dealings and negotiations with FAO (Food and Agricultural Organization of the United Nations), WHO (World Health Organization), the joint FAO/WHO Codex Alimentarius Commission, and any other organization concerned with the drafting of international and regional uniform food standards.

The Latin-American Food Council consists of representatives from all twenty Latin-American Republics and of Puerto Rico. It continues the task previously performed by the Permanent Latin-American Food Code Commission to keep the *Code* "up to date" by periodically revising it at its own initiative and upon recommendations received from the various Governments, from professional and scientific bodies and agencies concerned with public health and food technology, and from organizations representing the food industry and the consumers.

Since the publication of the *First Edition of the Latin-American Food Code in 1960,*[1] many such suggestions and recommendations have been received. These are reflected in a number of amendments consolidated in the second edition, which is more voluminous than the first. It consists of 19 chapters and one annex, as compared with 18 chapters and one annex of the first edition; it comprises 833 articles, as compared with the previous 798; and the total number of printed pages is 419, as compared with 377. This increase in volume is mainly due to the fact that the former chapter XII—"Aqueous Beverages and Refreshing Foods" has been split into two chapters: Chapter XII—Aqueous Beverages, and Chapter XIII—Other Refreshing Products.

The result is that all subsequent chapters starting with "Fermented Beverages" have been renumbered. Moreover, all articles have been renumbered in the second edition so that future references to individual provisions of the *Code* should be implemented by an identifying reference to either the first or the second edition to prevent misunderstandings.

---

[1] Compare Index of the First Edition 1960 with Introduction by Dr. Carlos A. Grau in 15 FOOD DRUG COSMETIC LAW JOURNAL 678 (October, 1960). English translations of the following chapters of the First Edition were published in the FOOD DRUG COSMETIC LAW JOURNAL: Chapters I, II, III and V in February, 1963, pp. 194—218; Chapter IV in February, 1961, pp. 121—126; Chapter X in May, 1961, pp. 297—311; Chapter XII in June, 1962, pp. 355—379; Chapter XIV in September, 1963, pp. 491—504; Chapter XVI in November, 1961, pp. 641—677.

Chapter XVII "Food Improving Agents (Additives)" which was formerly Chapter XVI "Correctives and Additives" has been enlarged considerably.

An English translation of the Index of the Second Edition is reproduced below. [The Index reproduced includes the topics but pagination has been omitted.]

Copies of the second edition (original Spanish text) are now available and may be obtained from The Food Law Institute, Inc., New York City, at the price of $10.00 a copy.

## Index

**Chapter and Title**

XI. **Fruits and Vegetables**

Fruits

Garden produce (green vegetables and legumes)

Legumes

Preserves of vegetable origin

XII. **Aqueous Beverages**

Waters

Carbonated waters and similar products

Carbon dioxide

Ice

XIII. **Other Refreshing Products**

Syrups

Vegetable juices

Ices, sherbets and iced beverages

XIV. **Fermented Beverages**

Beers

Ciders

Wines and similar products

XV. **Spirituous Beverages**

Distilled alcoholic beverages and liqueurs

XVI. **Stimulating and Pleasurable Products**

Cocoas and chocolates

Coffee and coffee substitutes

Processed tobaccoes

Tea

Mate

XVII. **Food Improving Agents (Additives)**

Acidulants, alkalizers and buffers

Artificial sweeteners

Emulsifiers

**Chapter and Title**

Thickeners and stabilizers

Humectants and anti-caking agents

Yeasts and ferments

Coloring matters (natural coloring matters, permitted synthetic organic colors)

Improving and enriching agents

Flavors and aromatics

Vegetable condiments

Aromatic extracts

Edible mushrooms

Salt

Sauces, dressings and seasoning extracts

Bitters

Foaming agents

Protective substances

Vinegars

XVIII. **Dietary Foods**

XIX. **Miscellaneous Products**

Animal foods and animal by-products

XX. **Appendix-Household Articles**

General Provisions

Office supplies, inks and similar products

Miscellaneous articles

Home fuels

Disinfectants, air purifiers and germicides

Pesticides, rodentocides and similar products

Cleansing products

Toys and school supplies

Cosmetics and toiletries

Candles

Industrial poisons

**[The End]**

*Detailed Guidance on*
*Drug and Cosmetic Regulation*

# Food Drug Cosmetic Law Reports

# Drugs-Cosmetics Edition

Drug and cosmetic executives and their counsel must keep posted on fast-changing federal and state rules covering drugs, cosmetics and therapeutic devices—while keeping on top of the many technological and processing advances that prompt many changes in the rules. Because of this never-ending battle, many of them welcome the help CCH's Food Drug Cosmetic Law Reports—DRUGS • COSMETICS Edition offers.

Subscription for the REPORTS provides coverage of the application and interpretation of the Federal Food, Drug, and Cosmetic Act, as administered through the Food and Drug Administration, plus additional valuable help in working with related federal and state requirements.

1. Weekly Reporting to Keep You Posted.—Today's complex drug, cosmetic and device control problems and fast-changing rules make essential "instant" coverage of new laws and amendments; FDA regulations, rulings and releases; court decisions; color additives petitions.

2. Three Catch-Up Volumes Bring You TODAY's Rules.—Included at no extra cost, these Volumes bring together currently effective rules, with emphasis on such features as:

INDEX TO SUBSTANCES, listing the thousands of substances dealt with in the federal laws, FDA regulations, and food or color additives petitions, with multiple listings for compounds.

NEW DRUGS requirements, including safety clearance procedures.

FEDERAL PURITY and LABELING requirements and prohibitions for drugs, cosmetics, and therapeutic devices.

COURT DECISIONS interpreting drug and cosmetic law issues.

STATE PURITY, PACKAGING and LABELING requirements.

FEDERAL HAZARDOUS SUBSTANCES LABELING requirements.

FORMS prescribed under the Act.

COLOR ADDITIVES and PESTICIDE rules and petitions.

ANTIBIOTICS TESTING and CERTIFICATION requirements.

Subscribe for Drug and Cosmetic Regulation Reporting Now

Just your OK on the attached post-free Card starts everything your way now. Your volumes will come to you immediately, followed by weekly reporting to keep you up to date on new developments. Your satisfaction is guaranteed.

**COMMERCE CLEARING HOUSE, INC.**
PUBLISHERS of TOPICAL LAW REPORTS
420 LEXINGTON AVE. NEW YORK 10017
4025 W. PETERSON AVE. CHICAGO 60646
425 13TH STREET, N. W. WASHINGTON 20004

FOOD DRUG COSMETIC
LAW JOURNAL

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

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

---


A COMMERCE CLEARING HOUSE PUBLICATION