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Food Drug Cosmetic Law JOURNAL

A Lawyer's View of Drug Investigation . . . . . JAMES F. HOGE

Food and Drug Administration, Federal Trade Commission and the Deceptive Packaging of Foods . . WESLEY E. FORTE

The "Generic Every Time" Case: Prescription Drug Industry in Extremis . . . . . HARRY A. SWEENEY, JR.

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

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

A Lawyer's View of Drug Investigation.—*James F. Hoge,* a member of the New York Bar, presented this paper at the Research and Scientific Development Conference, Symposium on Clinical Research for Proprietary Medicines, on December 9, 1965. In this article, beginning on page 184, *Mr. Hoge* discusses the 1962 Amendments and drug investigation.

Food Research and the Food Laws.—*Wilbur A. Gould,* professor and head of the Processing and Technology Division, Department of Horticulture and Forestry, College of Agriculture and Home Economics, The Ohio State University, Columbus, Ohio, and the Secretary-Treasurer of the Ohio Canners and Food Processors Association, presented this article at the Institute of Food Technologists Meeting in St. Louis, Missouri. The importance of food standards and the voluntary compliance program of FDA to food researchers is the topic of this article which begins on page 191. Citing the standard of identity for canned tomatoes as an example, *Mr. Gould* shows the importance of having practical, up-to-date, flexible food laws.

The Future of the Codex Alimentarius Commission.—In this article beginning on page 201, *J. H. V. Davies,* Assistant Secretary of the Food Standards Division, United Kingdom Ministry of Agriculture, Fisheries and Food, the United Kingdom Delegate to the Joint FAO/WHO *Codex Alimentarius* Commission, and Vice Chairman of the Commission since the end of its third session, examines the past, present and future of the Commission and its work.

Food and Drug Administration, Federal Trade Commission and the Deceptive Packaging of Foods. — This article by *Wesley E. Forte,* a member of the Pennsylvania Bar, concerns the jurisdiction held by the Food and Drug Administration and the Federal Trade Commission over the distribution of deceptive packaged foods in interstate commerce.

Part I of *Mr. Forte's* two-part article appears in this issue of the JOURNAL beginning on page 205. The FDA's power over deceptive packaging of foods is discussed in this first part. The succeeding section examines the FTC and its power in this area. This will be presented in a future issue.

The "Generic Every Time" Case: Prescription Drug Industry in Extremis.—The "generic every time" issue is the topic of the article commencing on page 226. *Harry A. Sweeney, Jr.,* who has had a number of years of experience in the drug industry, discusses the questions raised by drug manufacturers and the Pharmaceutical Manufacturers Association as to the statutory authority of the FDA to issue regulations requiring the generic name to be present each time the brand name is used. *Mr. Sweeney* also comments on the procedural aspects of the "generic every time" case.

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Journal

A Lawyer's View of Drug Investigation

By JAMES F. HOGE

The Following Article Was Presented at The Research and Scientific Development Conference, Symposium on Clinical Research for Proprietary Medicines, on December 9, 1965. Mr. Hoge Is a Member of the New York Bar.

THE LEGAL PURVIEW OF CLINICAL RESEARCH FOR PROPRIETARY MEDICINES has horizons never contemplated until the coming of the 1962 Amendments. Historically, clinical investigation of drugs is, of course, old. It has been applied principally to prescription drugs, but it has also accompanied the introduction of new proprietary products and uses. It has been employed to determine and support therapeutic claims in the preparation of labeling and advertising and in the trial of regulatory actions with respect thereto, and in product liability litigation.

Emphasis on Clinical Evaluation

However, until recently—and as to both prescription and over-the-counter medicines—it has not been freighted with the volume and consequence of present emphasis. The genesis of this importance was the new drug provision of the 1938 Act. The concept of a drug being proved safe before introduction led inevitably to emphasis on clinical evaluation, and the coming of wonder drugs with their high potentials heightened it. Then the 1962 Amendments—with the requirement for pre-marketing proof of effectiveness as well as safety—intensified the need for and the responsibility of clinical investigation to an extent not yet seen.

The 1962 Amendments came—you remember—with the beat of accusatory inquiry and sensational publicity. The public-at-large became interested in and knowledgeable of drugs and their marketing as never before. These elements—as though electrically supercharged—lighted up the subject of adverse reactions and side effects in cases here and abroad of personal injury intimately related to drug investigation.

Spotlight on Drug Evaluation

So these amendments and these circumstances have put a spotlight on drug investigation which will not fade until it reaches quite beyond new drugs and prescription drugs. While it is with respect to those drugs that the specifications for clinical investigation are so minutely laid out by the regulations, the legal purview—it seems to me—must include all drugs.

In the first place, the new drug controls are not going to apply as exclusively to prescription drugs as they do now. In the proprietary field there will be new formulations, new dosages and new uses. That is the hope, certainly, of enterprising proprietary manufacturers. And I suggest it is going to be the hope of society itself as public interest in health and governmental attention thereto continue to expand, as surely they will under Medicare and other public and private health programs.

It is becoming accepted, I think, that safe and effective home remedies will be essential to any scheme of government medicine. It is already accepted that there are not sufficient physicians and hospitals for the treatment of all the minor ailments of a population that is constantly expanding in its numbers and in its needs. So—in this lawyer's view—the need and the use of medicines in self-medication will expand in some ratio to the population.

If this be so, then I think it must follow that the government interest in proprietary medicines will also expand; that requirements as to the safety and effectiveness of them will enlarge and that the interest of the public will increase and will relate to their manufacture, sale, advertisement, use, abuse, misuse and product liability.

Usefulness of Proprietary Medicines

The importance to the proprietary product of the amendment requiring a showing of effectiveness cannot be over-emphasized. And it presents a challenge that can only be met by research and investigation. Many who are critically-minded of proprietary medicines will

concede that they are harmless but contend that they are useless. Now, in the new scheme of things, the usefulness of many of them will be attested by government approval of new drug applications and by professional recognition of their assistance in health care. The law, as amended, now says that an article of drug is "new" unless it is "generally recognized" as (1) safe and (2) effective. One of the "grandfather clauses"—the one applicable to most proprietaries—will relieve from new drug procedure drugs which were on the market at the time of the Amendments of 1962 and which are labeled for the same conditions as then.

As to all of this, you may say "So what?" Proprietary drugs for years have been required to be effective; they are misbranded if their labeling is "false or misleading in any particular"; misbranded drugs, and their purveyors, are subject to all the sanctions of the law; criminal and civil. But there is a significant difference. In cases of misbranding, the government has the burden of proof; it must take the initiative and show by a preponderance of the evidence that the article is not effective as represented. In matters of new drug control, the burden is on the manufacturer. He must take the initiative and show by "substantial evidence" that his product will be effective as represented. His labeling must be approved before—not after—introduction, and perhaps after trial.

The sanctions are different, too. There are criminal and civil procedures in the courts, but, in addition, there are exacting and compelling procedures in the administrative bureau. A new drug application must first be approved, and it must continue so. For the Secretary is empowered to withdraw approval of an application if he finds that on the basis of new information, evaluated with the evidence available to him at the time of approval, "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have."

Quality Control Amendments

At this point, we ought to associate the quality control amendments. They make no distinction between new and old drugs or between drugs sold on prescription or over-the-counter. Under 501(a), a drug—new or old, prescribed or over-the-counter—"Will be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture" do not conform to current good manufacturing practice to assure that it meets the law's requirements "as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

While a drug is in the investigational stages, it is repeatedly checked for stability and is frequently assayed. The methods, facilities and controls must be set forth in the new drug application. They will be of substantial importance in bringing about approval of the application, and later disregard of them would be of material consequence in a decision to withdraw approval.

It is an interesting commentary—and perhaps worth the time to make it—that the division of drugs into two classes by the Durham-Humphrey Amendment in 1951 may now become less significant by the very amendments which in 1962 so sharply drew distinctions between the two. For, as we have said: clinical investigation presently under discussion is an outgrowth or concomitant of these amendments.

In the research and testing of drugs we will often find the same persons working with prescription and proprietary products. For in the industry as organized today the same corporate roof covers prescription and proprietary divisions.

"The Law and the Prophets"

Perhaps I am loading too much on drug investigation. I see that I am giving it concomitance with controls which come in various parts of the law and in various aspects of drug production and distribution. Whether or not I am technically exact, I do believe we should think in these terms because drug investigation being directed to safety and effectiveness is closely tied to the ultimate idea of the whole drug law. Safety and effectiveness! Isn't that, as the Scriptures would put it: "the law and the prophets"?

If so, then should we not next project drug investigation to labeling and advertising? The 1962 Amendments projected the Food and Drug Law into the advertising of prescription drugs. Historically, the control of advertising was the dividing and retarding issue in the enactment of the 1938 Act. All other provisions of the Act, with the exception of the new drug section, were practically settled when the Bill passed the Senate in May, 1935. For three years thereafter, the contest went on in the House between the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) and their respective supporters for control of advertising.

In 1962—without any apparent stress or strain—FDA control was inserted as to prescription drug advertising. I pose a question whether the operation of these amendments in the areas which we

are discussing today will, by accretion, lead into indirect FDA control of proprietary advertising.

If the proprietary is sold under an approved new drug application, then representations of its effectiveness must conform to those contained in the new drug application. Certainly, that is so as to labeling. The amended law is specific on that. New proprietary drugs may not be shipped in the investigational stage without strict labeling control. A new drug application will not be approved if the submitted labeling is false or misleading in any particular. And if the labeling, as later used, is found by the Secretary to be false or misleading in any particular, the approval, previously granted, may be withdrawn. In these circumstances, I question that advertising claims which are inconsistent with those in the approved labeling will long survive.

So much for proprietaries under new drug control. The demands for drug investigation will probably come sooner and stronger as to them, but drug investigation is going to be of prime and increasing importance to all proprietaries. There is going to be an insistance, I think, by the government, the public and the professions upon control of therapeutic claims in labeling and especially in advertising. The security of the proprietary industry's future is very dependent on the character and integrity of its advertising. As the amended law unfolds and health programs develop, the labeling and advertising of proprietary medicines must be adequately supported by research and investigation.

A Legal View of Drug Investigation

At this point, a legal view of drug investigation must focus on what is in effect a "fourth phase". The regulations, as you know, set forth three phases: (1) when, after animal experimentation, a new drug is first tried in man to determine toxicity and pharmacological action; (2) when it is tried on patients with regard to specific disease; (3) when it is evaluated for safety and effectiveness at optimum level for the disease condition for which the drug is to be recommended.

Now what may be called a fourth phase is the requirement of the law and regulations for reporting adverse reactions—as to effectiveness, as well as to safety—which develop after wide use, and even after abuse. Investigational use, at the most, will be only a fraction of the wide and varied use after introduction of a popular drug. So, continuing experience in contemporary use will be related to main-

tenance of approved new drug status, to labeling and to advertising. For labeling and advertising must allow for, and must indicate, proper use; must be premised on the accuracy of directions and warnings under Sec. 502(f) and on the capability of the layman to follow them in self-administration of the drug.

Product Liability

This leads directly into an increasingly sensitive and active area within the legal purview: Liability! I cannot close without mentioning it. A lawyer's view of drug investigation must include it. But the subject is too large and too complex for brief treatment. A lawyer may do more harm than good in touching subjects of this sort under limitations of time and subject. Liability at law, in any area, is usually a matter of application to the particular facts of the given case. So, lawyers cannot safely or wisely generalize.

But I must say to you—what you probably already know—that product liability with respect to drugs has taken on importance never before attached to it. You know of actual cases. You know something of the number of them, of the sizeable judgments in them and of the evolution of the legal concept from negligence to express warranty, to implied warranty, to strict liability—to liability without fault.

An article in a recent issue of *Trial,* published by the American Trial Lawyers Association, points the direction of this evolution. The article—written by a law professor—advocated strict liability for unexpected allergic reactions on the ground that strict liability would encourage greater care and more extensive pre-testing before product distribution; that the manufacturer was in a better position to bear the expense or to insure against it and thus distribute the cost.

Conclusion

Finally, and with particular relation to the theme of this Symposium—there are three categories for continuing inquiry. First, should government assume some form of responsibility for clinical investigation? In new drug control, the FDA dictates the specific qualifications for the clinical pharmacologist who undertakes the initial study of a new drug in animal and human investigation. The subsequent clinical work is subject to FDA approval. As to these drugs, future circumstances may impose some responsibility on government for the approved product; may lead to some plan of compensation insurance.

Second, the manufacturer's liability for the clinical investigator will depend upon the relationship and the conduct of the parties; whether the investigator is an independent contractor or an agent. Manufacturers are reticent to publicize arrangements for insurance and indemnification. But surely they should have them, and probably do.

Third, the clinical investigator has responsibility for himself. A physician engaged in clinical investigation has a variety of responsibilities. He may have liability to his patients, to the manufacturer and ultimately to the public. He must look to malpractice insurance, patient consent and release, contractual arrangement and indemnification by the manufacturer or other person for whom he may be doing the work. Violations of the law are not insurable.

The conclusion of the matter, I think, is that all who have anything to do with the introduction of medicines for human use have a legal responsibility—as well as a moral one—to bring to their work the highest possible degree of skill and integrity. Manufacturers and advertisers of proprietary medicines must assume a greater degree of care and accountability than ever before. As they do, they will put more reliance on research and investigation, and their products will gain dignity and be more worthy of acceptance. **[The End]**

SECOND SEMINAR ON "CONTROL PROCEDURES IN DRUG PRODUCTION" TO BE HELD

Hershey, Pennsylvania will be the location of the second in a series of seminars on "Control Procedures in Drug Production." The purpose of the July 17-22 seminar is to bring together the best information available to government, industry, and university on quality controls in drug production. Topics to be discussed at the seminar include research and development—quality control communication, raw material controls, manufacturing and in-process controls, buildings and equipment, finishing operations, drug control inspection, drug recalls, and personnel and quality awareness.

Sponsors of the seminar are the University of Wisconsin's School of Pharmacy and the University's Extension Services in Pharmacy in cooperation with the Pharmaceutical Manufacturers Association and the Food and Drug Administration. Attendance will be limited to approximately 100 persons consisting primarily of quality control, production, and engineering personnel of drug manufacturers. All sessions will be closed, but the University will publish the proceedings.

Further information and application forms for attendance can be obtained from Dr. William L. Blockstein, University of Wisconsin, Chairman, Extension Services in Pharmacy, 190 Pharmacy Building, Madison, Wisconsin 53706.

Food Research and the Food Laws

By WILBUR A. GOULD

The Following Article Was Presented at the Institute of Food Technologists Meeting in St. Louis, Missouri. Mr. Gould Is Professor and Head of the Processing and Technology Division, Department of Horticulture and Forestry, College of Agriculture and Home Economics, The Ohio State University, Columbus, Ohio, and the Secretary-Treasurer of the Ohio Canners and Food Processors Association.

APPROXIMATELY A QUARTER OF A CENTURY AGO, I started my career as a government food inspector in a cracker plant in the state of Michigan. In these intervening 25 years, I have seen many changes and improvements in our food industries and in our regulatory agencies. Basically, these changes have involved a new revised food law with several amendments including the pesticide, factory inspection, food additive and color additive amendments. These amendments and the earlier adoption of the minimum standards of quality, minimum fill of container and the standards of identity have been milestones in the growth of the food industry in this country. Further, this law has served the food industry the world over as a model law.

Even though we have an outstanding law and we can pride ourselves that we are the best-fed people in the world, there are always shortcomings and areas wherein improvements must be made. These areas are of concern to the food industry and, particularly, to the food technologists in the food industry who are concerned with the development of new products, formulations and process methodologies. Let it be stated at the outset that I believe in the Food, Drug and Cosmetic Law of 1938, I believe that it has done much for the growth of the food industry; however, there are two areas of great concern as we move forward in the immediate years ahead. The first of these is the area of food standards.

Markel[11] stated,

much could be done to ease the food processor's burden of food standardization without compromising the indicated legitimate consumer's interest. This could be achieved by restricting standardization to basic essentials. These are fixing of the required ingredients to insure the identity and fixing of their ratio to other ingredients by establishing floors for the expensive ingredients and ceilings for the inexpensive ingredients. The standards now being promulgated go away beyond this. They are virtually recipes.

Markel aptly concluded his article by stating, "the food technologist should continue to assume his proper function, that is, as chef and that the secretary of HEW should continue to assume his function, that is, as a regulator."

Brady[3] stated,

the steady growth of regulation is becoming burdensome and could well become even more so. I am deeply disturbed by the far wider regulatory powers now being asked by the FDA. This additional authority—including the right to inspect, among other things, all records, files, papers, processes, controls and facilities—is unnecessary and unwarranted. It seems to me that the ultimate purpose of the law—and I speak here only about regulatory law—is to make people responsible. It seems to me that the very heart of the law is a basic and positive assumption that men can be responsible and that laws serve as a minimum standard of integrity. But when laws multiply to the extent that they hem in every action, they tend to become more nearly a maximum standard. People become so occupied with legality that they have no time for morality. I do not believe that it is the spirit or intent of the law to stifle responsibility and with it, enterprise. Instead, working within the framework of the law, we must find a means whereby companies will operate for the public good, not out of fear of governmental reprisal, but because operating for the public good is second nature to the corporation. The future we all want can be had only by research and innovation. These can be had only in an atmosphere of freedom, and responsibility must go hand in hand with freedom.

The present food law has been most detrimental to standardized foods and those manufacturers in the United States that process these standardized foods. The list of standardized foods is relatively short, but they represent many of our basic staple processed food items[4,12]. When one establishes a food standard, he establishes a recipe. Bell and Greenleaf[2] state,

The criticism frequently heard is that too many standards of identity are of the recipe type and that these impede technological progress in several ways. In the first place it is said that they include unnecessary restrictions on optional ingredients and in the second an amendment is cumbersome and difficult. In the third place it is slow.

Standards stifle research in, at least, three areas: (1) the basic ingredient itself; (2) the optional ingredients or as we would modernly state it, food additives; and (3) the process methodology.

[11] References are listed on page 200.

Weckel[15] has stated this problem very succinctly,

Much ado is made about the great array of new and improved foods available to the American consumer. Most of the innovations, however, are with foods for which strangling definitions and standards do not exist. Failure to appreciate the legitimate advances of food science, and an adherence to outworn prejudices in favor of "established" products on the part of legislators and regulatory officials are effectively strangling progress which would benefit the consumer as well as the ultimate producer—the farmer.

LACK OF RESEARCH INTEREST at academic institutions in foods defined by strangling standards which maintain the status quo parallels industry's lack of interest in these foods—but for somewhat different reasons. A well-organized college program in food science and technology, particularly in the land-grant colleges, must be in balance among three activities: (a) teaching students, (b) conducting extension activities and (c) undertaking research. The research programs are supported by State, Federal and industry funds. Some fundamental as well as applied research is essential to a research program. Selection of projects for research study normally is related to stress of need for information and availability of talent and facilities. Often such information needs are urgent. In such cases, it is difficult to convince the college administrative director of research that study of products or processes FROZEN BY DEFINITION is more fruitful than other more pressing problems. In any event, there definitely is less inducement to study problems and processes more or less 'anchored' by definition. On the other hand, it is not encouraging to the research personnel to anticipate that newly developed processes or products must inevitably become "buried," or attain the dubious nom de plume of "imitation."

STATUTORY DEFINITIONS (those enacted by the Congress) would appear to be especially limiting on the direction of research, since no ready procedure for their modification is available. Congress has, in a number of instances, drafted the definitions and standards, including those for filled cheese (1896), filled milk, (1923), meats (1906), grain (1916), butter (1923), non-fat dry milk (1941), and poultry (1959). Having been drafted by Congress, these can be revised only by Congress. ADMINISTRATIVE STANDARDS, that is those promulgated by the FDA under the FDC Act of 1938 can be changed without an act of Congress. The Hale amendment has simplified the procedure of making changes in standards by doing away with the necessity for having formal hearings in those cases where there is no challenge by interested parties (which, of course, includes competitors).

An example cited by Weckel was Foremost's Dairies proposal to amend the evaporated milk standard filed with the Food and Drug Administration on August 3, 1960. Four months elapsed before the proposal was first published in the Federal Register. The first formal action was received on April 5, 1962, and the standard amended as of June 4, 1962. Thus, it took 22 months to accomplish this "uncontested" amendment to a food standard.

Weckel continues:

Several years ago scientists in the USDA's Western Regional Research Laboratory developed an improved fruit spread having much more natural fresh fruit flavor. Basically it is a frozen fruit jam or preserve. Since it does not meet the fruit content requirement of the FDA identity standard for jams and preserves, it can only be marketed under the "imitation" label. When these and similar problems are called to the attention of the FDA, one is informed: "It should be well understood that if a new product is developed and its marketing can be

References are listed on page 200.

shown to 'promote honesty and fair dealing in the interests of consumers', the way is open for standardization of the product in its own right and under its own name!" In this case it would mean attempting to develop a market for a product labeled "imitation," and then if successful applying for a standard. While this may be a legally correct procedure, it appears quite frustrating to a scientist that a food has to be called "imitation" until a standard for it is promoted!

Standard of Identity for Canned Tomatoes

Using tomatoes as an example, we find in the Food and Drug Administration (FDA) standard of identity promulgated in 1939, canned tomatoes are mature tomatoes of red or reddish varieties which are peeled and cored and to which may be added one or more of the following optional ingredients: (1) the liquid draining from such tomatoes during or after peeling and coring, (2) the liquids drained from the residue from preparing such tomatoes for canning consisting of peelings and cores with or without such tomatoes or pieces thereof, (3) the liquids drained from mature tomatoes of such varieties, (4) purified calcium chloride, calcium sulfate, calcium citrate, monocalcium phosphate or any two or more of these calcium salts in a quantity reasonably necessary to firm the tomatoes, but in no case, such that the amount of the calcium contained in such salts is more than .026 per cent of the weight of the finished canned tomatoes. It may be seasoned with one or more of the optional ingredients, (5) salt, (6) spices, (7) flavoring. It is sealed in a container and so processed by heat as to prevent spoilage.

Today, with many of the new varieties of tomatoes developed by our plant breeders in industry, at the state experiment stations, or at the universities, it is not necessary to core these. This is because there is no core present. Thus, a canner who cans tomatoes that are not cored, technically, is in violation of the Food, Drug and Cosmetic Act because he did not remove something that is not present. In other words, coring of tomatoes, as required in the law, may be passé with some of the new varieties. In my opinion, this is an attribute of quality and it should only be recorded as a defect, that is, if the core is present.

Another part of the standard of identity statement states that the product must be peeled. This has always bothered me as we consistently eat the fresh tomato without peeling. However, I will agree from the standpoint of sanitation and from the esthetic standpoint, peeling should be a part of the process for canning of tomatoes. With some of the new varieties of tomatoes that are being developed, however, peeling should not be a requirement but again an optional method in the process simply because the tomato cannot be peeled.

The optional ingredients enumerated for canned tomatoes are the liquid drained from such tomatoes or the residues from peel and core or the entire raw product. This has been in vogue since the beginning of this industry for the canning of this product; however, there always has been a concern within the industry as to why this product should be packed in its own juice. If the product is to be used as a side dish and it is whole fancy tomatoes, it would be my opinion based on laboratory samples, that we should be able to pack this product in a salt brine or in water that has been sweetened and salt and acid added. This to me would be the modern way of canning tomatoes, and I am deeply concerned that in this country we must continue to use the liquid drained from such tomatoes after peeling and coring or the liquid drained from the residue from preparing such tomatoes for canning consisting of peel and core with or without such tomatoes or pieces thereof. For it would seem to me by using water, we would have a more sanitary product and certainly a product that would be more appealing, particularly for serving of tomatoes as a side dish. By allowing water to be used, this would necessitate: (1) a higher quality canned product on the market, (2) a more sanitary product and (3) a product that would have greater use by the homemaker or consumer in her menu planning. Again I believe this should be an optional ingredient and those who want to water pack, should be allowed to do so.

Also from the standpoint of ingredients, there is still another concern. The standard of identity enumerates a number of calcium salts that may be used. The important part of this phrase is that a value has been established, and the salts shall not exceed this value. This value is not adequate for some tomato varieties and consequently the effect of adding the salt does not accomplish the objective originally intended when the calcium salts were approved in the standard of identity. It would appear to me that this should be enumerated in another way and, that is, by determining the firmness of the tomato. Of course, the difficulty here, may be, how to measure firmness. There are methods available and I am sure that new and better ones will be developed as time goes on.

Another optional ingredient that should be enumerated, if we have to enumerate optional ingredients, is citric acid. Citric acid is an inherent acid in most tomatoes. It varies from .25 per cent up to 1.0 per cent among the varieties. Generally speaking, varieties grown within one area will have at least 50 per cent variation in citric acid content. It would appear to me that the standard should be amended to allow as optional ingredients both citric acid and sugar. Both of

these affect the flavor of tomatoes, and they would be just as important, in my opinion, as spices, flavorings or salt.[9] Any food technologist should know how much of these ingredients (salt, sugar and/or acid) to add to a basic food item. Thus, there should be no established limit here. Limits for these food additives should be established by the firm using them based on consumer acceptance for their products. Thus, the canner could process a more standardized product, and the consumer would be more satisfied with finding the same flavor in the product which she purchases.

The last point in this standard that is of great concern at the present time, is that the standard of identity states, "It should be so processed by heat as to prevent spoilage." We have much research underway at the present time in the area of acidification, and with the proper amounts of citric acid and certain acceptable food additives (preservatives), we have been able to preserve canned tomatoes for long periods of time without the application of heat. It would appear to me that even though heat is necessary in the older definition of canning, it can be a stumbling block to modern technology if we have to heat a product like tomatoes. I believe that this requirement is quite antiquated with our present day processing knowledge. This is not meant to imply that heat may not be necessary for certain processes; however, it should not be a part of the standard of identity.

This standard of identity for canned tomatoes illustrates one of the areas of great concern from a food research standpoint. The Food, Drug and Cosmetic Act of 1938 was developed to protect the consumer. This is fine, but it appears to me that the consumer is not fully benefitting from our research programs because we cannot, under the existing standard of identity, provide the best processed product for the consumer. In other words, times have changed since 1940 when the standard of identity for canned tomatoes was adopted, and much technology has taken place in the past 25 years, yet the standard has not kept pace. Similar examples for some of the other standardized food products could be cited.

It is gratifying to know, however, that the Joint FAO/WHO *Codex Alimentarius* Commission Expert Committee on Processed Fruits and Vegetables published a Draft of an International Standard for Canned Tomatoes dated January, 1965.[1] Several of the above points have been taken care of in this standard, that is, (1) they may or may not be peeled, (2) cores are removed except from tomatoes of varietal characteristics in which the internal core is insignificant as to texture

References are listed on page 200.

or appearance, (3) may be packed with or without any liquid or vegetable substance added other than liquid draining from the tomatoes during canning and (4) acidifying agents (citric acid) and seasonings (salt, sugar, etc.) may be added. In regard to these international standards, Oser[13] has pointed out that "food standards should be drawn no more rigidly than necessary to establish the identity of the product and to prevent outright fraud, and they should be flexible enough to permit variations and improvements without sacrifice of the essential integrity of the food." Depew[7] speaking before the American Chemical Society stated,

common standards of methods and control would greatly aid international trade, and still assure safety and purity. As scientists you should insist that any wholesome, honestly labeled food should have an equal chance in the marketplace.... Food Standards should be developed on a sound scientific basis—not on misinformation or political experiences. There should be an international acceptance of valid analyses and the results of competent tests.

As I see it at this time, we must point out that standards are needed; however, they must not be of the recipe type. They must be flexible, they must be practical, they must be reasonable and most of all, they must be kept up to date. These standards must allow the food technologist the opportunity to develop new products, to develop new manufacturing processes and to utilize all of the facets of the food law concerned with food additives as optional ingredients. We are moving at a very rapid pace in our food research work whether it be at the academic institutions, in private laboratories or with some of our larger food corporations. The whole field of plant breeding, the area of horticultural characteristics, the processing methodologies and most importantly the use of acceptable food additives in the development of these new processing methods require our standards to be kept up to date. Times change and as changes take place our food demands become different. We must keep pace with our regulations or we will not be able to continue to say that "We are the best fed people in the world."

Voluntary Compliance

The second area of food research and one where in our food law people are much interested and one in which much effort is being directed at the present time is the area of voluntary compliance. From my position in the food industry, I see this as a great milestone in our whole pattern of food regulations. As with any advancement there are complications; however, these complications are not unreasonable and it would appear that through the voluntary compliance program

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much can be accomplished. In the voluntary compliance program much has been published[5],[14]. These published statements are all good, but it appears to me that two areas of great concern in establishing a truly voluntary compliance program are: (1) personnel and (2) methodology.

Franklin D. Clark[5] in January of this year reported the following in describing the food-drug inspector:

He is very carefully selected and trained to carry out his important task of protecting the consumer, while at the same time protecting the legitimate processor by being aware of his special problems. The Food and Drug inspector is selected from Civil Service Commission lists. The position requires among other things a 4 year college course in a physical or biological science leading to a degree. A comprehensive investigation is made into an inspector and an inspector candidate's background of prior employment if any and we attempt to weed out at this point persons who for any reason would be unsuitable to meet the public in a role of a regulatory official and as a representative of your government. We are proud of our record of selecting capable and dedicated people to this most important position. After appointment the inspector serves a year's probationary period during which he is put through an extensive training program, both academic and on-the-job training being included. He is sent out with more experienced inspectors to visit a variety of food and drug establishments in order to learn the problems, inspectional techniques and procedures. He is given a modest training in bacteriology, entomology, and rodentology, not to make him an expert in these sciences, but to furnish him with sufficient information so that he can observe and report with clarity and accuracy the factory conditions found to allow others who are trained in these sciences to make accurate conclusions. The purpose is of course to determine whether or not the conditions in the plant are such that the product of the establishment is or is not in compliance with the law. Our inspector trainee will be assigned to visit a variety of kinds of food and drug plants from the simpler operations to the most complex. He will first observe, then learn by doing—first under closer observation and instructions and as his understanding and skills develop under more remote guidance. We are dedicated to the principle that the only kind of inspector that we should send alone to your plant is a trained one and that to do otherwise would be a disservice to the inspector, to you, to FDA and to the consumer.

I heartily agree with these statements, but I must also state that a fair criticism of the present FDA program is the problem of people. The typical FDA inspector as I know him is a relatively young man. In general, I have observed that he lacks food technology training, as a matter of fact, he probably has none. He is not familiar with processing techniques and least of all, he is not familiar with the food industry terminology as a food technologist or the food industry uses it. This is not to say that this young FDA inspector is not doing his best. We as industry people, educators, and citizens have three responsibilities in this total program. We must offer programs at our educational institutions to assist in the training of men for this dedicated profession, that is, the FDA inspector. Secondly, we must assist the FDA

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administrators to help raise the salaries of these men so that the FDA job opportunity becomes a first choice for our top graduates rather than the last job that they look for. Lastly, as industry representatives, we must provide in-plant training programs by conduction tours, workshops, seminars, etc., in our factories and in our laboratories to assist these people to do a better job for the benefit of all concerned. Only by cooperation of both parties can we hope to accomplish all that must be done in this area.

The other serious criticism that I have of the present food and drug voluntary compliance program is the lack of methodology to those of us in the industry. Littlefield[10] also speaking in January of this year to the National Canners Association stated that:

FDA has recently been conducting training programs for supervisors on inspection techniques with the hope that state supervisory staff personnel will in turn train their own staff, all designed for uniformity and improved techniques for good establishments inspections. We all share the view that continuous training efforts aid in uniformity. The Association of Food and Drug Officials has developed an inspectors' manual to be made available to all jurisdictions as a valuable tool and a base upon which to build greater uniformity in respect to all mutual activities. It is hoped that Federal money will be made available to FDA to provide sufficient copies for each regulatory official.

Durrenmatt[6] goes further and states, "One of the basic problems which makes food law standardization so difficult is the use of widely different analytical techniques. Uniform food standards require uniform methods of analysis." This to me is the crux of the problem. There is no doubt that the most serious problem industry faces is the interpretation of our food laws from an adulteration standpoint and that is, the lack of knowledge of the methods which FDA uses. We in industry and in some cases in our academic circles are not too familiar with the methods which FDA may be using. Sure, we are aware of the Association of Official Agricultural Chemists (AOAC) and its journal, the FDA Bureau by-line and other publications. However, it would appear to me that the details of their methods should be published and made generally available to the food industry. They must be shared and FDA would do industry a big service by conducting educational seminars and workshops in their laboratories so that we would be better able to comply on a voluntary basis with the up-dated regulations. From an industry standpoint and from an academic standpoint we all conduct programs and we do invite FDA to appear on our programs. It seems to me that this should be a two-way street, thus FDA could assist very greatly and we in turn could better be able to comply on a voluntary basis. These manuals and methodolo-

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gies which they have are excellent, but they need to be made available to industry and particularly to those of us in the academic profession to help train our "budding" food technologists.

SUMMARY

In summary, two areas of our food laws are of great concern to the food researchers. These are: food standards and the voluntary compliance program of FDA. Food standards are needed to serve the food industry and the consumer; however, they must be practical, be kept up-to-date, be flexible and they must not be the recipe type of standard. The voluntary compliance program is a good program. To be most effective, food technologists in industry and at the academic level must work with the FDA inspector and the administrators and exchange views, methodologies and manuals for growth of the industry and the best interpretation of our laws. **[The End]**

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The Future of the Codex Alimentarius Commission

By J. H. V. DAVIES

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THE *CODEX ALIMENTARIUS* COMMISSION was set up as a body jointly sponsored by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) to elaborate international food standards by a conference held at Geneva in October, 1962. The first session of the Commission was held in Rome in June, 1963, the second in Geneva in September, 1964, and the third in Rome in October, 1965.

The end of the third session of the *Codex Alimentarius* Commission is a good time to take stock. The Commission began its deliberations in considerable uncertainty with many differences of opinion about what the scope and nature of its work should be and, of course, general uncertainty as to how international food standards could be developed successfully. In two and one-half years, a very fair start has been made. A method of procedure for the elaboration of standards was agreed at the second session. It looks formidable but when set out continuously, it is not so frightening. It does make sure that governments are given an opportunity to comment on the drafts at two stages. This is absolutely essential; there is no point in drawing up international standards which no one is prepared to accept. The procedure is briefly as follows: the Commission decides that an international standard for a certain product is required and designates a country to organize and provide the chairman for a committee to draft it. The committee drafts and circulates the draft to governments for comments and then redrafts in the light of these comments. The redraft is considered by the Commission and, as approved or amended, it goes again to governments for comments. These comments go back to the committee which takes a final look at the draft standard and sends it to the Commission for final approval as a *Codex* standard. It is then issued to governments for acceptance and, when a sufficient number have accepted it, it is printed in the *Codex*.

This is set out in ten steps. No standard has got beyond step six as yet—second comments by governments—and most are at step three—first comments by governments.

General Principles of the Codex

The most important matter disposed of at the third session was the General Principles of the *Codex*; its purpose, the scope and nature of *Codex* standards and the methods of acceptance open to governments. The spade-work on this matter was done at the first meeting of the *Codex* Committee on General Principles held in Paris in October, 1965, under the chairmanship of France. In spite of certain expectations that the meeting would witness a dramatic confrontation of the Old World and the New, it showed from the start a general understanding of the problems involved and a very large measure of agreement. Apart from a considerable clarification of the texts prepared by the conference held in October, 1962 which set up the *Codex,* the committee agreed that there should be a single type of *Codex* standard instead of the two types "trading" and "minimum platform" which had existed before. These had created a good deal of confusion and many of the most eminent figures of the *Codex* had given very different explanations of what they meant. They sounded even more obscure in French. As they have now been buried with very few tears, I am luckily excused the task of adding my own exegesis to the confusion.

The committee did try to retain something of the idea behind the two standards by allowing countries to accept a *Codex* standard in different ways. It can be accepted in its entirety or with a declaration of more stringent requirements or as a target to be put into effect in a stated number of years. The third method is intended particularly for developing countries.

All the proposals of the committee were accepted unanimously by the Commission. This really completed the basic framework of the *Codex* since it was combined with a final—it is hoped—revision of the Rules of Procedure in the light of the experience so far gained. The only outstanding procedural matter is a guide-book for *Codex* committees on how they should run their business. It had been hoped that this might also be dealt with at the third session but this did not prove possible and the matter will have to be completed at the fourth session in November of this year.

It certainly seemed at the third session that the storms that had threatened to burst at the first and second sessions had passed away and that the Commission had settled down to a series of admittedly duller

but constructive sessions which would mainly be devoted to its real business. Of course, only one lot of draft standards have so far come before the Commission—those on sugar—and these (apart from one which was sent back to the committee for further study) were approved for transmission to governments for comment without much discussion. The hard work will come when a standard comes before the Commission for final approval. This is not likely to happen before the fifth session in 1967.

The Committees

At the moment the spotlight is on the committees—six general, eight on particular commodities and two joint groups with the Economic Commission for Europe. Most of these have made much more progress than was expected and have produced the first drafts of a fair number of standards. A year ago there was a good deal of criticism of the *Codex* on the grounds that its aims were good but with its lumbering procedure and vast numbers of committees nothing would ever get done. Now the general complaint is that people cannot keep up at the breakneck speed that everything is going.

It is true that the founding fathers underestimated the vast amount of paper that the committees would turn out that has to be translated into two other languages and sent all over the world and immediately provokes commenting paper in return which has again to be retranslated and circulated. The very modest Secretariat seems in danger of not having the time to keep the paper on the move let alone performing all the other tasks that are laid upon it and coping with an ever-increasing miscellaneous correspondence which will grow as the fame of the *Codex* grows. It seems increasingly clear that the sponsoring international organizations, FAO and WHO, are having difficulty in meeting the *Codex* Programme's increasing demands for translation. In many cases, it is necessary, if the committees are to proceed with their work in a smooth way and hold annual meetings, for a very strict time-table to be adhered to. There are already signs that this is not being managed. Severe delays, quite apart from losing years at a time, are bound to cause enthusiasm to fall off. This is a matter that the Commission will have to consider very carefully. It may be that the only solution will be for countries running committees to do more of the issuing and translating of papers themselves. Something has to be done to prevent the gathering speed and the harmony of views in committees from being thwarted by the twin curses of a tower too many in Babel and a duplicating machine too few in Rome.

But this is again basically a procedural matter. It is unfortunately true that procedure is a good deal more interesting than trying to hammer out international standards. But this is what the *Codex* has to do and it is not clear how it will tackle it. When a standard comes before the Commission for the last time—step eight—with no further opportunity for government comments, it may not get the same easy passage as on its former appearances. It will, of course, have had very close study by a committee of experts in the light of two sets of government comments, but attendance at these committees is usually of about 20 countries, whereas about 40 come to the *Codex* itself and this number is likely to grow. The extra countries are bound to wish to make their views known and the Commission will have to find a procedure that will enable them to do so effectively, without causing too much delay and without going over too much old ground again. A great deal of responsibility will need to be shown at this stage if the standards are to be dealt with constructively. The proper balance has to be struck between the perfect and the practical. A standard must not represent the minimum on which agreement can be reached but it must take account of reasonable commercial practice. It must be a standard which governments can be expected to accept, but it must not be one so undemanding that it would make no difference whether governments accept it or not. The great hope is that governments will accept *Codex* standards and will be prepared to change their laws to bring them into conformity with the standards—as a number have already done in respect of those evolved by the Committee on Milk and Milk Products which is now under the *Codex* aegis but considerably antedates it.

Conclusion

Will the *Codex* do any good? It could produce a harmony in food legislation which would be a distillate of common experience, a safeguard to health everywhere and of major assistance to international trade. It could also provide a corpus of the best that has been known and thought about food law which could be used by any developing country which was at an early stage in the production of its own food legislation. This is what the *Codex* could do in the future; it has already produced a great deal more understanding between people working in this field, whether in government or not, and has given them a sense of common purpose. Some of the many meetings have been more interesting or more successful than others, but I am sure none of the participants regrets any of the time and effort that they have entailed. **[The End]**

Food and Drug Administration, Federal Trade Commission and the Deceptive Packaging of Foods

By WESLEY E. FORTE

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IN 1914 CONGRESS EMPOWERED THE FEDERAL TRADE COMMISSION (FTC) to stop "unfair methods of competition in commerce." [1] In 1938 Congress further empowered the FTC to stop "unfair or deceptive acts or practices in commerce." [2] In 1938 Congress also authorized the United States Department of Agriculture to stop the distribution of containers of foods, drugs, devices, and cosmetics in commerce which were "so made, formed, or filled as to be misleading." [3] This power was transferred to the Secretary of

[1] Federal Trade Commission Act § 5, 38 Stat. 719 (1914), as amended, 15 U. S. C. § 45(a)(6) (1964).

[2] 52 Stat. 111 (1938), as amended, 15 U. S. C. § 45(a)(6) (1964).

[3] The 1906 Federal Food and Drug Act prohibited false and misleading labeling and required a correct statement of the weight or measure of the contents but did not prohibit the use of misleading containers. See ch. 3915, 34 Stat. 768 (1906). The need to protect the public from economic fraud by slack-filled and other deceptive containers became apparent almost immediately after the passage of the 1906 act and a proposed amendment intended to prohibit this deception was introduced in the House of Representatives in 1919. See Depew, "The Slack-Filled Package Law," 1 *Food Drug Cosm. L. Q.* 86 (1946). In 1938 Congress, in the Federal Food, Drug and Cosmetic Act, enacted the first provisions in the federal food and drug laws prohibiting the use in commerce of containers for foods, drugs, and cosmetics "so made, formed, or filled as to be misleading." Federal Food, Drug and Cosmetic Act § 403(d), 52 Stat. 1047 (1938), 21 U. S. C. § 343(d) (1964); Federal Food, Drug and Cosmetic Act § 502(i)(1), 52 Stat. 1051

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Health, Education and Welfare (HEW) in 1953 and is administered by the Food and Drug Administration (FDA) acting under the Secretary's supervision.[4] Despite these broad grants of authority, Congress is now considering new legislation which would authorize the FDA and the FTC to promulgate regulations, having the force of law, to prevent the distribution of consumer commodities for retail sale in packages of sizes, shapes, or dimensional proportions which are likely to deceive retail purchasers.[5] The proposed new legislation

(Footnote 3 continued.)
(1938), 21 U. S. C. § 352(i)(1) (1964); Federal Food, Drug and Cosmetic Act § 602(d), 52 Stat. 1054 (1938), 21 U. S. C. § 362(d) (1964). These provisions have never been amended.

[4] The functions of the Secretary of Agriculture under the Federal Food, Drug and Cosmetic Act were transferred to the Federal Security Administrator in 1940 and the functions of the Federal Security Administrator were transferred to the Secretary of HEW in 1953. See CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 34, at 4108 n.1. (1965).

[5] See S. 985, 89th Cong., 1st Sess. § 3(c)(2) (1965). The purpose of S. 985 is to prevent the use of unfair or deceptive methods of packaging or labeling of consumer commodities. Under S. 985, the FDA and the FTC would be authorized to promulgate various regulations governing packaging and labeling of consumer commodities, if these regulations were necessary to preserve fair competition or to enable consumers to make rational comparisons with respect to price or other factors, or to prevent the deception of consumers. The FDA would issue the regulations relating to foods, drugs, cosmetics, and devices and the FTC would issue regulations relating to all other consumer commodities. S. 985, 89th Cong., 1st Sess. § 3(b)(1) (1965).

Nothing in S. 985 would solve the potential problems which exist because of the concurrent jurisdiction of the FDA and the FTC over deceptively packaged foods, drugs, devices and cosmetics. While the bill, in §§ 3(b)(1)(a) and 3(c), provides that new regulations concerning the packaging and labeling of these products shall be promulgated by the Secretary of Health, Education and Welfare, it also provides, in § 9(a), that nothing contained therein shall supersede or adversely affect the Federal Trade Commission Act. The FDA regulations would therefore not be binding upon the FTC and the FTC could probably issue trade practice and trade regulation rules which conflict with the regulations issued by the FDA under S. 985. Packaging which complied with FDA regulations also might be the subject of a cease and desist order issued by the FTC. A jurisdictional quagmire may thus result. Proponents of S. 985 argue that the new bill merely continues the concurrent jurisdiction which both agencies have had over deceptively packaged foods since 1938. This ignores the increased likelihood of a conflict between the FDA and the FTC if the FDA is given increased power to issue substantive regulations over packaging at a time when the FTC has begun to exercise its long dormant power over deceptively packaged foods.

Prior versions of S. 985 are S. 3745, 87th Cong., 2d Sess. (1962) and S. 387, 88th Cong., 1st Sess. (1963). Companion bills have also been introduced from time to time in the House. S. 387 was reported favorably by the Senate Subcommittee on Antitrust and Monopoly to the Senate Judiciary Committee. The bill died there. S. 985 has been referred to the Senate Committee on Interstate Commerce. 111 Cong. Rec. 3163 (daily ed. Feb. 19, 1965).

Senator Philip A. Hart of Michigan is regarded as the most prominent sup-

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makes a review of the present law of deceptive packaging both timely and appropriate.

The foregoing congressional grants of authority give the FTC and the FDA concurrent jurisdiction over the distribution of deceptively packaged foods, drugs, devices and cosmetics in interstate commerce.[6] The FTC has usually left the policing of deceptive packages of these products to the FDA, an arrangement which conforms generally to the working agreement between these two agencies.[7] However, there is no legal barrier to the exercise of the FTC's jurisdiction over deceptively packaged foods, drugs, devices and cosmetics and therefore the only deterrent to FTC action is this vague "gentlemen's agreement" between the FTC and the FDA.[8] Industry sources

(Footnote 5 continued.)
porter of this type of legislation and these bills have been variously referred to as the "Truth-In-Packaging Bills," the "Hart Bills" or more recently the "Fair Packaging and Labeling Bills."

[6] In 1938, Congress passed the Wheeler-Lea Act. As noted above, the Wheeler-Lea Act amended the Federal Trade Commission Act to give the FTC jurisdiction over "unfair or deceptive acts or practices in commerce" in addition to its previous jurisdiction over "unfair methods of competition in commerce." 52 Stat. 111 (1938), as amended, 15 U. S. C. § 45(a)(6) (1964). The Wheeler-Lea Act also gave the FTC the right, under certain circumstances, to sue for an injunction or criminal penalties for false advertisements of foods, drugs, devices or cosmetics. Federal Trade Commission Act §§ 13-15, 52 Stat. 115 (1938), as amended. 15 U. S. C. §§ 53-55 (1964). Labeling is exempted from the definition of false advertisements. Federal Trade Commission Act § 15(a), 52 Stat. 116 (1938), as amended, 15 U. S. C. § 55(a)(1) (1964). It was contended in *Fresh Grown Preserve Corp. v. FTC,* 125 F.2d 917 (2d Cir. 1942). that the Wheeler-Lea Act put labeling beyond the FTC's jurisdiction, but the court rejected that argument. See also Freer, "The Federal Trade Commission's Procedures and Policies in the Administration of the Wheeler-Lea Amendments Relating to Food," Drug and Cosmetic Advertising, 3 *Food Drug Cosm. L. Q.* 350, 355-56 (1948); Kelley & Cassedy, "The Federal Trade Commission Act as Amended by the Wheeler-Lea Act," 2 *Food Drug Cosm. L. Q.* 315, 326-28 (1947). These authorities agree that Congress intended the Wheeler-Lea Act to increase the FTC's powers and that the exemption for labeling is only an exemption from the injunction remedy or criminal penalties relating to false advertisements of products under FDA jurisdiction. The FTC can still challenge false or misleading labeling of these products under its general cease and desist power as an unfair method of competition or unfair or deceptive act or practice and does so. Deceptive packaging of foods is almost by definition an unfair method of competition or deceptive act or practice and there is no exemption in the FTC Act relating to it. Deceptive packaging of foods is therefore even more plainly within FTC jurisdiction than false or misleading labeling.

[7] The working agreement between the FTC and the FDA is set forth at 3 Trade Reg. Rep. ¶ 9850 (1954).

[8] The working agreement between the FTC and the FDA provides that unless the agencies otherwise agree, the FTC will exercise sole jurisdiction over all advertising of foods, drugs, devices, and cosmetics and the FDA will exercise sole jurisdiction over all labeling of foods, drugs, devices, and

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report that the FTC's traditional reluctance to tackle cases involving deceptively packaged foods is now ended and that attorneys from the FTC are diligently shopping in their neighborhood grocery stores for deceptive packaging cases.[9] If this is true, we are entering an era in which, without any new legislation, the food industry at least will be subject to dual regulation of its packages in practice as well as in theory.[10] While the FDA's power over deceptive packaging of foods has been partly crystallized by litigation and analyzed by the commentators,[11] the FTC's concurrent power remains almost unexplored.[12] For that reason, this article will examine the FTC's power to prevent the deceptive packaging of foods in somewhat greater detail than the FDA's corresponding power.

(Footnote 8 continued.)
cosmetics. 3 *Trade Reg. Rep.* ¶ 9850, at 16482-83 (1954). Labeling includes the printed material on the container but does not include the container itself. See Federal Food, Drug and Cosmetic Act § 201(m), 52 Stat. 1041 (1938), 21 U. S. C. § 321(m) (1964). Since labeling is more closely related to the container than advertising, it could be reasoned that the FDA was intended to have jurisdiction over the regulation of the container as well. FTC Chairman Dixon's position is that the FDA has the responsibility for policing deceptive packaging of foods, drugs, devices and cosmetics under the present working agreement between the agencies. See Hearings Pursuant to S. Res. 258 Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 87th Cong., 1st & 2d Sess. 821-22, 824 (1962) [hereinafter 1962 Hearings]. He feels, however, that the FTC should be given this responsibility under the new legislation since the FTC's expertise concerns economic fair dealing while the FDA's expertise concerns safety and purity. Hearings on S. 985 Before the Senate Committee on Commerce, 89th Cong., 1st Sess. 81 (1965) [hereinafter 1965 Hearings].

[9] See *Food Chemical News,* April 6, 1964, pp. 3-5; *Advertising Age,* April 13, 1964, p. 3; *Food Chemical News,* Aug. 17, 1964, pp. 13-15; *Advertising Age,* Jan. 4, 1965, p. 36. See also Brennan, "Affirmative Disclosure in Advertising and Control of Packaging Design Under the Federal Trade Commission Act," 20 *Bus. Law.* 133, 142-44 (1964).

[10] The FTC's last reported action against a deceptively packaged food (or other articles subject to the FDA's jurisdiction) took place over twenty years ago. See Harry Greenberg, 39 F. T. C. 188 (1944). FTC activity concerning deceptive packaging of items not subject to FDA jurisdiction has also been infrequent. See, for example, Papercraft Corp., Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964); U. S. Packaging Corp., 53 F. T. C. 1174 (1957) (consent order).

[11] Depew, above, cited at footnote 3, at 86; Martin, "Section 403(d)—Containers So Made, Formed or Filled as to Be Misleading," 8 FOOD DRUG COSMETIC LAW JOURNAL 663 (1953); Legislation and Administration, "The Consumer in the Marketplace—A Survey of the Law of Informed Buying," 38 *Notre Dame Law.* 555 (1963); see Note, "Federal Regulation of Deceptive Packaging: The Relevance of Technological Justifications," 72 *Yale L. J.* 788 (1963).

[12] The courts have had almost no opportunity to pass on the FTC's powers over deceptive packaging although there have been a number of decisions at the FTC level. See text accompanying notes 146-60 infra. The FTC's powers over packaging were

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I

The FDA and the Deceptive Packaging of Foods

A. Rulemaking

The FDA can establish a reasonable standard of fill of container for any food when such action will promote honesty and fair dealing in the interest of consumers.[13] Notice of the proposed standard of fill is published in the *Federal Register* and interested persons are given an opportunity to present their views on the proposal.[14] After views have been considered, the proposed standard is made public as an order [15] and persons adversely affected may object to the order and demand a public hearing.[16] After the public hearing, the final order is published [17] and persons adversely affected may petition the United States court of appeals for a judicial review of the order.[18] The courts will probably not permit the standard to be collaterally attacked in civil enforcement actions thereafter.[19]

The FDA has established standards of fill for certain canned fruits and fruit juices,[20] canned shellfish,[21] canned tuna fish,[22] canned

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(Footnote 12 continued.)
reviewed briefly in 38 *Notre Dame Law.*, above, cited at footnote 11, at 568-70; and in Brennan, above, cited at footnote 9, at 133, 139-44.

[13] Federal Food, Drug and Cosmetic Act § 401, 52 Stat. 1046 (1938), as amended, 21 U. S. C. § 341 (1964).

[14] Federal Food, Drug and Cosmetic Act § 701(e), 52 Stat. 1055 (1938), as amended. 21 U. S. C. § 371(e)(1) (1964).

[15] Ibid.

[16] Federal Food, Drug and Cosmetic Act § 701(e), 52 Stat. 1055 (1938), as amended, 21 U. S. C. § 371(e)(2) (1964).

[17] Federal Food, Drug and Cosmetic Act § 701(f)(1), 52 Stat. 1055 (1938), amended, 21 U. S. C. § 371(e)(3) (1964).

[18] Federal Food, Drug and Cosmetic Act § 701(f)(1), 52 Stat. 1055 (1938), as amended, 21 U. S. C. § 371(f)(1) (1964).

[19] See *Byrd v. United States,* 154 F.2d 62 (5th Cir. 1946) (collateral attack prohibited in a civil action except on constitutional grounds); see also *United States v. Bodine Produce Co.,* 206 F. Supp. 201 (D. Ariz. 1962) (collateral attack prohibited in a criminal action except for challenges based on statutory requirements relating to notice and hearing). Cf. *Butler v. Kavanagh,* 64 F. Supp. 741 (E. D. Mich. 1945), aff'd per curiam, 156 F. 2d 158 (6th Cir. 1946); Developments in the Law—The Federal Food, Drug and Cosmetic Act, 67 *Harv. L. Rev.* 632, 670 (1954). But see *United States v. Lord-Mott Co.,* 57 F. Supp. 128 (D. Md. 1944) (collateral attack permitted in a criminal action).

[20] Standards of fill for canned fruits and fruit juices include: peaches, 21 C. F. R. § 27.4 (1965); apricots, 21 C. F. R. § 27.12 (1965); pears, 21 C. F. R. § 27.22 (1965); cherries, 21 C. F. R. § 27.32 (1965); fruit cocktail, 21 C. F. R. § 27.42 (1965); crushed pineapple, 21 C. F. R. § 27.52 (1965); and pineapple juice, 21 C. F. R. § 27.56 (1965).

[21] Standards of fill for canned shellfish include: shrimp, 21 C. F. R. § 36.3 (1965); and oysters, 21 C. F. R. § 36.6 (1965).

[22] 21 C. F. R. § 37.3 (1965).

vegetables [23] and canned tomatoes.[24] Some of these standards are quite specific (for example, the standard of fill for canned crushed pineapple is a fill of not less than ninety per cent of the total capacity of the container).[25] Other standards seem merely a reminder that the FDA expects industry to avoid unnecessary slack-fill (for example, the standard of fill of a container for canned peaches is the maximum quantity of peaches that can be sealed in the container and heat-processed without crushing and breaking).[26] A food which falls below the standard of fill must be labelled "Below Standard in Fill." [27] Foods not so labelled are misbranded and subject to condemnation.[28] Even if the food is correctly labelled "Below Standard in Fill," it may be considered misbranded if it is so slack-filled as to be misleading.[29]

There has been only one action in which a litigant contended that an FDA standard of fill was invalid and in that action the court sustained the standard.[30]

B. Individual Actions

1. Seizures

Section 403(d) of the Federal Food, Drug and Cosmetic Act provides that a food is misbranded "if its container is so made, formed, or filled as to be misleading." [31] The FDA may have condemnation (or "seizure") proceedings instituted in a federal district court against misbranded foods having the requisite connection with interstate commerce.[32] If the district court finds the food is misbranded, the food will be condemned and destroyed or returned to its owner ("claimant") under bond to be repackaged under FDA supervision.[33] After the first judgment in the FDA's favor, multiple seizures may be made.[34]

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[23] Standards of fill for canned vegetables include: peas, 21 C. F. R. § 51.3 (1965); corn, 21 C. F. R. § 51.22 (1965); and mushrooms, 21 C. F. R. § 51.503 (1965).

[24] 21 C. F. R. § 53.42 (1965).

[25] 21 C. F. R. § 27.52 (1965).

[26] 21 C. F. R. § 27.4 (1965).

[27] 21 C. F. R. § 10.7 (1965). See Federal Food, Drug and Cosmetic Act § 403(h)(2), 52 Stat. 1047 (1938), 21 U. S. C. § 343(h)(2) (1964).

[28] Federal Food, Drug and Cosmetic Act § 304, 52 Stat. 1044 (1938), as amended, 21 U. S. C. § 334 (1964).

[29] 21 C. F. R. § 10.1(c) (1965); see Austern, "The Formulation of Mandatory Food Standards," 2 *Food Drug Cosm. L. Q.* 532, 570-71 (1947).

[30] *Willapoint Oysters, Inc. v. Ewing*, 174 F. 2d 676 (9th Cir.), cert. denied, 338 U. S. 860 (1949).

[31] 52 Stat. 1047 (1938), 21 U. S. C. § 343(d) (1964).

[32] Federal Food, Drug and Cosmetic Act §§ 304(a), (b), 52 Stat. 1044 (1938), as amended, 21 U. S. C. §§ 334(a), (b) (1964).

[33] Federal Food, Drug and Cosmetic Act § 304(d), 52 Stat. 1045 (1938), as amended, 21 U. S. C. § 334(d) (1964).

[34] Federal Food, Drug and Cosmetic Act § 304(a), 52 Stat. 1044 (1938), as amended, 21 U. S. C. § 334(a) (1964).

There have been four principal cases involving foods which were allegedly packed in containers which were so made, formed or filled as to be misleading and these cases, which are summarized below, are basic to an understanding of the law of deceptive packaging.

The first significant case involving section 403(d) was *United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding.*[35] In that case, condemnation proceedings were instituted against cases of vanilla pudding which had been shipped in interstate commerce and which were allegedly misbranded under section 403(d). The pudding filled fifty-five per cent of the exterior box without allowance for the removable inner package which the court found "reasonably necessary." [36] The court found that the container used for the pudding was a standard container for this and similar commodities, and contained a standard amount of ingredients to make a standard amount of finished product and the amount of finished product expected by the consuming public. The court also found that the container was universally recognized as containing enough ingredients to produce one pint of pudding; that this fact was known to the public generally, and that there was no relationship between the size of the container and the reasons causing the public to purchase this product. Since the container was not so made, formed or filled as to be misleading in fact, the district court rendered a judgment for claimant.

In *United States v. Cataldo,*[37] the FDA sought to condemn certain boxes of candy for alleged violation of section 403(d). The candy occupied 45.3 per cent of the carton, the remainder of the space being filled primarily with bulky wrappings. The district court held that the packages were not misleading and the court of appeals affirmed a judgment for claimant, refusing to lay down a rule that 50 per cent slack-fill was illegal per se.

United States v. 116 Boxes of Arden Assorted Candy Drops [38] also involved boxes of candy. The boxes usually contained 17 drops of candy with 33 per cent empty space. Claimant proved that 17 drops per box were the maximum possible with machine packing and that when the machine was set to put 18 drops in each box, it occasionally jammed. 20 drops could be put in each box if it were filled by hand. The district court held that the issue was whether the ordinary customer (not necessarily an adult) would expect to receive more candy in the box. That issue was resolved in favor of claimant. A dictum

[35] 71 F. Supp. 279 (D. Ariz. 1946).
[36] Id. at 280.
[37] 157 F. 2d 802 (1st Cir. 1946).
[38] 80 F. Supp. 911 (D. Mass. 1948).

indicates that knowledge of the problems of machine packaging will be imputed to the ordinary purchaser.[39]

In *United States v. 174 Cases of Delson Thin Mints,*[40] a third case concerned with boxes of candy, the evidence showed that only 44 per cent of the total volume and only 75 per cent of the practical volume of the boxes was filled with candy. Much of the space was filled with hollow dividers. A marketing research consultant testified that many purchasers were influenced in their selection of a commodity by the size of its package, and government witnesses attested that many purchasers expected from the size of this and similar boxes to receive more candy than was actually present in the boxes. Claimant's witnesses testified that the boxes with hollow ends and partitions were necessary to protect the candy from breakage and that there was no intention to mislead the purchaser. The district court rendered a judgment for claimant, holding that there was no adequate proof that the average adult of normal intelligence would purchase the boxes expecting to receive any particular number of pieces of candy.[41]

The court of appeals reversed and remanded, holding that there are two ways in which a trial court can hold for a claimant in a deceptive packaging suit under section 403(d):

> First, the court can find as a fact that the accused package is not made, formed, or filled in such a way that it would deceive the ordinary purchaser as to the quantity of its contents. . . . Alternatively, the court may find as a fact that even though the form or filling of the package deceives the ordinary purchaser into thinking that it contains more food than it actually does, the form and filling of the package is justified by considerations of safety and is reasonable in the light of available alternative safety features.[42]

The district court had erred, according to the court of appeals, because it had made neither of these findings. On remand, the district court made each of these findings against the government and the court of appeals affirmed.[43]

Although the limited number of judicial decisions makes definitive conclusions impossible, careful analysis of these four cases, a few analogous decisions, and the act itself yields the principles by which

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[39] Id. at 913.

[40] 180 F. Supp. 863 (D. N. J. 1960), rev'd, 287 F. 2d 246 (3d Cir. 1961). The opinion of the court of appeals is generally regarded as the leading decision under § 403(d).

[41] 180 F. Supp. at 868. The court of appeals graciously said that the district court's misconception derived from the language employed in *Arden Assorted Candy Drops,* 287 F. 2d at 248 n. 1. But in Arden the court found that the purchaser would not expect any particular number of lozenges in the container. 80 F. Supp. at 913.

[42] 287 F. 2d at 247.

[43] *United States v. 174 Cases of Delson Thin Mints.* 195 F. Supp. 326 (D. N. J. 1961), aff'd per curiam, 302 F. 2d 724 (3d Cir. 1962).

containers of foods should be judged in proceedings for seizure under section 403(d). These principles include the following:

(1) A container may mislead the ordinary purchaser in regard to the quantity of its contents even though the correct net weight is stated prominently and conspicuously on the label.[44] A container normally makes at least two representations to the ordinary purchaser. One representation relates to the weight (or measure or count) of its contents while the other relates to the volume of its contents.[45] In deciding whether the container is misleading because of slack-fill, the court should first ask what representations were made concerning the volume of the contents and then consider whether those representations were misleading.[46]

[44] See *United States v. Cataldo,* 157 F. 2d 802 (1st Cir. 1946); *United States v. 116 Boxes of Arden Assorted Candy Drops,* 80 F. Supp. 911 (D. Mass. 1948). Cf. FDA Trade Correspondence No. 23, February 9, 1940, in Kleinfeld & Dunn, Federal Food, Drug and Cosmetic Act 1938-1949, at 580-81 (1949). [The five volumes under this title for 1938-1949, 1949-1950, 1951-1952, 1953-1957, and 1958-1960 are hereinafter cited as 1938-1949, 1949-1950, 1951-1952, 1953-1957, and 1958-1960 Kleinfeld. The fifth edition was co-authored by Kleinfeld and Kaplan.]

[45] Section 403(e) of the Federal Food, Drug and Cosmetic Act states that a food is misbranded if it is in package form and does not bear a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. 52 Stat. 1047 (1938), 21 U. S. C. § 343 (e) (1964). The statement must be prominently placed on the label with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Federal Food, Drug and Cosmetic Act § 403(f), 52 Stat. 1047 (1938), 21 U. S. C. § 343(f) (1964). The statutory labeling requirement is separate and independent from the statutory prohibition against misleading containers. Cf. Federal Food, Drug and Cosmetic Act § 403(d), 52 Stat. 1047 (1938), 21 U. S. C. § 343(d) (1964). Noncompliance with either section of the act is a misbranding.

[46] In *United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding,* 71 F. Supp. 279 (D. Ariz. 1946), the most important issue was to determine the representation made by the package. In *United States v. Cataldo,* 157 F. 2d 802 (1st Cir. 1946) and *United States v. 174 Cases of Delson Thin Mints,* 287 F. 2d 246 (3d Cir. 1961), the courts skipped over this issue. In these simple cases involving finished foods and no question of secondary meaning, the courts asked only if the containers were misleading. In *United States v. 116 Boxes of Arden Assorted Candy Drops,* 80 F. Supp. 911 (D. Mass. 1948), the court was again dealing with a finished food in a nonstandard container. Here, however, one of the principal issues in the case was whether the package represented that it was reasonably full, or reasonably full considering the problems of machine packing. While most of the problems of machine packing are more properly part of the technological justification defense, the case follows the approach of first identifying the representation made by the package and then deciding whether that representation is misleading. Cases involving allegedly misleading labeling often follow this type of approach. See, for example, *Colusa Remedy Co. v. United States,* 176 F. 2d 554 (8th Cir. 1949), cert. denied, 338

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(2) The ordinary purchaser is the standard by which the court will determine (a) the representations made by the container and (b) whether those representations were misleading.[47] This is in contrast

(Footnote 46 continued.)
U. S. 911 (1950); *United States v. Six Dozen Bottles of Dr. Peter's Kuriko,* 158 F. 2d 667 (7th Cir. 1947); *United States v. 38 Dozen Bottles of Tryptacin,* 114 F. Supp. 461 (D. Minn. 1953); *United States v. 50¾ Dozen Bottles of Sulfa-Seb,* 54 F. Supp. 759 (W. D. Mo. 1944).

In more complex cases (for example, *Jiffy-Lou Vanilla Flavor Pudding*) courts may fall into error if they merely repeat the words of the statute rather than break the problem into its component parts. In every case the problem is to determine what is the representation (or "promise") and then to determine whether that representation (or "promise") is misleading. Cf. Millstein, "The Federal Trade Commission and False Advertising," 64 *Colum. L. Rev.* 439, 465-83 (1964).

[47] Support for the ordinary purchaser concept can be gleaned from § 403(f) of the act, 52 Stat. 1047 (1938), 21 U. S. C. § 343(f) (1964), which provides that mandatory labeling of foods is tested by the standard of the "ordinary individual under customary conditions of purchase and use." Similar provisions regarding drugs and cosmetics are found in §§ 502(c) and 602(c) of the act. 52 Stat. 1050 (1938), 21 U. S. C. § 352(c) (1964); 52 Stat. 1054 (1938), 21 U. S. C. § 362(c) (1964). If the representations on the label are tested by the standard of the ordinary purchaser, it would seem reasonable to test the alleged deceptiveness of the container by the same standard. Cf. *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), cert. denied, 342 U. S. 861 (1951), which applied the same type of reasoning to an economic adulteration case. The § 403(d) cases have, with some inconsistency, accepted the standard of the ordinary purchaser. See *United States v. 174 Cases of Delson Thin Mints,* 287 F. 2d 246, 247-48 (3d Cir. 1961) ("ordinary purchaser"); *United States v. Cataldo,* 157 F. 2d 802, 804 (1st Cir. 1946) ("average purchaser"); *United States v. 174 Cases of Delson Thin Mints,* 195 F. Supp. 326, 328 (D. N. J. 1961) ("ordinary purchaser"), aff'd per curiam, 302 F. 2d 724 (3d Cir. 1962); *United States v. 174 Cases of Delson Thin Mints,* 180 F. Supp. 863, 868 (D. N. J. 1960) (average adult of normal intelligence who purchased the product), rev'd on other grounds, 287 F. 2d 246 (3d Cir. 1961); *United States v. 116 Boxes of Arden Assorted Candy Drops,* 80 F. Supp. 911, 913 (D. Mass. 1948) ("ordinary purchaser" or "ordinary noninfantile purchaser"). But see *United States v. 174 Cases of Delson Thin Mints,* 302 F. 2d 724, 725 (3d Cir. 1962) ("purchasing public"); *United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding,* 71 F. Supp. 279, 280 (D. Ariz. 1946) ("general public," "consuming public" or "buying public"). While cases under other sections of the Federal Food, Drug and Cosmetic Act have on occasion accepted an FTC type standard, see, e.g., *United States v. 39 Bags of Elip Tablets,* 150 F. Supp. 648 (E. D. N. Y. 1957); *United States v. 62 Packages of Marmola Prescription Tablets,* 48 F. Supp. 878, 887 (W. D. Wis. 1943), aff'd, 142 F. 2d 107 (7th Cir.), cert. denied under the name of *Raladam Co. v. United States,* 323 U. S. 731 (1944), the courts seem more likely to apply the ordinary purchaser standard or some variation of it. See Nelson, "What Standard for the Nonstandardized Food?," 8 FOOD DRUG COSMETIC LAW JOURNAL 425, 433 (1953). See also, for example, *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), cert. denied, 342 U. S. 861 (1951); *Colusa Remedy Co. v. United States,* 176 F. 2d 554 (8th Cir. 1949), cert. denied, 338 U. S. 911 (1950); *United States v. 46 Cases of Welch's Nut Caramels,* 204 F. Supp. 321 (D. R. I.

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to the reasonable man standard or the more liberal standard frequently applied to FTC actions against deceptive advertising—("the public—that vast multitude which includes the ignorant, the unthinking, and the credulous").[48] Both words, "ordinary" and "purchaser" are significant. "Ordinary" excludes those persons who are substandard, either in intelligence or sophistication.[49] "Purchaser" has more subtle connotations. A purchaser is likely to have a greater interest in the container and more experience with similar products than the ordinary person or reasonable man. For example, the ordinary purchaser of breakfast cereals or potato chips would expect to find the contents had settled during transit and that therefore some slack-fill had occurred.[50]

The legal concept of the ordinary purchaser is probably not the same as that of the ordinary purchaser as revealed by market research. While it may be statistically true in many situations that the ordinary purchaser has purchased the same product before, it is unlikely that the courts will imply this experience as part of the ordinary purchaser standard. [51] Such an approach would leave initial purchasers

(Footnote 47 continued.)
1962); *United States v. Vitamin Indus., Inc.*, 130 F. Supp. 755 (D. Neb. 1955); *United States v. 50¾ Dozen Bottles of Sulfa-Seb*, 54 F. Supp. 759 (W. D. Mo. 1944). See also the following cases unreported officially: *United States v. 10 Cartons of Black Tablets*, 1958-1960 Kleinfeld 27 (W. D. Pa. 1956); *U. S. v. Pinaud, Inc.*, 1938-1949 Kleinfeld 526 (S. D. N. Y. 1947).

[48] *Charles of the Ritz Distribs. Corp. v. FTC*, 143 F. 2d 676, 679 (2d Cir. 1944). See also *Exposition Press, Inc. v. FTC*, 295 F. 2d 869, 872 (2d Cir. 1961), cert. denied, 370 U. S. 917 (1962), holding that the FTC should not look to the most sophisticated readers but to the least. The FTC applies a somewhat less liberal rule in deceptive packaging cases. See text accompanying footnotes 163-67 below.

[49] See *United States v. 88 Cases of Bireley's Orange Beverage*, 187 F. 2d 967, 971 (3d Cir.), cert. denied, 342 U. S. 861 (1951); *United States v. Vitamin Indus., Inc.*, 130 F. Supp. 755, 767 (D. Neb. 1955).

[50] See *United States v. 116 Boxes of Arden Assorted Candy Drops*, 80 F. Supp. 911, 913 (D. Mass. 1948), in which the court implied that the ordinary purchaser had come to expect some slack or air space through similar purchases of candy.

[51] Assume that market research indicates that the average or ordinary purchaser of Brand W Cereal has purchased the same product on six prior occasions during the past two years and assume that all boxes of Brand W Cereal sold during the last two years were only filled to 50% of the volume of the container. Could it be argued that the ordinary purchaser is not misled because his prior experience has taught him that Brand W Cereal is always slack-filled? If this were true, the initial purchaser of a box of Brand W Cereal would always be deceived and the manufacturer's defense would always be that the ordinary purchaser was the legal standard and that the ordinary purchaser was not deceived. The answer must be that the legal concept of the ordinary purchaser cannot be defined by marketing research any more than the legal concept of the reasonable man can be defined by psychological research.

with almost no protection. The courts will probably charge the ordinary purchaser with those facts which seem apparent from a reasonable inspection of the container (including a reading of the more prominent parts of the label) but not charge him with knowledge of hidden defects.[52] The courts will probably also decide that the ordinary purchaser has been misled by the representations made by a package when the evidence indicates that any substantial number of ultimate purchasers have been deceived, although there is little authority on this point yet.[53]

(3) In general, representations concerning volume will fall within one of the following categories, depending upon the type of container used and the type of food under consideration:

First, a nonstandard nontransparent container for a food other than a mix for food (that is, a "finished food") will probably be deemed to represent that it is reasonably full of the finished food,[54] considering settling after packing and other limitations on fill which

[52] Cf. 1 Williston, Sales § 234 (rev. ed. 1948): "It is rightly held that ordinarily in a purchase of goods which the buyer inspects or has an opportunity to inspect, no warranty is implied as to defects which the examination ought to disclose, for the basis of implied warranty is justifiable reliance of the buyer upon the seller's judgment."; Vold, Sales 436 (2d ed. 1959); Uniform Commercial Code § 2-316(3)(b): "[W]hen the buyer before entering into the contract has examined the goods . . . as fully as he desired or has refused to examine the goods there is no implied warranty with regard to defects which an examination ought in the circumstances to have revealed to him."

While § 403(d) can be violated when the net weight is stated correctly on the label, in other instances labeling may prevent a § 403(d) violation. Assume a manufacturer states prominently on the front of his package, "This package is approximately 80% full." Such labeling could prevent the ordinary purchaser from being misled and when the ordinary purchaser is not misled, there is no violation of § 403(d).

[53] Cf. Stapleton, "The Consuming Public," 7 FOOD DRUG COSMETIC LAW JOURNAL 793, 801 (1952) ("substantial portion of the literate purchasing public"); *United States v. Two Bags of Poppy Seeds,* 147 F. 2d 123 (6th Cir. 1945) (ultimate purchasers rather than middlemen are the test in economic adulteration cases); *Libby, McNeill & Libby v. United States,* 210 Fed. 148 (4th Cir. 1913) (ultimate purchasers rather than middlemen are the test in 1906 act adulteration case).

[54] Cf. on requirement of "reasonable fill": *United States v. 174 Cases of Delson Thin Mints,* 287 F. 2d 246, 248 (3d Cir. 1961) (in the absence of technological justification 75% fill might well violate the statute); *United States v. 149 Cases of Black Eyed Peas,* 1953-1957 Kleinfeld 27, 29 (D. Colo. 1953): "Where no specific standard for fill of container exists for a food, the test to be applied is that fill of container which can be achieved by the use of proper and feasible commercial practices." (dictum). But see *United States v. Cataldo,* 157 F. 2d 802 (1st Cir. 1946) (50% fill is not misleading per se).

would be known by the ordinary purchaser.[55] No container, of course, represents that it is 100 per cent full because this is practically impossible [56] and the implied representation of reasonable fill may be negated by express representation to the contrary.

Second, a nonstandard nontransparent container for a mix for food (for example, a cake mix or a dry mix for soup) may represent either that (a) the container is reasonably full, considering "settling" after packing and other limitations on fill which would be known by the ordinary purchaser, or, (b) the container contains sufficient fill to make a specified volume of food.[57] It is likely that the representation will be the latter, since the ordinary purchaser is probably more interested in the volume of finished food that the contents can make than in the volume of the mix. Almost all mixes state the quantity of finished food that can be made from the package contents and it becomes a question of fact in each case whether this disclosure was enough to preempt the usual representation of reasonable fill. On behalf of the claimant, it can be argued that initial purchasers would probably look at the directions to determine the quantity of finished food that could be made before purchasing the product and that "repeat purchasers" already know the amount of finished food that can be made from the contents.[58] More prominent disclosure rather than mere directions (for example, a conspicuous statement on the principal display panel of the label "makes one pint") should be sufficient

[55] See *United States v. 116 Boxes of Arden Assorted Candy Drops,* 80 F. Supp. 911, 913 (D. Mass. 1948), which held that the test is what would be expected by an ordinary person—not necessarily an adult—who has been led to expect and desire machine-packing. In broader language the court then stated that the standard is the expectations of a person who has the common degree of familiarity with our industrial civilization. Ibid.

[56] See *United States v. 174 Cases of Delson Thin Mints,* 287 F. 2d 246, 248 n. 2 (3d Cir. 1961): "The United States does not argue that the box had to be packed tight. It has argued that Delson mints could have been packed tighter and yet could have been safe, while not misleading the consumer."; *United States v. 116 Boxes of Arden Assorted Candy Drops,* above, cited at footnote 55, at 913.

[57] See *United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding,* 71 F. Supp. 279, 280 (D. Ariz. 1946), in which the court held that the package represented that it contained enough formula to make one pint of pudding.

[58] In *United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding,* supra note 57, a package had through secondary meaning become universally recognized as containing a mix sufficient for one pint of pudding and thus was not misbranded because of "slack-fill." Certainly, if this result follows through secondary meaning, it must also follow when the label of the package states directly and prominently that the contents will make a specified quantity of finished food.

to prevent a package containing a mix from misleading the ordinary purchaser.[59]

Third, a standard nontransparent container (an opaque container which has been used by most manufacturers for a uniform quantity of food for some time) probably represents that it contains that uniform quantity of food. The standard quantity may be either a fill of uniform weight if the container contains a finished food or a fill sufficient to make the uniform volume of finished food if the container contains a mix for food. In either situation the container has acquired a secondary meaning in regard to volume of fill which has displaced the ordinary meaning (that is, the container is representing that it contains an expected standard quantity of food rather than the ordinary representation—reasonably full considering "settling" after packing and other limitations on fill which would be known by the ordinary purchaser).[60]

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[59] But see *FDA Trade Correspondence* No. 161, March 14, 1940, in 1938-1949 Kleinfeld 632.

[60] There are four fascinating cases which lend support to the secondary meaning doctrine under the Federal Food, Drug and Cosmetic Act. The first is *United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding,* 71 F. Supp. 279 (D. Ariz. 1946). This case, which holds directly that a package is not misleading under § 403(d) because it was commonly and universally recognized as containing enough formula to make one pint of pudding, is summarized in the text accompanying notes 35-36 supra. The other three cases are analogous authority, having been brought under the labeling provisions of § 403(a) of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1047 (1938), 21 U. S. C. § 343(a) (1964). The cases are: (1) *United States v. 46 Cases of Welch's Nut Caramels,* 204 F. Supp. 321 (D. R. I. 1962) in which the court held that a product labeled nut caramels was not misbranded when there were no nuts, only peanuts in the product. The evidence showed that peanuts were technically legumes rather than nuts but that in the candy business peanuts were universally considered as nuts. The court noted that there was no evidence indicating that the ordinary consumer did not consider peanuts as nuts and dismissed the contention that the name "Nut Caramels" was misleading; (2) *United States v. Pinaud, Inc.,* 1938-1949 Kleinfeld 526 (S. D. N. Y. 1947) in which the FDA contended that a product labeled "Eau de Quinine" was misbranded because it implied that the product contained significant amounts of quinine whereas the amount of quinine in the product was trivial. The court charged the jury that if they found the name had acquired a secondary meaning (that the name was associated with this product and not quinine), their verdict should be for the defendant. The jury did render a verdict for the defendant; and (3) *United States v. 70½ Dozen Bottles of "666",* 1938-1949 Kleinfeld 89 (M. D. Ga. 1944) in which the FDA contended that a product labeled 666 was misbranded because the name and label had been used for many years for a product containing iron and quinine and was thereafter used for a product without these ingredients. The jury returned a verdict for the government. It is interesting to note that the FDA has been on both sides of the secondary meaning cases and is therefore unlikely to argue that this concept has no place in food and drug law.

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Fourth, a transparent container usually makes no implied representation concerning the volume of its contents [61] and a nontransparent container usually makes no implied representation concerning its volume which is inconsistent with a reasonable inspection of the container. When it is obvious from the exterior of the container that the interior volume has been reduced (for example, cans with deeply inset tops and bottoms) the ordinary purchaser is probably not misled.[62] Only misleading containers are prohibited and a manufacturer can always avoid a charge of deceptive packaging by proving that the representations made by the container to the ordinary purchaser were accurate.

(4) In deciding what representations were made by the container in regard to volume and whether these representations were misleading, the courts will consider the following evidence (in addition to evidence relating to the type of food and type of container under consideration):

(a) Percentages of fill of the volume of the container before and after removing all dividers and other fillers; [63]

(Footnote 60 continued.)

It could be argued that the *Pinaud* case and the *666* case should have been tried under § 403(d) rather than under § 403(a). In these cases the label remained the same but the contents of the packages were changed. Thus it might be said that the container was "filled so as to be misleading." The FDA probably preferred to treat these as misleading labeling cases because of its universal lack of success under § 403(d). Perhaps alternative charges under § 403(a) and 403(d) should be alleged in such situations.

[61] Commissioner Larrick's comments on the *Delson Thin Mints* case (quoted in text accompanying footnote 78 below) seem to imply that transparent containers are not subject to the same rules as nontransparent containers. Cf. Letter of Deputy Commissioner Harvey, 1965 Hearings 761. See also 21 C. F. R. § 36.3 (1965) (standard of fill for *nontransparent* containers of shrimp). The difference would seem to be that a transparent container makes no implied representation so long as it does not distort the contents of the container. Distortion would occur if the volume of the contents were magnified or if the transparent wrapper were colored to make the contents look better than they are. See Martin, "Section 403(d) — Containers So Made, Formed or Filled As to Be Misleading," 8 FOOD DRUG COSMETIC LAW JOURNAL 663, 671-72 (1953). Wrappers which are transparent in part and opaque in part can cause a host of problems. For example, bags of potato chips which are transparent at the bottom where the bags are full and opaque at the top where the bags are empty may mislead the ordinary purchaser in regard to fill.

[62] This is a logical sequel to the first part of the rule concerning transparent containers but the FDA takes a contrary view. See FDA Ann. Rep. 18 (1940): "Deception may occur in cardboard, fiber, or metal containers because of . . . indented bottoms, sometimes found in ice cream and cosmetic cartons."

[63] *United States v. 174 Cases of Delson Thin Mints,* 287 F. 2d 246, 248 (3d Cir. 1961); *United States v. Cataldo,* 157 F. 2d 802, 804 (1st Cir. 1946); *United*

(Continued on next page.)

(b) Claimant's intent in adopting the container; [64]

(c) Consumer surveys showing the percentage of purchasers tending to select their purchase by the size of the container; [65]

(d) Consumers' testimony that they expected more food in the container than was actually present; [66]

(e) Psychologists' opinions (based on consumer interviews) that the size of containers is more significant to purchasers than the net weight of the contents; [67]

(f) Complaints or the absence of complaints about the container to the FDA from city, county or state regulatory officials; [68]

(g) Complaints or the absence of complaints about the container from the public to the FDA or to the claimant.[69]

(5) Even if representations made by the container in regard to volume are misleading, the form or filing of the container may be justified by other considerations (such as safety) if it is reasonable in the light of available alternatives.[70] The question is whether the container's efficacy outweighs its deceptive quality.[71]

(Footnote 63 continued.)
States v. 174 Cases of Delson Thin Mints, 195 F. Supp. 326, 327 (D. N. J. 1961), aff'd per curiam, 302 F. 2d 724 (3d Cir. 1962); *United States v. 116 Boxes of Arden Assorted Candy Drops,* 80 F. Supp. 911, 912 (D. Mass. 1948); *United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding,* 71 F. Supp. 279, 280 (D. Ariz. 1946).

[64] *United States v. 174 Cases of Delson Thin Mints,* 195 F. Supp. 326, 328-29 (D. N. J. 1961); *United States v. 174 Cases of Delson Thin Mints,* 180 F. Supp. 863, 867 (D. N. J. 1960), rev'd on other grounds, 287 F. 2d 246 (3d Cir. 1961).

[65] *United States v. 174 Cases of Delson Thin Mints,* 195 F. Supp. 326, 327 (D. N. J. 1961).

[66] Id. at 328.

[67] *United States v. 174 Cases of Delson Thin Mints,* 180 F. Supp. 863, 866-67 (D. N. J. 1960).

[68] *United States v. 174 Cases of Delson Thin Mints,* 195 F. Supp. 326, 328 (D. N. J. 1961).

[69] Ibid.

[70] *United States v. 174 Cases of Delson Thin Mints,* 287 F. 2d 246, 247 (3d Cir. 1961). Cf. *United States v. 116 Boxes of Arden Assorted Candy Drops,* 80 F. Supp. 911 (D. Mass. 1948) in which the court recognized the efficiencies of machine packing as a defense but classified it as part of the reason why the package was not misleading rather than as part of the technological justification defense.

[71] Technological justification is certainly broader than mere considerations of product safety. Economy and suitability for mass production line packing must also be considered. See *United States v. 174 Cases of Delson Thin Mints,* 195 F. Supp. 326, 330 (D. N. J. 1961); *United States v. 116 Boxes of Arden Assorted Candy Drops,* 80 F. Supp. 911, 913 (D. Mass. 1948). While less deceptive alternatives may be theoretically available to the manufacturer, they are not practically available to him unless the alternatives are within a reasonable cost range. For example, Congress had no intention of requiring the abandonment of the economies of machine packaging when it passed § 403(d). See the *Delson Thin Mints* and *Arden Candy Drop* cases above. Additionally, merchandising considerations will probably be given some weight. The courts have not said this,

(Continued on next page.)

One suspects that section 403(d) harbors subtleties which have not yet been exposed in litigation. Although this section has been in effect for twenty-seven years, there have only been four cases of any significance litigated under it and all of these cases relate to slack-fill and have been decided on fairly rudimentary law—that the FDA must prove the container to be misleading and that the FDA cannot require the impossible (have the container condemned as misleading when there is no better alternative). There are no cases involving containers which were allegedly misleading for reasons other than slack-fill.

The Canadian Food & Drug Directorate recently declared that shingle-type packs of bacon are misleading if the window on the package shows lean bacon while the concealed bacon is much more fatty.[72] This is similar to the more common complaint of United States housewives concerning meats which are packed with a transparent wrapper on top and a cardboard tray on the bottom. The top which is visible is frequently lean red meat while the concealed underside is largely fat.[73] Such a package makes an implied representation that the visible portion of the meat fairly typifies the contents.[74] If the visible portion is much better than the hidden portion of the meat, the representation may be misleading and the package, while completely filled, may be considered as filled so as to be misleading.

If "filled so as to be misleading" can be given this broad meaning, the other prohibitions in the statute against foods "made or formed so as to be misleading" are probably equally flexible. This has already been suggested and a number of examples of cases which would fit within these words are apparent from the legislative history of section 403(d).[75] The words "made, formed or filled" were intended to be all-inclusive and they encompass many types of deceptive pack-

(Footnote 71 continued.)
probably because there is a suspicion that some manufacturers would try to justify all misleading packages on the theory that they increase sales. Despite this concern, it is unlikely that the courts will disregard all aesthetical considerations in judging containers. Cf. United Drug Co., 35 F. T. C. 643, 647 (1942).

Technological justification is also discussed in Note, "Federal Regulation of Deceptive Packaging: The Relevance of Technological Justifications," 72 *Yale L. J.* 788 (1963).

[72] *Food Field Reporter*, March 15, 1965, p. 9.

[73] Hearings on S. 387 Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 88th Cong., 1st Sess. 586 (1963) [hereinafter 1963 Hearings]: "The meat—lean and appetizing face up—too often turns out to be fat and bone underneath."

[74] See Martin, supra note 61, at 672: "Where better-grade products are placed on top of the pack and the inferior beneath, we have an illustration of a container 'so filled as to be misleading' by means other than slack-filling."

[75] Id. at 671-72.

aging which have not been challenged to date.[76] The problem in each case is to determine what representation was made by the container and whether that representation was misleading.

The FDA's record of four successive losses under section 403(d) has caused undue pessimism in some quarters. One law review analyzed the present state of the law as follows: "In view of the decision in the *Delson Thin Mints* case, it is difficult to conceive how the government will ever win a case under the present wording of section 403(d)."[77] The Commissioner of the FDA took a more realistic view when he commented on the first decision of the court of appeals in the *Delson Thin Mints* case, saying:

> [W]e did, last year, obtain from the Court of Appeals in Philadelphia, a ruling which gives promise of greatly helping to improve this situation. In effect, this ruling says that where a packer uses a nontransparent package which is not full, the burden is on the user to justify the slack filling by proving that the deception was required by considerations of product protection and that no less deceptive alternate was available. This, in our opinion, is a most reasonable rule.[78]

The Assistant General Counsel of HEW, who handled the appeal in *Delson Thin Mints* commented on the same decision in these terms: "I do not think we can improve on that rule announced by the court of appeals that the burden is on the person who is using the deceptive container to justify it in terms of reasonable need."[79] Thus it is plain that the FDA regards the rules of law established thus far as encouraging. Greater success may be achieved when the FDA extends its enforcement from slack-fill cases to other cases which are apparently included under section 403(d).

2. *Injunctions and Criminal Penalties*

The FDA can also seek a court injunction against the sale of foods which have the requisite connection with interstate commerce and are misbranded through deceptive packaging.[80] This remedy has

[76] Cf. id. at 672, in which it is suggested that the FDA could require through regulations a statement of the percentage of fill, a "filled-to-here-line" on the package or a warning against shrinkage. However, there is no specific grant of authority to promulgate such regulations and therefore the regulations could only be based on the general powers of the Secretary of HEW. See Federal Food, Drug and Cosmetic Act § 701, 52 Stat. 1055 (1938), as amended, 21 U. S. C. § 371 (1964).

[77] Legislation and Administration, "The Consumer in the Marketplace—A Survey of the Law of Informed Buying," 38 *Notre Dame Law.* 555, 571 (1963). But see 72 *Yale L. J.* above, cited at footnote 71, at 797 in which it is concluded that § 403(d) as construed in the *Delson Thin Mints* case "appears to offer adequate scope for a balanced treatment of conflicting consumer interests and to provide an effective means for regulating the use of slack-filled packages."

[78] 1962 Hearings 801.

[79] 1962 Hearings 805.

[80] Federal Food, Drug and Cosmetic Act § 302, 52 Stat. 1043 (1938), as amended, 21 U. S. C. § 332 (1964).

not been utilized yet in deceptive packaging cases.[81] Any such suit would require proof of the misbranding in accord with the principals of *Delson Thin Mints*. It is therefore difficult to see how the injunction remedy offers any advantage over seizure proceedings in deceptive packaging cases. While an injunction would prevent future sales of the deceptively packaged food, the FDA can in practice accomplish the same result through multiple seizures after there has been an initial judgment of misbranding.[82]

The ultimate penalties for misbranding through deceptive packaging are criminal in nature.[83] The FDA has never instituted criminal proceedings for deceptive packaging, probably because such proceedings would be incongruous so long as the FDA has not succeeded in winning a civil deceptive packaging case. However, neither intent to defraud nor awareness of the violation need be proved for the imposition of criminal penalties under the deceptive packaging section of the Food, Drug and Cosmetic Act.[84] The possibility of criminal penalties may therefore be an effective weapon in controlling deceptive packaging in the future.[85]

C. Summary

The FDA's powers over deceptive packaging have not yet been fully utilized. In general the standards of fill approach has worked well. In the only instance in which the FDA's standard of fill was

[81] The injunction is considered by the FDA as a supplementary mode of enforcement, to be used less freely than the other remedies. "Developments in the Law—The Federal Food, Drug and Cosmetic Act," 67 *Harv. L. Rev.* 632, 714 (1954).

[82] See footnote 34 above and accompanying text.

[83] See Federal Food, Drug and Cosmetic Act § 303, 52 Stat. 1043 (1938), as amended, 21 U. S. C. § 333 (1964).

[84] See *United States v. Dotterweich*, 320 U. S. 277, 281 (1943): "Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." See also *United States v. Parfait Powder Puff Co.*, 163 F. 2d 1008 (7th Cir. 1947), cert. denied, 332 U. S. 851 (1948).

[85] See Statement by George P. Larrick, Commissioner of Food and Drugs, 1965 Hearings 29, in which Commissioner Larrick recommends that criminal sanctions be made applicable to the proposed new laws regulating deceptive packaging. Once the FDA wins a civil action under § 403(d), the possibility of imposing criminal penalties will become quite real to the corporate officers who have to approve or disapprove proposed new packages. While the FDA can be expected to seek criminal penalties in few cases, the threat of such penalties may be made with more frequency. It is probably this threat which Commissioner Larrick referred to when he said, "Inclusion of the criminal sanction in the law contributes a great deal to compliance." Ibid.

challenged by industry, the standard was sustained.[86] While increased problems may be anticipated in fixing standards of fill for other than canned foods,[87] the FDA's experience with standards of fill thus far gives no cause for pessimism.

The FDA has had greater problems with seizure cases involving deceptively packaged foods. The findings of fact in such cases have been uniformly adverse to the FDA. The rules of law laid down in these cases have, however, been just and reasonable. It is the rules of law and not the findings of fact which will govern future cases. The rules of law are still in their rudimentary stages, primarily because there have only been four cases, but also because these cases have all been slack-fill cases while section 403(d) seems to have much broader applications.

In the past, the FDA has tended to become discouraged in its regulation of deceptive packaging following adverse decisions by the courts.[88] This may not happen following the *Delson Thin Mints* decision since the FDA appears satisfied with the legal principles enunciated by the court in that case. Another factor may, however, reduce the FDA's willingness to become involved with the regulation of deceptive packaging. The Second Citizens Advisory Committee Report on the FDA was transmitted to the Secretary of HEW in late 1962. The Report suggested that the FDA should reevaluate its priorities of work, concentrating more on health hazards and dropping certain other activities.[89] The Report said, "For example, the FDA should be relieved of the responsibility for such activities as policing container fill . . . by turning these matters over completely to state and local agencies to be conducted in accordance with FDA standards." [90]

[86] *Willapoint Oysters, Inc. v. Ewing*, 174 F. 2d 676 (9th Cir.), cert. denied, 338 U. S. 860 (1949).

[87] See *72 Yale L. J.*, above, cited at footnote 71, at 798-802.

[88] See Larrick, "Some Comments on Packaging," 17 FOOD DRUG COSMETIC LAW JOURNAL 442, 444 (1962). Cf. Letter of Deputy Commissioner Harvey, 1965 Hearings 761.

[89] Second Citizens Advisory Committee Report on the Food and Drug Administration, 17 FOOD DRUG COSMETIC LAW JOURNAL 581, 616 (1962).

[90] Ibid. This recommendation can be interpreted as meaning either that the states should police container fill where the FDA has set standards of fill or that the state should police all deceptive packaging problems under FDA guidelines. It must be remembered, however, that slack-fill cases are the only cases the FDA has tried under § 403(d) and, therefore, that all § 403(d) enforcement in the courts has been a matter of "policing container fill." Administratively, it is likely that the FDA has used this section for broader purposes, thus discouraging those who have asked for advisory opinions at least from deceptive packaging. If the state officials are used to police standards of fill, it would seem logical to also have them report to the FDA concerning excessive slack-fill in products for which no standard of fill has been established.

For this reason, we may see a decrease in attention given to deceptive packaging by the FDA unless new legislation passes or unless Congress makes known its desire that the FDA continue to handle these matters.[91] This decrease in activity would not imply in any way, however, that the FDA's present powers are inadequate to properly regulate deceptive packaging of foods if Congress gives the FDA adequate appropriations to handle this aspect of its work.[92] Without such appropriations, perhaps the priorities of the FDA's work will require that the FDA regulate deceptive packaging through state officials acting in accord with federal guidelines. Time will be required to determine whether that is an effective means of regulation.[93]

[To be continued in the May issue]

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[91] Legislation giving the FDA increased powers over deceptive packaging would certainly be notice that Congress intends that the FDA handle this problem, notwithstanding the recommendations in The Second Citizens Advisory Committee Report on the FDA. In the absence of such legislation, even the current hearings may be sufficient for the FDA to ascertain congressional intent.

[92] See Janssen, "FDA Since 1938: The Major Trends and Developments," 13 *J. Pub. Law.* 205, 216 (1964):

> The FDA has never been considered one of the affluent Government agencies. Until recent years, in fact, it had been so chronically short of funds that it was necessary to curtail protection of the consumer's pocketbook in favor of protecting his health and safety. Even the latter objectives were not adequately financed, however. While Congress generally went along with measures to strengthen the law, the limited FDA budgets and appropriations had the effect of curbing enforcement.

[93] If the FDA tries to delegate the entire regulation of deceptive packaging to the state officials under federal guidelines it will have at least two major problems—variations in the power given to these officials by the various state statutes and variations in the quality of the officials in the various states. In the immediate future these two problems would inevitably lead to uneven enforcement of the law. For example, California has fairly stringent laws against deceptive packaging. See Cal. Bus. & Prof. Code §§ 12605-06. Another important industrial state, Pennsylvania, has no prohibition against oversized packages so long as they bear the correct net weight. See Appendix to 1963 Hearings at 916. Therefore Pennsylvania officials could report excessive slack-fill to the FDA but could not prosecute slack-fill cases in the state courts. Variations in the quality of state officials are more difficult to assess. The author has had an opportunity to meet the officials in charge of the regulation of deceptive packaging in some of our states and while most of these officials appear to be capable and energetic, a few state officials appear to be political appointees with little ability for, or interest in, their jobs.

The "Generic Every Time" Case:[1] Prescription Drug Industry In Extremis

By HARRY A. SWEENEY, JR.

Mr. Sweeney Has Had Eight Years of Experience in the Drug Industry.

> No experienced Food and Drug lawyer resorts to court save *in extremis* . . .[2]

IN OCTOBER 1963, by joining with their trade association, Pharmaceutical Manufacturers Association (PMA),[3] to challenge certain regulations pertaining to the advertisement of prescription drugs, 37 drug manufacturers served notice to the Food and Drug Administration (FDA)[4] of a significant shift in a 25-year-old industry-wide policy—a policy which could simply be stated as: Avoid litigation at all costs.

That this policy existed—indeed, still exists to a large extent today—is beyond question. Consider, for example, this commentary by a leading practitioner in the field of food and drug law:

> . . . Government counsel usually wins—if only because he is the knight in white armour defending the helpless consumer against the predatory peddler, or because minor economic regulations are often framed as public health issues, and because questions of political and economic policy are paraded as scientific prob-

[1] *Abbott Labs. v. Celebrezze,* 228 F. Supp. 855 (D. Del. 1964), *rev'd, Abbott Labs. v. Celebrezze,* 352 F. 2d 286 (3rd Cir. 1965), *petition for cert. filed,* CCH 1965 FOOD DRUG COSMETIC LAW REPORTS No. 146 (Dec. 23, 1965) (Dkt. No. 824).

[2] Austern, "Sanctions in Silhouette" (excerpt), in *Administrative Law: Cases and Comments* 671-74, at 673, (Gellhorn and Byse eds. 1960).

[3] The Pharmaceutical Manufacturers Association (PMA) is a trade association representing 140 member-companies who manufacture and distribute more than 90 per cent of the nation's prescription drugs through interstate commerce.

[4] While the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 U. S. C. Sec. 321-92 (Supp. IV, 1962), [hereinafter sometimes referred to as the "Act, as amended" or the "Drug Amendments of 1962"] vests power in the Secretary of HEW and in practice, the Secretary delegates it to the FDA.

lems, for expert administrative judgment, and as ill suited as any for court determination. If, for example, on an issue whether the Act requires a hearing, FDA counsel can intrude some reference to "cancer," the judge will probably grab his stomach, recall that his mother-in-law died of cancer, remember John Foster Dulles, and never even hear the most cogent legal argument.

That is why no experienced Food and Drug lawyer resorts to court save *in extremis*—why here the conventional talk about the "administrative process" and "court review" is largely academic, why seizures usually go uncontested, why what I shall call "jawbone enforcement" is the real area of administrative activity, why reported decisions and formal regulations bear as little relation to what really goes on as the visible top of an iceberg to the whole, and why the question of enforcement of administrative views by Madison Avenue techniques of publicity demands such close scrutiny in this field. . . .[5]

Or this comment:

. . . in the twenty-five years since the passage of the new drug provisions of the Act, which allow a full administrative hearing on request before any new drug application can be denied or before the withdrawal of a previously approved drug can be ordered, *not a single manufacturer has ever proceeded to a hearing on an initial new-drug application, and there has been only one case of a hearing before a previously approved human prescription drug was ordered withdrawn.* I need hardly add that the hearing examiner upheld the FDA position, and the Commissioner approved.[6] (emphasis added)

Or these more recently published reports:

Some 300 members of the Pharmaceutical Manufacturers Association met in Chicago last week [December 1965] for their annual two-day midyear meeting. . . . Out of all the public discussion, some industry leaders seemed to be saying —almost out loud—that the time had come to stop "running scared" . . . the men who make drugs are becoming perhaps a bit more provocative themselves.[7]

Despite the fact that the drug industry has been accused of "running scared" . . . some observers are reading a different attitude. They point to instances where individual firms are more ready to speak out publicly when they feel the situation warrants.

Abbott [Abbott Laboratories] fired a volley in rebuttal to a Fountain subcommittee news release, as a recent instance. . . . On another front, Pfizer [Pfizer Labs. Division of Chas. Pfizer, Inc.] expressed sharp disagreement not only with the FDA's revised label requirements for the drug meclizine but also with the "scientific rationale for such requirements."

In both cases company reaction was strong, prompt, and public. While they are unrelated incidents, some onlookers remind that heretofore individual companies have shown a reluctance to criticize governmental units and their pro-

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[5] Austern, *op. cit. supra* note 2, at 673.

[6] Cutler, *Practical Aspects of Drug Legislation,* in *Drugs in Our Society* 149-159, at 154 (Talalay ed. 1964). *Drugs in Our Society* is an outstanding contribution to an understanding of the complex socio-politico-economic problems facing members of government, industry, and the health professions. It is highly recommended as a reference work and for basic understanding of the importance and complexity of the development and use of drugs to the nation's health.

[7] *"Problems Aired by Drug Makers," N. Y. Times,* Sunday, December 12, 1965, Section 3 (Business & Financial), p. 1, col. 6.

mulgations. They wonder whether events portend a new trend in industry-government relations.[8]

To understand how remarkable this policy shift by the ethical drug industry really is, and to gain better insight into the importance of the first challenge to FDA authority under the Drug Amendments of 1962, one must first consider some basic facts of industry life.

Consider, for example, the phenomenon of an industry regulated by a statute with elaborate provisions for administrative and judicial review, which provisions have almost *never* been invoked, largely because of a feeling of utter hopelessness on the part of that industry—hopelessness born from the knowledge that the chances of prevailing in an administrative hearing or the courts are "virtually nil." [9]

Next, consider the position of a drug industry executive who, when confronted by an official FDA frown, must chart the future of his organization by weighing the benefits to be gained from a challenge to FDA authority against the possibility of serious, even devastating commercial consequences which could result from an adverse FDA publicity release about his company.[10]

Then, pause to consider what has been characterized as the "terrifying armory of legal weaponry" that the FDA possesses, ranging from injunction, or seizure of an offending drug *before* trial, to criminal prosecution.[11]

And finally, consider the all-too-human attitude of many drug industry executives, that even if they win in a public confrontation, they lose, because they have to go back to the same people, in the same agency, again and again, without the benefit of a public audience, for daily decisions which affect the lifeblood of their business [12] —all without benefit of detailed written findings and conclusions, without benefit of public hearings, without review of a record by independent experts, and without any judicial review at all.[13]

Despite these apparently overwhelming considerations *not* to bring an action—and experienced drug men can cite many more—the drug industry has contested regulations issued by the FDA to implement certain provisions of the Drug Amendments of 1962,[14] regulations calling for the appearance of the established or generic

[8] *Medical Marketing Digest* (December) 1965—an industry newsletter published by Medical Digest Inc., 41 East 42nd Street, New York, N. Y. 10017.

[9] Cutler, *op. cit. supra* note 6 at 153.

[10] Austern, *op. cit. supra* note 2, at 672-673 (1959 cranberry scare; diethylstilbestrol in chickens episode). Common knowledge of stock market fluctuations in response to news releases concerning drugs is also pertinent.

[11] Cutler, *op. cit. supra* note 6 at 153.

[12] Industry experience.

[13] Cutler, *op. cit. supra* note 6 at 152.

[14] *Abbott Labs. v. Celebrezze, supra* note 1.

name of a drug with the proprietary or brand name, *each and every time* such brand name appears on a label,[15] in labeling,[16] or in a prescription drug advertisement.[17]

Statutory Provisions and Regulations

The Federal Food, Drug and Cosmetic Act as amended,[18] provides in pertinent part—section 502(e)(1)(B) (21 U. S. C. 352 (e)(1)(B)—that a drug shall be deemed to be misbranded, unless:

(B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling in which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient . . .

Section 502(n) (21 U. S. C. 352(n)) provides that a prescription drug shall be deemed to be misbranded, unless:

(n) . . . the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in Section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under Section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in the procedure specified in Section 701(e) . . .

To implement these statutory provisions, the Commissioner after public proceedings as required by section 4 of the Administrative Procedure Act issued the following regulations:[19]

21 C. F. R. 1.104 *Drugs: statement of ingredients.*

(g) (1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, *shall accompany each appearance of such proprietary name* or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of" preceding the established name, or by brackets surrounding the established name. (emphasis added)

(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name appears, taking into ac-

[15] 21 C. F. R. 1.104 (g) (1) (1964), 28 *Fed. Reg.* 6375 (1963).

[16] Ibid.

[17] 21 C. F. R. 1.105 (b) (1) (1964), 28 *Fed. Reg.* 6375-76 (1963).

[18] Federal Food, Drug and Cosmetic Act, Sections 502 (e) (1) (B), and 502 (n), 52 Stat. 1050 (1938), as amended, Kefauver-Harris Amendments of 1962, Sections 112 (a), 131 (a), 76 Stat. 780, 790, 791, 21 U. S. C. 352 (e) (1) (B), and 352 (n) (Supp. IV, 1962).

[19] *Op. cit. supra* notes 15 and 17.

count all pertinent factors, including typography, layout, contrast, and other printing features.

21 C. F. R. 1.105(b) *Prescription-drug advertisements* is essentially identical with the substitution of "advertisement" for "label" or "labeling."

The Procedural Issues

Thirty-seven prescription drug manufacturers and the PMA challenged the statutory authority of the FDA to issue regulations requiring the appearance of the generic name each time the brand name was used, by seeking a declaratory judgment and requesting an injunction against enforcement of the regulations.[20] In the Federal District Court in Wilmington, Delaware, Caleb M. Wright, Chief Judge, ran a procedural gauntlet to reach the "generic every time" issue, declared that the FDA had indeed exceeded its statutory authority, and issued the requested injunction. The government appealed.

The Third Circuit Court of Appeals never reached the central issue of the case. Instead, the appellate court reversed the lower court decision on procedural grounds, finding that Congress had not specifically provided for prior judicial review of administrative actions performed under the authority of this specific section of the Act, and that there was no actual "case or controversy" as required for justiciability under the Declaratory Judgment Act. Industry and the PMA have filed a petition for *certiorari* to the Supreme Court.

It would appear at the time this article is being written that the "generic every time" issue is lost in a procedural quagmire. A long list of traditional arguments against judicial intervention in the field of public administration has been used successfully by the government at the intermediate appellate level.[21] Should the United States

[20] *Abbott Labs. v. Celebrezze, supra* note 1.

[21] Brief for Appellants, *Abbott Labs. v. Celebrezze,* In the United States Court of Appeals, Third Circuit, No. 15054, 15055. [Hereinafter cited as FDA Appellant Brief, PMA Appellee Brief, or FDA Reply Brief, with appropriate pagination.] This list is not all inclusive, but highlights the claims made by government counsel as being the traditional ones, which a student of this field of law will readily recognize or which can be compared with those in the landmark case, *Columbia Broadcasting System v. United States* 316 U. S. 407 (1942). A list of the contentions includes: (1) That the regulations are mere statements of opinion, (2) that they are not self-executing and have no force of law, (3) that they were promulgated by officials who have no power to enforce them in judicial action, (4) that the Attorney General is exclusively charged with responsibility for the initiation of enforcement actions, (5) that the lower court exercised judicial discretion to prevent exercise of executive discretion, (6) that the lower court failed to exercise caution, (7) that the lower court did not attempt to give

(Continued on next page.)

Supreme Court take the same view of these procedural issues, the Bar will have to wait to see whether the "generic every time" problem will arise again in a "proper setting" for its determination. Hopefully, the Court will not accept the traditional arguments, but will examine the realities of this case, find the "circumspect sense of its fitness" which Justice Jackson viewed as controlling whether or not a case was ripe for declaratory relief,[22] and reach the central issue.

Although the main purpose of this article is to examine the "generic every time" issue, it seems proper to address some comments to certain contentions that concern the procedural aspects of the case.

For example, the FDA contends that there is no threat of enforcement that would cause irreparable harm to industry, therefore no justiciable controversy exists.[23] Yet, as the District Court noted,[24] the regulations at issue have placed industry in the dilemma of either complying with the "generic every time" requirement and incurring the costs of changing over their promotional materials—the cost of which has been estimated to be $100,000,000,[25] an amount which it would seem could reasonably be construed as "irreparable harm"—or of following their present course of operation and risking seizure of drugs advertised in a manner contrary to the regulations, as well as risking possible criminal prosecution of the wilful violators. The District Court concluded that:

(Footnote 21 continued.)
meaning to the statute, (8) that there is no proof of threatened or probable enforcement action that would cause irreparable harm, (9) that industry found a direct threat of harm in the mere existence of the regulations, (10) that the question is still nebulous and contingent, (11) that the lower court preempted and pre-judged issues committed to the FDA, (12) that adjudication was sought only as a preliminary step to provide members of industry with a defense against future enforcement, (13) that adjudication would not finally settle the controversy, (14) that the issue was hypothetical and abstract in character, (15) that the regulations were merely advisory, have no other force and effect, impose no sanctions, and are no different than any other opinion expressed by officials of FDA whether by phone, letter, speech or statement of policy, (16) that a decision in industry's favor would open the floodgates of litigation, (17) that a decision would not be final and conclusive against PMA membership or members of industry who were not parties to the case, (18) that fear of criminal prosecution (provided for by the Act as amended) is more imaginary than real, and (19) that this kind of litigation would lead to disruption in the administration of the nation's drug laws.

[22] *Public Serv. Comm'n v. Wyckoff Co.*, 344 U. S. 237, 243 (1952).

[23] *Op. cit. supra* note 21, at 19-24.

[24] *Abbott Labs. v. Celebrezze*, 228 F. Supp. 855, 861 (D. Del. 1964).

[25] Worley, "Problems of Compliance with the Drug Amendments of 1962" 19 *Bus. Law.* 218-19 (1963).

The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril. To bar the courts to plaintiffs would be to do an injustice.[26]

The District Court's conclusion is not bald-faced, but is supported by a line of outstanding cases treating the question of the reviewability of administrative action. In these cases, the administrative agency generally argues that its action does not of itself affect the complainant, but only affects his rights contingent on some future action taking place. In *Rochester Telephone Corporation v. United States,* 307 U. S. 125 (1939), the Supreme Court agreed with this argument and refused to take jurisdiction.

Later, however, the Court began to recognize that there were instances when such controversies should be heard even though the agency action which caused the controversy might otherwise be characterized as interlocutory, because the conflict had reached a point at which the losing party would be irreparably injured if judicial review was unavailable. The leading case for this proposition is *Columbia Broadcasting System v. United States,* 316 U. S. 407 (1942). In that case, regulations had been promulgated by the Federal Communications Commission (FCC) which provided that no licenses would be granted to stations or applicants who had specified contractual relationships with broadcasting networks. The Commission urged that the order issuing the regulations was not reviewable, since in and of themselves the regulations did not affect the contract rights of CBS or its affiliate stations, and that they merely laid down principles to govern future action of the Commission.

The Court looked behind the form of the argument to the substance of the controversy, decided that there was an immediate, adverse effect on CBS, and rejected the Commission's contentions. It is of particular interest to note that many of the identical arguments asserted in *Columbia Broadcasting System* and rejected by the Court therein are used in the "generic every time" case.[27]

After *Columbia Broadcasting System,* two other cases arose with similar fact patterns. In *Frozen Food Express v. United States,* 351 U. S. 40 (1956), regulations were issued by the Interstate Commerce Commission (ICC) establishing that certain commodities were not to be classified as an "exempt agricultural product," which as a practical matter meant that the common carrier became subject to the Interstate Commerce Act. The regulations were deemed to have an immediate and practical impact on carriers who were transporting such

[26] *Op. cit. supra* note 24, at 862.

[27] *Op. cit. supra* note 21.

commodities, were deemed to set standards for the conduct of an important segment of the trucking business, and were therefore reviewable. In *United States v. Storer Broadcasting,* 351 U. S. 192 (1956) the FCC entered an order amending its rules concerning multiple ownership of various kinds of broadcasting stations, limiting the number of television stations which could be owned by one party to five stations. Although no challenge to *Storer's* right to judicial review had been made in any proceeding, the Supreme Court addressed itself to the issue of justiciability and decided that on the facts, *Storer* was presently aggrieved, and therefore had standing to bring the action.

The Court of Appeals in *Abbott Labs. v. Celebrezze* does not address itself to the *reasoning* of these cases in its opinion, but dismisses *Columbia Broadcasting System* and *Frozen Food Express* on the ground that they arose in situations in which statutory provisions for review had been provided.[28] The opinion fails to mention *Storer* at all. The court also states its view that where Congress fails to specifically provide for review of regulations prior to enforcement, such regulations merely represent the Commissioner's *interpretation* of the meaning of the act.[29]

This view leaves much to be desired, however, since it ignores the line of reasoning followed in *Columbia Broadcasting System, Frozen Food Express,* and *Storer Broadcasting,* and fails to consider the nature and thrust of the regulations, which should be the determining factors as to whether or not review is granted.

The court was apparently impressed with the FDA argument[30] that since the "generic every time" regulations were issued under the blanket provision empowering the promulgation of regulations, Section 701(a),[31] and *not* under certain sections specified in 701(e)[32] which are subject to direct judicial review under 701(f),[33] they are not subject to judicial review prior to an enforcement proceeding.

This interpretation assumes, however, that Congress meant to preclude direct review of any regulation not issued under 701(e), an interpretation which strains credulity, since it would preclude direct judicial review of any regulation having the force and effect of law not issued under this limited section.

A more logical explanation of section 701(e) and (f) might be that Congress recognized that certain administrative regulations should

[28] *Abbott Labs. v. Celebrezze,* 352 F. 2d 286, 288-89 (3rd Cir. 1965).
[29] Id. at 289.
[30] FDA Appellate Brief, at 33-41.
[31] 21 U. S. C. 371(a).
[32] 21 U. S. C. 371(e).
[33] 21 U. S. C. 371(f).

be directly reviewable because of the subject matter with which they deal—whether interpretative or legislative in nature—and that those regulations not issued under the limited provision, that is, issued under the broad provision of 701(a), should be the subject of judicial construction. Then it may logically be concluded that where a court construes a section 701(a) regulation as *legislative* in nature, under ordinary administrative law principles such a regulation will be directly reviewable.

Unfortunately, the appellate court in the *Abbott* case concluded, without discussing it in its opinion, that the regulations at issue are "interpretative" in nature. When, as this article is attempting to point out, the regulations are analyzed to determine their practical impact on industry, the conclusion is virtually inescapable that they are *not* interpretative in nature, but rather, having the force and effect of law, they are *legislative* in nature, and should be directly reviewable.

The FDA also contends that industry's apprehension of prosecution is ill-founded, and that a real threat of enforcement is lacking since neither the Commissioner of Food and Drugs, nor the Secretary of Health, Education and Welfare (HEW) is empowered to bring suit directly, but must depend on the discretionary power vested in the Attorney General.[34]

Since, however, the discretionary power of the Attorney General is exercised after consultation with the legal staff of the interested agency, upon whose expertise in a given field of law some reliance must be placed, as a practical matter this contention is not as weighty as it might appear at first glance.[35] It would be interesting to know, for example, what percentage of cases referred by FDA to the Attorney General for initiation of prosecution, are in fact *not* prosecuted by the Attorney General.

Absent the answer to this question, Judge Wright's pragmatic analysis still leaves little force to the government's argument, for as Judge Wright stated:

> It is of no moment that the Attorney General and not the Food and Drug Administration may enforce these rules. Nor does it matter that the Attorney General has not yet threatened enforcement. Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means.[36]

The FDA goes further, however, to contend that the effect of the regulations is merely to "advise" industry of the interpretation

[34] FDA Appellate Brief, at 19-21.
[35] Industry Experience.
[36] *Op. cit. supra* note 24, at 861-862.

which they have put upon the statutory language involved, that they are mere statements of "opinion," and that they have no force and effect, impose no sanctions, and are no different than any other FDA opinion, whether transmitted by telephone, letter, speech, or policy statement.[37]

Do these contentions mean that the Commissioner's regulations are only meant to be *suggestions* to industry? That industry may view them with a take-them-or-leave-them attitude? This seems preposterous, for if the regulations have no force and effect, if there are no sanctions, if indeed, they are mere opinions, then why would industry *ever* obey them? The answer is obvious. Industry obeys them because they *do* have the force and effect of law, and because they are *not* mere opinions, and because there *are* sanctions to be imposed on those who violate them. An exchange between the Court and Mr. William W. Goodrich, Assistant General Counsel for Food and Drugs, counsel for the defendants, in the District Court underscores the point:

> The Court: Mr. Goodrich, when your department makes a regulation, I certainly hope that you intend for the drug industry to obey those regulations?
> Mr. Goodrich: We do indeed, sir.[38]

The mandatory terms in which the regulations are written, further belie the government's attempt to characterize them as "interpretative."[39] They do not state that the generic name "may" or "should" accompany each appearance of the brand name—they state that the

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[37] FDA Appellate Brief, at 21-22.

[38] PMA Appellee Brief, at 4 (citing Joint Appendix filed with the Court, at 24a).

[39] Reliance on *Helco Products Co. v. McNutt,* 137 F. 2d 681 (D. C. Cir. 1943), to support the contention that the regulations at issue in the 'generic every time' case are "interpretative", seems somewhat outdated, in view of the intervening cases which have been decided. *Helco Products* was decided in 1943 shortly after the *Columbia Broadcasting System* case. The regulations at issue prohibited shipment of a certain kind of artificially colored poppy seed. An owner of a company wrote to the FDA asking for an opinion, which was given, and which ruled adversely against him. He sued for a declaratory judgment. And while the Court found that the case was not appropriate for declaratory judgment because the "pronouncements, policies and programs" of an administrative agency do not give rise to a justifiable controversy, a leading administrative law treatise has taken a different view:

> . . . the owner of the poppy seeds should be entitled to find out whether the seeds can properly be shipped, *without having to risk either confiscation of the property or prosecution.* One who thinks that sometime he might like to dye poppy seeds should not be entitled to a declaratory judgment; one who has dyed seeds ready to ship and has been officially advised that shipping them is illegal has a case that is ripe for judicial consideration. 3 Davis, Administrative Law Treatise, Sec. 21.08 [emphasis added]

And of course, the *Frozen Food* and *Storer* cases, decided subsequent to the *Helco Products* case, would also reenforce the District Court finding that a justifiable controversy existed.

generic name ". . . *shall* accompany each appearance of such proprietary name or designation." (emphasis added) 21 C. F. R. 1.104(g)(1).

With these considerations in mind, it seems that the District Court view that the threat of danger to industry is imminent, is all the more reasonable and supportive of its decision to reach the central issue of the case.

One other FDA procedural contention deserves brief mention. Section 502(e) contains a provision which permits the Secretary to exempt the listing of the formula, or of the generic name of the drug in type one-half the size of the trade name, on labeling, where it is impracticable to comply with the statutory requirements. FDA argues that since no attempt to use this exemption provision was made by any manufacturer in the litigation, that administrative remedies have not been exhausted and therefore, that the case is not ripe for adjudication.[40]

The short answer to this contention is that industry is not claiming that the requirement is *impractical* for *some* labels, but that it is an *ultra vires* act to require that the generic name be printed every time the trade name appears on *any* labeling or advertising.

Furthermore, it may be asserted that the 502(e) exemption was meant to excuse certain deviations from the letter of the law due to the practicalities of a given situation, for example, when a long generic name won't fit on a small ampule or sample package. Assuming *arguendo* that a regulation is in fact *ultra vires,* it seems specious to argue that a plaintiff must apply for an exemption from such illegal regulation before he can challenge it. Failure to resort to an exemption provision in this kind of case should not place plaintiffs within the prohibitions of the "exhaustion of remedies" rule.

Whether or not the Supreme Court grants *certiorari* in this case —and again, on an objective view of the facts it would seem that they should—the "generic every time" issue must be faced eventually. Since it has received little judicial attention as yet, an examination of its background is in order.

The "Generic Every Time" Issue

Should a law meant to protect the public health be used in an attempt to promote economic ends? It has been done. In the final analysis, it is the use of public health means to attain antitrust and monopoly ends that has generated the "generic every time" issue.

[40] FDA Appellate Brief, at 24, 28.

And, in the final analysis a decision on this issue must be made by balancing the economic interests against the public interests in health.

In January, 1957, the late Senator Estes Kefauver became the new chairman of the Senate Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary.[41] Certain economists on his staff prevailed on him to initiate the study of "administered prices," an economic term used to describe prices which are set, not by the competition of the marketplace, but by administrative action (that is, by the managers of the business), and held constant for a period of time.

After investigation and hearings on administered prices in the steel and automobile industries, at the urging of one of his staff economists, Kefauver turned to drugs. He apparently realized that the allegedly high prices of drugs did not cause substantial injury to the public health,[42] but he was also a political realist who believed that in the controversial field of antitrust and monopoly, to get a piece of progressive legislation through Congress, he needed an issue, and he had to get "the people" stirred up about it.[43] In the drug industry he found his issue, and at the hearings he conducted, he got the public stirred up about it.

At the conclusion of the hearings, Senator Kefauver and the majority decided that drugs were overpriced.[44] The minority report concluded that during the ten-year period preceding the hearings, drug prices had *not* increased as much as drug costs and other prices.[45] Interestingly, one Law Review has concluded after an impartial analysis of the evidence introduced at the hearings, that either conclusion could be reached.[46]

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[41] Much of the purely historical background of this section is taken from Harris, *The Real Voice* (1964), also published in serialized form, Harris, "Annals of Legislation—The Real Voice" (Pts. 1-3), *New Yorker,* March 14, 1964, p. 48; March 21, 1964, p. 75; March 28, 1964, p. 46. [Hereinafter, citations will be to "The Real Voice"—*New Yorker,* with pagination from the serialized version.]

[42] S. Rep. No. 448, 87th Cong., 1st Sess. 3 (1961) where Senator Kefauver stated that the number of consumers who lacked money to pay for necessary drugs was small.

[43] "The Real Voice"—*New Yorker,* March 21, 1964, p. 76, where Senator Kefauver is quoted:

> If you hope to get through a piece of progressive legislation in an area as controversial as monopoly and antitrust, you've got to have a good, clear-cut issue . . . Then, it must be an issue that will stir up the public. Otherwise, you won't get anywhere.

[44] Hearings on S. 1552 Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 87th Cong., 1st & 2d Sess. 2-5 (1961).

[45] Id. at 17.

[46] 38 *N. Y. U. L. Rev.* 1082 n. 5.

Kefauver was aware that limiting the duration of patent protection would be the most direct way to lower drug prices.[47] But again, political pragmatism dictated the choice of a less risky route, for he realized that a direct attack on the patent system would bring such massive resistance from the business community at large, that it would destroy the chances of getting any drug legislation through the Congress.[48]

His alternative plan was based on a simple premise: federal controls over the production, distribution, and promotion of prescription drugs would encourage doctors to prescribe by generic name, enable patients to make savings on drug purchases, and provide smaller companies with a competitive boost.[49] In short, it was the hope of the Senator that by legislative fiat, all generic drugs could be created equal, and competition alone would dictate the cost in the marketplace.

An incisive comment on the shortcomings of this kind of economic reasoning has been made by Robert Pitofsky, Professor of Law at New York University.[50] Acknowledging Senator Kefauver's good intentions and high degree of personal integrity, in a review of Kefauver's posthumously published book, *In a Few Hands: Monopoly Power in America* (1965), Professor Pitofsky states:

> Few would argue that competition in the drug industry, judged by the goals that an economic order is generally supposed to serve, often has been defective. But when the Senator turns to an analysis of what he believes is wrong and what can be done about it, his suggestions are remarkable. Having just explained that basic economic conditions in the drug industry are not conducive to price competition among the few large firms in the industry, he nevertheless concludes that price uniformity and high profits are primarily the result of the unwillingness of business managers in the industry to compete. Explanations by drug executives, often disarmingly matter-of-fact, that it would be pointless to cut prices on a standardized product where total demand is inelastic are treated with scorn and disbelief. In short, the Senator is simply not prepared to face up to the fact, virtually unavoidable in view of his own analysis of economic conditions in the drug industry, that price uniformity may be the result of the independent response of businessmen to the prevailing conditions that he had been discussing, and that the antitrust laws apparently are incapable of dealing with persistent and consciously parallel business behavior in this kind of market setting. . . . His major proposal to remedy the economic ills which he describes is simply the continuation of proceedings like his own subcommittee hearings, which would focus national publicity on particular noncompetitive industries to alert the public to the worst excesses in these industries.
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> It is hard to believe that the technique of public exposure will do much to cure the economic ills with which Senator Kefauver was deeply concerned.[51]

[47] "The Real Voice"—*New Yorker*, March 21, 1964, p. 141-142.

[48] Id. at 143.

[49] *Op. cit. supra* note 47, at 144.

[50] Pitofsky, "Book Review," 40 *N. Y. U. L. Rev.* 816 (1965).

[51] Id. at 818, 820.

Professor Pitofsky points out, however, that with respect to certain excessive business practices in the drug industry, Senator Kefauver's approach was more successful in getting at the *problems* involved. He states: "Unfortunately, it is precisely because such excesses do not flow from any economic setting, but instead stem from delinquent business conduct, that the technique of exposé followed by enactment of revised standards constitutes an effective solution." [52] One might comment that the technique of exposé is a two-edged sword, and point to certain practices indulged in by those conducting investigative hearings as examples of behavior that calls for revised standards in the conduct of such hearings.[53] And, one might comment further, that while the technique of exposé may result in illumination of certain *problems* in a given area, it does not assure that type of thoughtful deliberation which leads to effective *solutions* for those problems.

Once the decision was made to attempt to promote the lowering of drug prices through the Food, Drug and Cosmetic Act, a statutory scheme was devised to attain this end. Reluctance on the part of the medical profession as a whole to prescribe generic drugs had been established to Senator Kefauver's satisfaction. He concluded that this reluctance was the result of industry promotional pressure,[54] despite strong evidence in the record that the real concern of the medical

[52] *Op. cit. supra* note 50, at 818-819.

[53] See "The Real Voice"—*New Yorker,* March 21, 1964, p. 80 where it is explained that Kefauver had "a genius for publicity creation" because he would make bold, inflammatory assertions shortly before 11:30 A. M. (for afternoon newspapermen) and 4:30 P. M. (for morning newspapermen), deadline times for reporters, which in effect left the statement unexplained in the article which headlined the accusation, or left the witness in the uncomfortable position of being unable to refute the assertion until the next morning. See also, "The Real Voice"—*New Yorker,* March 14, 1964, p. 104 where it is explained that shortly after the hearings were announced, Dr. Austin Smith, head of the PMA, requested that (1) generic names *only,* be used at the hearings, and (2) that he be called as the first witness. Kefauver conferred with his staff, who recommended that he turn Dr. Smith's requests down. The reasons given are that any agreement to use generic names only, would have turned the hearings into a "farce"; and that if Dr. Smith was called first, his testimony would cause the press to lose interest, and "the impact of the staff's case would be weakened" or lost altogether. Even more disturbing is the disclosure that one of Senator Kefauver's staff attempted to talk the staff members of another Congressman out of bringing Dr. Helen Taussig in to testify at a hearing, since her testimony would be the first hint of the scope of the Thalidomide tragedy, and it was deemed to be ". . . too early to spring this kind of story." "The Real Voice"—*New Yorker,* March 28, 1964, p. 66. When such sharp practices are conducted by businessmen their actions are subject to severe censure. Perhaps the same principles should be applied when legislators or their staffs are the perpetrators.

[54] "The Real Voice"—*New Yorker,* March 28, 1964, p. 47.

profession was with the quality, safety, and efficacy of so-called "generic equivalents.[55]

It was decided that the resistance of the medical profession to the "generic prescribing" concept might be overcome by enacting federally established quality-control standards and expanded FDA inspection powers.[56] These measures, it appears, were expected to assure doctors of the safety and efficacy of a drug regardless of its source, that is, its manufacturer.[57]

Then, by empowering the Secretary of HEW to review and simplify existing generic names, and to establish new ones, and by making it mandatory that the drug industry promote the generic name to physicians,[58] it was hoped that more generic prescribing would occur, competition would flourish, and drug prices would drop.

As it was finally enacted, the statutory scheme of Drug Amendments rarely make it mandatory for a manufacturer to perform specific acts or abide by specific prohibitions. Instead, the Drug Amendments invest the FDA with broad discretionary powers to promulgate regulations designed to be more specific than the statute.[59] The fear in the drug industry has been that FDA will be overcautious in its view of

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[55] Hearings Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 1st & 2d Sess. (1961), and S. Rep. No. 448, 87th Cong., 1st Sess. 223-44 (1961).

[56] "The Real Voice" — *New Yorker,* March 21, 1964, p. 144.

[57] For an up-to-date view of how some thoughtful physicians and pharmacists regard the 'generic drug' concept, see Sadove, "What is a Generic Equivalent?" *American Professional Pharmacist,* p. 23 (Feb. 1965) in which *24* separate factors are listed which can markedly alter the pharmacologic action of supposedly 'generic equivalents'. See also, Ulrich, "The Generic Drug Dispute in Louisiana," 117 *J. Louisiana State M. Soc.* 141 (May 1965), in which a review of the published material on generic prescribing is presented. One of the interesting facts Dr. Ulrich cites is testimony of Commissioner Larrick to Senator Kefauver's Committee on June 3, 1960, in which statistics were given which show that the likelihood of legal action resulting from composition of drug violations is over 100 times greater if the drugs are manufactured by the smaller companies, which included *all* the 'generic houses'. For an understanding of some practical long-range problems which may arise under a regime of 'generic prescribing', see Buatti, "An Appraisal of Progress in Drug Marketing," Address presented at the Ninth Annual Food Law Institute—FDA Educational Conference, Washington, D. C., Dec. 6, 1965. Professor Buatti states:

> The producers of generic products, for the most part, do little if any research in terms of new and better products. Their forte is to benefit price-wise from the competition with trade-marked products, while assuming little risk in identity and a small, mainly distributive, cost. Hundreds of products are marketed which have limited use, but are as essential as any of the glamour pharmaceuticals. Generic-name products, if not dealt with in competitive terms by the reputable firms, can seriously affect the future health of the American people. (At page 5.)

[58] *Op. cit. supra* note 56.

[59] 38 *N. Y. U. L. Rev.* 1082, 1083.

how to protect the public interest in health, to industry's detriment, and that the courts will continue to automatically reject any appeal from an FDA decision as soon as the FDA raises the "scare issue" of possible harm to health. As has been suggested,[60] the public's interest in health is not always fostered by restrictive regulations, and it is therefore the responsibility of the FDA to carefully consider both present and future interests in health and strike a balance between them, before issuing such regulations. It might be further suggested that where, as here, the broad powers of an administrative agency are dramatically expanded, a concomitant expansion of judicial interest and scrutiny of that agency's actions would be in the highest public interest.

Senator Kefauver believed that constant repetition of the generic name of a drug would induce physicians to prescribe generically.[61] There is little doubt that *he* wanted the "generic every time" requirement enacted into law. The fact remains that the statutory language did *not* precisely spell out this requirement. The statutory language merely requires that the generic name must appear on labels, in labeling, and in advertisements, ". . . printed prominently and in type at least half as large as that used thereon for any . . . " proprietary or brand name.[62]

The FDA contends that the legislative history of this section of the act supports its view of the statutory language as expressed in the regulations it has issued. An objective reading of the portions of the legislative history used by the FDA to support this contention might leave one with a first impression that the FDA's contention is a reasonable one.[63] However, there are other illuminating portions of

[60] Id. at 1132.

[61] *Op. cit. supra* note 56.

[62] *Op. cit. supra* note 18.

[63] See the Committee Report on the Senate version of the bill (S. 1552) which explains that the amendment adopted by the Senate would require the generic name to appear ". . . wherever a trade or brand name is used . . ." The Committee Report, Senate Report No. 1744, Part 2, to accompany S. 1552, 87th Cong., 2d Sess., page 8. See also the O'Brien floor amendment to the House version of the drug bill (H. R. 11581) which was adopted, 108 Cong. Rec. 21081, September 27, 1962, and later rejected by the Senate-House Conference Committee, Conference Report, Report No. 2526, 87th Cong., 2d Sess., Statement of the Managers on the Part of the House, pp. 23 and 24. See also 108 Cong. Rec. 22039, October 3, 1962, where Senator Kefauver expressed his views on what the Conferees rejection of the O'Brien amendment meant. See also the colloquy between Commissioner Larrick and Mr. William Goodrich, with a fragmentary comment by Congressman O'Brien, which is used to assert Congressman O'Brien's acknowledgement that his amendment was a limitation. Hearings before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 88th Cong., 1st Sess., April 26, 1963.

the legislative history which cast a different light on the intention of Congress. These portions refer back to facts brought out in testimony at the investigative hearings, to the effect that the evil to be remedied by statutory amendment was the publication of promotional materials with *no* generic name, or with the generic name in "microscopic" type so small as to be illegible.[64]

The District Court concluded that the chief concern of Congress was the prominent display of the generic name of a drug,[65] prominent in the sense of size and position of display, and not with the frequency with which the generic name should appear. FDA appealed this decision.

In the appellate court, the FDA cited the *Stanford Law Review* as "explicitly" agreeing with its position that the act as amended requires the use of the generic name every time the brand name is used, which intention the FDA further asserts is spelled out by the Commissioner's regulations.[66] The *Stanford Law Review* does take the position that a reading of the legislative history indicates that the statute might be *reasonably construed* as requiring such repetition of the generic name, and it states that it "seems clear that the FDA regulations are consonant with legislative purpose",[67] *but it also states:*

> The drug industry's position is tenable in that the statute does not explicitly require that the generic name accompany each use of the trade name.[68]

and even more importantly, it concludes after a consideration of many practical ramifications of the act that:

> Drastic price changes cannot be expected to result from the 1962 Drug Amendments . . . it is doubtful that the legislation will stimulate additional generic name prescribing. There is little assurance that the provisions enacted will persuade physicians that drugs produced by small manufacturers and sold by generic name will be as consistently reliable as their trade name counterparts. . . . Furthermore, even if some increase in generic-name prescribing were to result, will the pharmacist be persuaded that all drugs are now safe? Will he be willing to fill generic-name prescriptions with the less profitable generic-name drugs? . . . the variables are numerous and complex.[69]

In short, on a complete reading of the comment, the *Stanford Law Review* does *not* "explicitly" agree with the government "generic every

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[64] See Senator Kefauver's remarks upon the introduction of S. 1552 where he stated, in part: "The amendment is intended to help physicians to identify the family to which the drug belongs by showing clearly the official name of the product . . . ." 107 Cong. Record 5640 (April, 1961). See also S. Rep. No. 1744, 87th Cong., 2d Sess. 38-39 (1962), and 108 Cong. Rec. 17369 (Aug. 1962).

[65] 228 F. Supp. 855, 863 (D. Del. 1964).

[66] FDA Appellate Brief, at 46, note 15.

[67] *Stan. L. Rev.* 649, 656-657 (May 1964).

[68] Id. at 656.

[69] *Op. cit. supra* note 67, at 662-663.

time" position, but in fact, it raises serious doubts as to whether or not the economic ends Senator Kefauver hoped to promote through the food and drug law can be attained this way.

Nor is the *Stanford Law Review* alone in its reluctance to accept the policy reasons advanced by the government to support the "generic every time" requirement. The *New York University Law Review* has also expressed doubt as to whether such mandatory repetition of the generic name will lead to lower drug prices.[70] It concludes that since the "generic every time" regulations are meant to serve economic rather than health ends, the economic interest should be subordinated to the public interest in health which might be injured by the constant repetition of the generic name. A pertinent portion of the article highlights the reasoning:

> Labeling and advertising may be useful in informing doctors and pharmacists about new drugs and in disseminating information about all drugs, and the public interest in health will be promoted by any such use. But constant repetition of nonproprietary names, which often must be lengthy, will increase the length of labeling and advertising and the difficulty of reading them. The result could be a decrease in the frequency with which labeling and, especially advertising are read, to the detriment of the public health.
>
> The public health is, of course, served by making a drug's nonproprietary name conveniently available to doctors. . . . The only conceivable function of such repetition would be to lower the price of drugs by increasing doctor's familiarity with nonproprietary names, which would induce them to prescribe by such names. However, since it is doubtful that such repetition would in fact lead to lower prices and since the requirement serves economic rather than health ends, it should be subordinated to the public interest in health which might be injured by the constant repetition of nonproprietary names. 38 *N. Y. U. L. Rev.* 1082, 1120 (1963).

Summary and Conclusion

It appears from an over-all reading of the legislative history of pertinent portions of the Drug Amendments of 1962 that the District Court's decision on the merits is well-reasoned and should be upheld by the Supreme Court. Furthermore, the reasoning of the Court would seem to be supported by three authoritative comments on the "generic every time" issue.[71]

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[70] 38 *N. Y. U. L. Rev.* 1082, 1120. As to whether or not mandatory generic prescribing is desirable from a physician's point of view, see Ulrich, *op. cit. supra* note 57.

[71] 38 *N. Y. U. L. Rev.* 1082 (1963), 16 *Stan. L. Rev.* 649 (1964), 18 *Rutgers L. Rev.* 101 (1963).

Nor should the practical impact of these regulations be overlooked. A requirement of "prominence" which would lead to conspicuous display of the generic name and promote that increased awareness of the class to which a drug belongs is clearly in the public interest. On the other hand, the requirement of "frequency" may very will have the opposite effect, since the constant repetition of the generic name will lengthen the copy and make it more difficult to read. The result may well be a decrease in readership of such materials to the obvious detriment of the public health. And it should be pointed out that this is not a remote possibility, for readership surveys already indicate that the "brief summary" of warnings, side effects, etc., which has been added to advertisements and promotional material as required by the Drug Amendments of 1962, is not being read by physicians to any significant degree.[72]

The "generic every time" case may become a landmark in food and drug law for several reasons. First, it signals a significant shift in drug industry policy concerning the challenge of FDA decisions. Secondly, it highlights the need for increased judicial involvement in areas of food and drug law, *real* involvement which goes beyond mere automatic approval of any FDA decision simply because it is based on an alleged "health" matter, and especially in providing imaginative solutions to the procedural problems which abound in this field of law.

Third, this case and its background demonstrate a vital need for increased cooperation between government, industry, and the health professions.[73] Increased cooperation is a must because the pool of expert manpower in this field is not large enough to permit diverse interests and political factions to destroy its single-mindedness of purpose. That purpose is to provide the best health care for the nation that it is possible to provide. It is a purpose which calls for immediate, practical solutions, arrived at by calm deliberation and proper balancing of competing interests. **[The End]**

[72] Industry experience.

[73] Contrary to this opinion is that of one writer, Mintz, *The Therapeutic Nightmare* (1965) whose muckraking book questions the competence of industry, government, and the health professions with equal abandon.

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