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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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Privity of Contract Doctrine.—New York decisions on the extension of the benefits of warranty to persons other than the purchaser which generally limit actions to recovery against the immediate seller are construed by the author as indicating a rebirth in that state of the privity of contract doctrine. *Warren Freedman,* a New York City attorney, predicts that this limitation will be applied by the New York courts in limiting the effect of Section 2-318 of the Uniform Commercial Code which will become effective September 27, 1964. Mr. Freedman's comments appear at page 287.

***Codex Alimentarius* Commission Meeting.**—*Franklin M. Depew,* president of the Food Law Institute, Inc., will present a paper entitled "Suggested Principles for Consideration in Drawing Up International Food Standards," at the initial meeting of the *Codex Alimentarius* Commission at FAO Headquarters in Rome, Italy on June 25-July 3, 1963. Mr. Depew will attend this meeting as an observer in behalf of the Institute.

The *Codex Alimentarius* Commission was established by the Joint FAO-WHO Conference on Food Standards held in Geneva, Switzerland in October, 1962, under the auspices of the Food and Agriculture Organization and the World Health Organization of the United Nations. The Commission will begin its work of formulating international standards for various food products on a worldwide and regional basis at this meeting.

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Food·Drug·Cosmetic Law
Journal

The Effect of Food and Drug Laws on Producers of Paper and Paperboard Used for the Packaging of Food

By CHARLES W. WALTON

The Author Is Assistant Vice President of the K V P Sutherland Paper Company, Kalamazoo, Michigan. This Paper Was Presented to the Western Michigan University as Part of the Requirements for a Masters Degree in Business Administration, Which He Received in January, 1963.

IN 1958 THE FOOD ADDITIVES AMENDMENT to the Federal Food, Drug and Cosmetic Act was adopted causing a great deal of concern on the part of producers of packaging material. Any ingredient of the package that might migrate or transfer to food contained in the package became, by definition, a food additive subject to regulation and prior approval of the Food and Drug Administration.

Other acts and regulations have been adopted since 1958 indicative of increasing concern by the federal government for consumer welfare. This activity can be expected to have far-reaching effects on manufacturers who must depart from some of the traditional ingredients used in their products and in the marking or labeling of their products.

Since 1958, there have been several industry committees in the paper and paperboard industry which have done tremendous amounts of work in evaluating chemicals used in their industries, meeting with food and drug officials and otherwise attempting to reach an under-

standing as to the effect of these new laws and to insure compliance by the members of their industries.

This paper is a survey of the basic legal problems in this field for those concerned with food packaging material made from paper and paperboard.

INTRODUCTION

The purpose of this paper is to explore and discuss the various laws affecting producers of food protection packaging material and, particularly, manufacturers and converters of paper and paperboard used to make food containers.

The importance of food is self-evident. As a nation, we claim that our people are the best fed in the world. A trip through any modern supermarket will testify to this proposition, but it will also demonstrate the importance of food packaging materials. As an agrarian society, each family raised its own food. Even 50 years ago, fresh foods were sold from open containers and could be inspected by the consumer. However, as the food processing industry grew and developed, foods were processed and packed far from the place of sale. We now have foods that are canned, frozen, concentrated and dehydrated. They often have preservatives, colorants, sweeteners, thickeners, and other chemicals added to preserve them in the period until they are consumed.[1]

First Poison Labeling Law

We have come a long way from the illustration [2] of the candy-maker's assistant in England in 1858, who brought back arsenic of lead instead of sulphate of lime, causing the death of 20 customers and the severe illness of 200 others. This negligence did not violate any laws of England and it wasn't until 1868 that Parliament passed the first poison labeling law. This was the start of our labeling laws.

Food production is now a highly complex, technical industry and the packaging industry devoted to food protection has developed with it. Paper and paperboard manufacturing in themselves are highly technical and a great deal of sophisticated chemistry is in-

[1] Manufacturing Chemists' Association, Inc., *Food Additives What They Are/How They Are Used,* Washington, D. C., Manufacturing Chemists' Association, Inc., 1961, pp. 19-31.

[2] Stanley C. Hollander, "Problems and Puzzles in Trade Regulation," *Business Topics,* Michigan State University, Graduate School of Business Administration, Vol. 10, No. 3, Summer, 1962, p. 24.

volved in making a food wrapper or carton. The combination of these two industries makes the consumer an amateur when it is necessary to select a food item from a store shelf. The old legal doctrine of *caveat emptor* meaning "let the buyer beware" [3] is meaningless and out-of-date when it comes to determining the wholesomeness of a food grown in one part of the country, processed or packed in another, and offered to the buyer in a sealed, tamper-proof container with nothing but a picture and a label to indicate the contents. The basis for governmental regulation and control is obvious.

The statutes involved are primarily federal enactments promulgated under the general authority of the federal government, as provided in the Constitution,[4] to regulate interstate commerce. Because of the sizable investment in paper and paperboard making equipment, and the large volume produced by even a single-machine mill, it is safe to assume that no primary producer's activities are confined to intrastate commerce. Nevertheless, since some converters of paper and paperboard are small with a localized distribution and since many food packers serve a single state area, the existence of state laws and municipal ordinances affecting food sold within their boundaries must be recognized.

Federal Laws Primary Concern

However, the primary concern of the larger producers and of this paper are the federal laws which (except for a few relatively limited acts) begin with the original Federal Food and Drugs Act of 1906 (commonly known as the Pure Food and Drug Act or the Wiley Act).[5] The enactments since then include the Meat Inspection [6] and Poultry Products Inspection Acts [7] administered by the Department of Agriculture, the Federal Food, Drug and Cosmetic Act of 1938 (often referred to as the Copeland Act),[8] the 1958 Food Additives Amendment [9] and several additional new acts, regulations and proposals for legislation and regulation of food ingredients and labeling.

After following this field for over five years, the writer has been unable to find an up-to-date, comprehensive survey of this field. It

[3] Henry Campbell Black, *Black's Law Dictionary*, 4th ed., St. Paul, Minnesota, West Publishing Company, 1951, p. 281.

[4] United States Constitution, Art. I, Sec. 8.

[5] United States Statutes, C. 34, Secs. 768-772; 21 USC 1 et seq.

[6] 34 Stat. 1260, 21 USC 71 et seq. (1907).

[7] 46 Stat. 689, 21 USC 451 et seq. (1957).

[8] 52 Stat. 1040, 21 USC 301 et seq.

[9] 72 Stat. 1784, 21 USC 348.

is believed that a survey of this type will be a contribution to the packaging industry and might well serve as a primer on the basic legal problems with which not only students, but managers, technical personnel and legal counsel working with paper and paperboard, either as a producer or a user, should be acquainted.

Very simply stated, papermakers were aware of the early federal laws, used their own judgment over the years as to what was suitable for contact with food and had little contact with the federal government. With the enactment of the Food Additives Amendment in 1958, all this was changed. Industry groups organized committees to study the significance of this new legislation and through the efforts of their technical and legal personnel, working with governmental personnel, have substantially satisfied the newly imposed requirements. However, more regulation looms on the near horizon.

It is the intention of this paper to look into the earlier laws as to their legislative histories, the aspects of packaging they regulated, the case law relating to the liabilities of package and container manufacturers, and some of the state laws in this field. Congressional activity leading up to the enactment of the Food Additives Amendment will be reviewed, along with its provisions and regulations issued by the Food and Drug Administration (FDA). Additional recent (since 1958) regulations and enactments having an effect on the paper and paperboard packaging industry will be surveyed. This will then be followed by a more detailed discussion of the practical effects of these laws on the industry, the steps taken to comply therewith and the liabilities assumed by producers.

Some of the proposals in Congress and the current probe of packaging and labeling will be commented upon, followed by some observations and conclusions.

The references relied upon in this paper to a large extent are papers delivered at industry meetings by FDA officials and by technical and legal experts in the packaging industry. A glance at the bibliography appended to this paper will reveal that Commerce Clearing House is the principal publisher of those articles that have been printed. It might be parenthetically observed that the food industry and others concerned with this subject should applaud this publisher's commendable effort to keep them informed in this somewhat specialized, technical, but highly significant, field of law and regulations.

These industries should also recognize and support the public service performed by The Food Law Institute in editing the many

papers which appear in the FOOD DRUG COSMETIC LAW JOURNAL, and the valuable research books of The Food Law Institute Series, all published by Commerce Clearing House.

CHAPTER I

BACKGROUND

According to one writer [10] the efforts of the state to prevent food and drug adulteration date back to early Athens and Rome, where provisions against the adulteration of wine were enacted. In this country, the first efforts were state laws passed in the early nineteenth century to maintain the purity of medicines.

The first food law, enacted in 1883, was a federal law designed to prevent the importation of adulterated and spurious teas. This was followed by legislation aimed at specific commodities, and general measures passed by several states. In 1890, a federal law prohibiting the importation of adulterated or unwholesome food, drugs or liquor was adopted [11] and finally in 1906, the first national Pure Food and Drug Law was passed.

Pure Food and Drug Act of 1906

The original 1906 Federal Food and Drugs Act was designed to prevent the manufacture, sale or transportation of adulterated or misbranded, poisonous, or deleterious foods, drugs, medicines and liquors. Although there were some problems of constitutionality as applied to manufacturing in a state, the commerce clause of the Constitution supported the prohibition of introducing such items into interstate commerce.[12]

As pointed out by Dunn,[13] this was the third major law enacted by Congress to regulate interstate and foreign commerce (following enactment of the Interstate Commerce Act in 1887 and the Sherman Antitrust Act in 1890).

The most notable of the provisions in this Act were those directed against misbranded, as well as adulterated, foods, drugs and liquors.

[10] Stephen Wilson, *Food and Drug Regulation*, Washington, D. C., American Council on Public Affairs, 1942, p. 7.

[11] 26 Stat. 415, cited in FOOD DRUG COSMETIC LAW REPORTS, topical law reports in four loose leaf volumes, Chicago, Commerce Clearing House, Inc., p. 4005.

[12] FOOD DRUG COSMETIC LAW REPORTS, cited at footnote 11, at p. 4005.

[13] Charles Wesley Dunn, *The Food and Drug Law in the United States*, Commerce Clearing House, Inc., Chicago, 1955, p. 6.

As applied to food containers, labeling was not mandatory, but any labeling was required to be true and not misleading.[14]

Food, Drug and Cosmetic Act of 1938

Difficulties in administering the 1906 law became apparent almost immediately and as early as 1911, a new law was advocated.[15] As the food and drug industries progressed to more complicated products, and the consumers literally got farther away from the farm, the cry for consumer protection increased. Although a few minor acts were passed to plug loopholes, it wasn't until May of 1935 that the Copeland Bill passed the Senate and, over a year later, the House, with amendments.[16] Finally, a Conference Committee rewrote an acceptable bill, which became law on June 25, 1938, as Public Act No. 717 of the 75th Congress.

The revisions provided by the 1938 Act included labeling of foods and drugs, authority for the promulgation of definitions and standards of identity for foods, the establishment under certain conditions of tolerances for poisonous and deleterious substances in foods, the mandatory pretesting of new drugs, obtaining permission of the Secretary of Agriculture to market new drugs, and the inclusion of cosmetics as subject to control and regulation.[17]

The provisions of interest to the packaging industry are the definitions of adulteration [18] and misbranding [19] of food.

The Food and Drug Administration

The original responsibility for enforcement of the 1906 Act was placed in the Secretary of Agriculture. Penalties were fixed for violations and authorization given for the sampling of foods, inspection of premises and shipping records, seizures and condemnation of adulterated and misbranded foods and drugs, and trial of offenders in the United States district courts.[20]

The 1938 Act provided for the issuance of administrative decisions by the Food and Drug Administration, subject to appeal to the United States Circuit Court of Appeals.

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[14] Manufacturing Chemists' Association, Inc., *Food Additives Manual,* Parts One, Two and Three, Washington, D. C., Manufacturing Chemists' Association, Inc., 1962, p. 2.

[15] Stephen Wilson, cited at footnote 10, at p. 72.

[16] FOOD DRUG COSMETIC LAW REPORTS, cited at footnote 11, at p. 4005.

[17] Manufacturing Chemists' Association, Inc., *Food Additives Manual,* cited at footnote 14, at p. 2.

[18] Sec. 402.

[19] Sec. 403.

[20] Manufacturing Chemists' Association, Inc., *Food Additives Manual,* cited at footnote 14, at p. 2.

The Food and Drug Administration, as we know it today, grew out of the Bureau of Chemistry of the Department of Agriculture. Its chief, in 1906, was Harvey W. Wiley, who spearheaded the drive for the 1906 Act.[21] The Bureau's personnel in 1906 numbered 110 and its appropriation for the fiscal year of 1906 was $130,920.

With the establishment of the Department of Health, Education and Welfare, enforcement and administration of the Food and Drug Act was transferred to the Secretary of Health, Education and Welfare.[22] Today, although still a relatively small governmental agency, the FDA staff has grown to 2,260 and its budget for fiscal year 1961-1962 was $26,328,000.[23] A new headquarters building is currently under construction in Washington. The agency's authorized strength in 1962 was approximately 3,200—up from 1,400 just prior to the passage of the Food Additives Amendment.[24]

FDA administers, in addition to the Food, Drug and Cosmetic Act, the Tea Importation Act,[25] the Import Milk Act,[26] the Federal Caustic Poison Act,[27] the Filled Milk Act [28] and the Federal Hazardous Substances Labeling Act.[29]

The FDA is similar to other governmental agencies which have grown up during the last 30 to 40 years. However, FDA has been a career agency with a minimum of change in personnel and policy despite political changes in Washington. Its decisions on safety of products offered to the public have, until recently, generally been accepted without challenge. Drawing on the experience of handling new drug applications, the General Counsel of the FDA opined in 1958 [30] that formal hearings and judicial review of FDA decisions and actions under the Food Additives Amendment would be a rarity indeed.

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[21] Stephen Wilson, cited at footnote 10, at pp. 11-44.

[22] Manufacturering Chemists' Association, Inc., *Food Additives Manual,* cited at footnote 14, at p. 2.

[23] *New York Times,* August 5, 1962, p. 50.

[24] L. L. Ramsey, "Progress Under the Food Additives Amendment of Interest to the Cereal Chemist," an address to the annual meeting of the American Association of Cereal Chemists in St. Louis, Missouri, May 20-24, 1962, published in 17 FOOD DRUG COSMETIC LAW JOURNAL 485 (1962).

[25] 29 Stat. 604, 21 USC C. 2.

[26] 44 Stat. 1101, 21 USC 141-149.

[27] 44 Stat. 1406, 15 USC 401 et seq.

[28] 42 Stat. 1486-87, 21 USC 61-64.

[29] Public Law 86-613, 74 Stat. 372.

[30] William W. Goodrich, "Rule-Making Under the Food Additives Amendment," a paper delivered at the Washington Conference to discuss the 1958 Food Additives Amendment, November 24-25, 1958, published in 13 FOOD DRUG COSMETIC LAW JOURNAL 761 (1958).

However, it should be noted that recently the FDA has been severely criticized for its handling of the drug thalidomide and the anti-cholesterol drug Mer/29.[31] Following these outbursts and the very recent report [32] of the Citizens Advisory Committee, appointed in 1961 to study FDA, it is expected that the agency will be reorganized in the near future. The report of the 16-man Citizens Advisory Committee headed by Dr. George Y. Harvey of the Department of Political Science of the University of Missouri, recommended,[33] among other things, that the top posts of FDA be filled by scientists and not primarily by persons with backgrounds as inspectors. It severely criticized the emphasis on "investigation and prosecution" and urged more preventive and educational measures. It also recommended improvement of FDA-industry relations.[34]

Meat Inspection Act

The Federal Meat Inspection Act became law in 1907 and under it interstate and foreign commerce in meat has been rigidly controlled by means of federal inspection of livestock before entering any slaughtering, packing, meat canning, rendering or similar establishment, and the inspection of meat and carcasses after slaughter. The use of dyes, chemicals, preservatives or ingredients which render meat or meat products unsound, unwholesome, unhealthy, or unfit for human food is banned. The Secretary of Agriculture is authorized to issue regulations specifying what may or may not be used.[35] Packaging materials used in federally inspected plants must meet the approval of the Meat Inspection Division of the Department of Agriculture.

Poultry Products Inspection Act

The Poultry Products Inspection Act, approved August 28, 1957, became effective January 1, 1959. It applies not only to poultry and poultry products produced and moving in interstate commerce, but also to those moving in major consuming areas regardless of whether or not they move across state lines. Such consuming areas are designated by the Secretary of Agriculture.[36]

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[31] *The Washington Post,* October 4 and 5, 1962.

[32] *The Washington Post,* October 26, 1962.

[33] *New York Times,* October 26, 1962.

[34] *Food Chemical News,* October 29, 1962, pp. 3-15. The full Report of the Citizens Advisory Committee is reprinted in 17 FOOD DRUG COSMETIC LAW JOURNAL 581-717 (1962).

[35] Manufacturing Chemists' Association, Inc., *Food Additives Manual,* cited at footnote 14, at p. 1.

[36] Manufacturing Chemists' Association, Inc., *Food Additives Manual,* cited at footnote 14, at p. 1.

This Act prohibits processing, sale or transportation in interstate commerce, or in any designated consuming area, of any poultry not inspected and stamped with approval under the Act. Federal inspection of poultry processing plants is provided under the Act and packaging materials used in such establishments must have the necessary approvals.

Federal Trade Commission Act

Another act affecting one aspect of food is the Federal Trade Commission Act,[37] as amended on March 21, 1938, by the Wheeler-Lea Act.[38] One of the major purposes of this amendment was to broaden the powers of the Federal Trade Commission over unfair methods of competition by extending its jurisdiction over unfair or deceptive acts or practices. More specifically, Section 12(a) of the Amendment was aimed directly at false advertisement of foods, drugs, devices and cosmetics.

The distinction [39] between the Wheeler-Lea Act and the Federal Food, Drug and Cosmetic Act is that the former is concerned with false advertising of food, drugs, devices and cosmetics, while the latter deals with adulteration, packaging and labeling of the products.

Although there are several additional statutes affecting food, they are not particularly concerned with packaging and probably need not be singled out for comment here.

Product Liability

As modern mass production methods made it possible to prepare food in factories more efficiently and at less cost than at home, and more items were sold in cans and bottles, occasionally some foreign substances would get into the finished product. Thus began the deluge of exploding bottles, mice in beverages, and similar cases known as product liability cases.

Product liability law is the principal legal avenue for the recovery of damages for person injury resulting from food or its container.

As a legal proposition, one of the earliest obstacles was the fact that there was usually no contractual relationship between the producer of the product and the ultimate consumer, due to the intervention of middle men (wholesalers, retailers, and so forth). In product

[37] 38 Stat. 717, 15 USC 41.
[38] 52 Stat. 111.
[39] Food Drug Cosmetic Law Reports, cited at footnote 11, at p. 4010.

liability cases based on the theory of negligence, the leading American case, followed today by most states, is *MacPherson v. Buick*[40] which put aside the notion that liability can grow only out of a contractual relationship.

In addition to negligence theories, product liability cases are often based upon theories of warranty, either expressed or implied. In fact, under the Uniform Commercial Code, there are implied warrantees of merchantability[41] and of fitness for a particular purpose[42] that may be invoked in a legal action. It is the writer's view that any producer of paper and paperboard packaging material warrants, upon its sale, that it may legally be sold and that it is suitable for the use for which it was produced or for uses to which it can reasonably be expected to be applied. This, of course, implies that the producer of the material knows, or should know from the nature of the goods, the use to which they will be put. This is not an unreasonable assumption, since most packaging material is printed to indicate the product it will contain.

A further basis for product liability is for violation of a state or municipal pure food law. In the next section of this chapter, brief comments will be made on these laws.

Manufacturers have sought to limit their liability by disclaimers and by attempting to shift the burden to retailers. But particularly in nationally advertised, brand name items, the courts have looked with disfavor on these devices. As a practical matter, it is believed that most manufacturers (except possibly the largest who may be self-insurers) carry product liability insurance to cover liability for damages caused by their products. The tendency is to place the burden of strict liability on any seller of food in a defective condition, making him liable for any bodily harm caused to the consumer even though the seller exercised all possible care and despite the absence of any contractual relationship.[43]

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[40] PRODUCT LIABILITY CASES 827, 217 N. Y. 382, 111 N. E. 1050 (1916).

[41] *Uniform Commercial Code (U. L. A.)*, Brooklyn, New York, Edward Thompson Company (1962) Sec. 2-314.

[42] Cited at footnote 41, at Sec. 2-315.

[43] Reed Dickerson, "The Basis of Strict Products Liability," a paper presented before the Division of Food Drug Cosmetic Law, Section of Corporation, Banking and Business Law of the American Bar Association, St. Louis, Missouri, August 9, 1961, published in 16 FOOD DRUG COSMETIC LAW JOURNAL 585-596, (1961).

State Food Laws

The passage of revised federal legislation in 1938 started a movement for a Uniform State Food, Drug and Cosmetic Act. A model uniform act was accepted and endorsed in 1940 by the Executive Committee of the Association of Food and Drug Officials of the United States. All 50 states have some type of food or drug law and 42 of them have patterned their laws on the Federal Act of 1938. In general, these laws require labeling to show the source of the product, the ingredients and the presence and quantity of imitation or artificial color and flavoring. If the container is a so-called measure container, the weights and measures laws of several states require special marking.

Although the writer is unaware of any legal action involving paper or paperboard packaging material under state laws, this could become a most troublesome area if the various states adopted variations of the 1958 Food Additives Amendment. In addition, the various state laws present real problems to the food packers who often have to have special copy printed on their food containers to meet state labeling or weights and measures requirements. This involves extra costs for press stops in the printing of cartons or wrappers.

A complex legal issue involving the doctrine of federal preemption can arise whenever a conflict arises between a state and federal law. The only practical solution, according to one of the legal specialists in this field, is uniform state laws.[44]

CHAPTER II

THE FOOD ADDITIVES AMENDMENT OF 1958

The Food Additives Amendment of 1958 amended the basic Food, Drug and Cosmetic Act of 1938. The old law prohibited any food additive which was a poisonous or deleterious substance, except where it was required in the production of food or could not be avoided by good manufacturing practice.[45] However, the 1938 law did not reach an unsafe additive until the food containing it was sold and injuriously consumed.[46] As pointed out in the report by the House Committee on Interstate and Foreign Commerce concerning H. R. 13254:[47]

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[44] Michael F. Markel, "Federal Preemption," a paper presented to the P. M. A. Law Section meeting in White Sulphur Springs, West Virginia, May 7-9, 1962, published in 17 FOOD DRUG COSMETIC LAW JOURNAL 453 (1962).

[45] Charles Wesley Dunn (ed.), *Legislative Record of 1958 Food Additives Amendment to Federal Food, Drug and Cosmetic Act,* Commerce Clearing House, Inc., Chicago, 1958, p. X.

[46] Dunn, cited at footnote 45.

[47] Dunn, cited at footnote 45, at pp. 9-10.

The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food. On the other hand, present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies.

In the early (1952) Report by the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics (known as the Delaney Committee)[48] the scope of the problem was presented as follows:

The number of chemicals entering the food supply of the Nation has increased tremendously in the last decade. Chemical substances are being introduced into the production, processing, storage, packaging and distribution of food at an ever-increasing rate. There is hardly a food sold in the market place today which has not had some chemicals used on or in it at some stage in its production, processing, packaging, transportation or storage. These foods include those items eaten by every family, ranging from staples like bread to such luxury items as the maraschino cherry. Some eminent pharmacologists, toxicologists, physiologists and nutritionists expressed the fear that many of the chemicals being added to food today have not been tested sufficiently to establish their toxicity and suitability for use in food. These scientists are not so much concerned with the acutely toxic compounds, whose harmfulness can readily be detected, as with those chemicals which may produce harmful effects only after being ingested for months or perhaps years.

The indirect addition of chemicals to our food supply also raises serious problems. For example, cattle are being treated with antibiotic drugs in the control of mastitis, anthrax and other diseases. There is a question whether the presence of small amounts of antibiotics in milk and milk products has any effect on the consumer; that is, whether the consumer develops a sensitivity or resistance to these chemicals.

For this reason a law requiring pretesting of food additives and permitting the use of additives at safe levels was urged.

Legislative History

As summarized by Dunn,[49] the Congress began an investigation in 1950-1952 by the House Delaney Committee which held public hearings and thereafter recommended that the Food, Drug and Cosmetic Act be amended to require an industrial safety pretesting of such additives similar to that required for new drugs. As a result in 1954, the Congress enacted an amendment to provide for the safety of pesticide chemical residues in natural food.[50] Additional house bills were introduced during the 83rd and subsequent Congresses.

[48] House Report No. 2356, 82nd Cong., 2d Sess., reprinted in Dunn, cited at footnote 45, at p. 89.

[49] Dunn, cited at footnote 45, at p. XI.

[50] Public Law No. 518, 83rd Cong., approved July 22, 1954.

During the second session of the 84th Congress, five days of hearings were held on 10 bills dealing with chemical additives in food [51] and in the 85th Congress 11 days of hearings were held on 9 bills. As a result of the hearings and after consideration of the various bills, the Chairman of the Subcommittee on Health and Science, Congressman John Bell Williams of Mississippi introduced a "clean" bill [52] which was reported unanimously by the subcommittee to the full committee. The full House Committee unanimously reported the bill out with one amendment and thereafter added the so-called Delaney cancer amendment. The House and Senate unanimously passed the bill with further amendments increasing the salary of the Commissioner of Food and Drugs, and another minor amendment. The President approved the bill on September 6, 1958, when it became law.[53]

Mention of packaging material is found in the report of the Delaney Committee [54] as follows:

> Nor is the problem confined to inadequately tested insecticides or other chemical substances added to foods. Paper, fiber, and plastics are becoming increasingly popular as food containers and food handling equipment. These, together with the use of chemicals in wrappers, may create a hazard to health. It is obvious that the toxicity and potential dangers of these materials should be studied before their use in the food industry is permitted.

Provisions

The amendment itself is long and technical containing numerous sections and totalling six printed pages. However, its principal provisions will be outlined.

Definitions.—The amendment first provides the citation name of the "Food Additives Amendment of 1958" and then broadly defines the term "food additive" [55] as:

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

[51] Report of House Committee on Interstate and Foreign Commerce, reprinted in Dunn, cited at footnote 45, at pp. 10-11.

[52] H. R. 13254, 85th Cong., 2d Sess.

[53] Dunn, cited at footnote 45, at p. XI.

[54] House Report No. 2356, reprinted in Dunn, cited at footnote 45, at p. 89.

[55] Sec. 201(s).

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; or

(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 USC 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 USC 71 and the following).

This definition is presented in full since it sets forth the distinction between an intentional additive (covered by the Amendment) and an accidental additive (not covered by its provisions). It also clearly brings packaging materials within its scope if they contain ingredients which may reasonably be expected to become a component (or otherwise affect the characteristic of any food) under the conditions of their intended use.

The definition further provides for the exclusion of materials generally recognized as safe (GRAS) by qualified experts or, if used in food prior to January 1, 1958, has proved to be safe through either scientific procedures or common use.

It also excepts those items previously approved for use under the 1938 Act, the Meat Inspection Act and the Poultry Products Inspection Act. Finally, it excludes any pesticide chemical in or on a raw agricultural commodity and any such chemical intended to be used in the production, storage or transportation of such a commodity.

Thus, in the case of a food additive, the question of safety must be determined scientifically if it has not been determined by the experience of common use in the case of old food additives used before January 1, 1958. In the case of a substance accidentally added to food, it remains regulated by the prohibition contained in the Act against any food that bears or contains any poisonous or deleterious substances which may render it injurious to health.[56]

Prohibitions.—The Amendment adds to the Act a new Section 409 which makes a food additive, or a food bearing or containing an additive, adulterated within the meaning of the Act and therefore outlawed from interstate and foreign commerce if it is unsafe within the meaning of that Section. This is considered to be the basic regulatory law of the Amendment.[57] The procedure for petitioning for an administrative regulation, the standards by which the FDA shall act on the petition, and procedures for judicial review are spelled

[56] Sec. 402(a)(1).

[57] Dunn, cited at footnote 45, at p. XVI.

out in this Section also. As Dunn [58] summarized the law, it provides that after the manufacturer of a food additive, or a food bearing or containing it, completes the required safety pretesting, he must file a petition with the FDA regarding it. This is a petition that proposes the issuance of an administrative regulation prescribing the conditions under which such additive may be safely used. The FDA is directed to publish the regulation proposed by such petition in general terms within 30 days after it has been filed.

Section 409(b)(2) sets forth the requirements of the petition which shall contain: (A) the name and all pertinent information concerning the food additive, including, where available, its chemical identity and composition; (B) a statement of the conditions of the proposed use of the additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling; (C) all relevant data bearing on the physical or other technical effect the additive is intended to produce, and the quantity of the additive required to produce such effect; (D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and (E) a full report of the investigation made with respect to the safety for use of the additive, including full information as to the methods and controls media used in conducting such investigation. Moreover, upon request, the petitioner must furnish a full description of the methods used in, and the facilities and controls used for, the production of the additive.[59] Upon request, the petitioner shall also furnish "samples of the food additive, or articles used as components thereof, and of the food in or on which the additive is proposed to be used." [60]

The law further requires [61] the FDA to fairly evaluate the pretesting and other data submitted and issue an order within 90 days after the petition is filed unless that period is extended, upon written notice to the petitioner, for further study and investigation of the petition. The order will either establish a regulation prescribing the conditions under which the additive may be safely used or deny the petition. The law further provides standards which the FDA must follow in promulgating its regulation.[62] Further tolerance limitations may be imposed on the use of additives.

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[58] Dunn, cited at footnote 45, at p. XXI.

[59] Sec. 409(b)(3).

[60] Sec. 409(b)(4).

[61] Sec. 409(c).

[62] Sec. 409(c).

Upon issuance of an order or regulation, it shall be published [63] and within 30 days, any person adversely affected thereby may file objections.[64] A public hearing shall be held and by order, the FDA shall act upon the objections. Provision is further made for appeals to the United States Court of Appeals and, by certiorari, to the Supreme Court of the United States.[65]

Delaney Cancer Clause.—One of the much discussed provisions of this law is found in the standards which FDA is bound to follow. It was added on to H. R. 13254 [66] by the House Commerce Committee and has become known as the Delaney Cancer Amendment. It provides:

> That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, . . .

The comments on this clause are two-fold: first, that no tolerance limitations can be imposed where a carcinogen may be safe in small quantities; and second, that since medical experts do not know the cause of cancer, this clause seems administratively unworkable. As pointed out by one scientific group,[67]

> The conservative position would demand that substances that produce cancer in experimental animals should be excluded from human foods as a precautionary measure, even though it is known that a substance carcinogenic in one species is not necessarily carcinogenic in others.

However, it should also be mentioned that the Senate Committee on Labor and Public Welfare, in its report on H. R. 13254 and its amendment [68] commented: ". . . We believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration."

Guaranties

In discussing the burdens added by the Amendment, Dunn [69] points out that the responsibility for complying with the industrial safety pretesting requirements in the case of a chemical food additive normally resides in the manufacturer of the additive and secondarily resides in the manufacturer of a food bearing or containing this addi-

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[63] Sec. 409(e).
[64] Sec. 409(f)(1).
[65] Sec. 409(g).
[66] Sec. 409(g).
[67] National Research Council, Food and Nutrition Board, National Academy of Sciences, statement on "Cancer and Food Additives," published in *Public Health Reports*, Vol. 72, No. 5, May, 1957, p. 449.
[68] Senate Report No. 2422, 85th Congress, 2d Session, reprinted in Dunn, cited at footnote 45, at p. 69.
[69] Dunn, cited at footnote 45, at p. XXI.

tive. But the food manufacturer may obtain a guaranty from the additive manufacturer as authorized by the Act,[70] that a food bearing or containing his additive is not adulterated or misbranded within the meaning of the Act when it is used as directed by him. If a food manufacturer obtains such a guaranty in good faith from a responsible chemical additive manufacturer and uses his additive as thus directed, it is a legal defense against a criminal prosecution of the manufacturer for using the additive. But, if the food manufacturer deviates significantly from the directed use of the additive or if he independently develops his own use of this or another chemical additive, he is subject to the safety pretesting requirements of the law. It should be noted that a guaranty, while a defense against criminal prosecution, is not a defense against seizure of the food or an injunction proceeding under the Act. As for guaranties from container manufacturers, this subject will be discussed further in Chapter IV.

Summary

It seems clear that by comparison with the earlier Food, Drug and Cosmetic Act, the 1958 Amendment made substantial and fundamental changes in the food and drug law and in the procedural burdens when a new chemical is introduced into the food supply whether directly or indirectly. As one executive in the packaging field observed:[71]

> . . . [T]he packaging industry found itself directly concerned with some of the legal and safety aspects of the food and drug industries, its major customers. The law had defined a food additive as any substance directly or indirectly becoming a part of the food product. The package, thus, became a part of the finished product and had to be treated in a manner similar to the product itself from the viewpoint of potential health hazards.

It also put the federal government further into the activities of the food industry while at the same time placing severe burdens on the smaller food manufacturers that do not maintain the laboratories and personnel for extensive research and testing. The responsibility on chemists and the chemical profession is great to assure compliance with the law as well as safeguarding the nation's food supply.

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[70] Sec. 303(c)(2).

[71] Adolph Miller, "The Effect of the Food Law on Packaging Materials," an address to the 1961 Joint National Conference of Food and Drug Administration and the Food Law Institute, in Washington, D. C., November 27-28, 1961, published in 17 FOOD DRUG COSMETIC LAW JOURNAL 38 (1962).

CHAPTER III

RECENT ADDITIONAL LEGISLATION AND REGULATIONS AFFECTING FOOD PACKAGING

Since the passage of the Food Additives Amendment in September, 1958, there have been several events which indicate a continuing concern of the federal government that the consuming public be protected and informed through regulation and labeling of the items it purchases.

Color Additive Amendments

One such enactment was the Color Additive Amendments [72] to the Federal Food, Drug and Cosmetic Act, passed on July 12, 1960. As stated by the Department of Health, Education and Welfare [73] in transmitting the proposed color additive bill to Congress, the objective of the legislation is as follows:

> The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug and Cosmetic Act, with a scientifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

The pressure for this law came from the Food and Drug Administration following its decertification of Red, No. 32, a coal-tar derivative used for the artificial coloring of oranges. As pointed out by an FDA spokesman [74] following the delisting of three coal-tar colors in urging new law:

> Further, there is a prospect of gradual removal of colors from the permitted list, with no indication that adequate substitutes will be developed which are suitable for acceptance on the list . . . In such case, they will be unable to meet the stringent requirements of the present law that they be harmless for unrestricted use, although in the quantities needed to color particular foods they might be used under tolerance limitations. . . .

Under the old law, only *harmless* coal-tar colors could be used. Then FDA interpreted "harmless" to mean harmless in any amount and that no color could be used in limited amounts that were safe, if

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[72] Public Law 86-618, 74 Stat. 397.

[73] Manufacturing Chemists' Association, Inc., *Food Additives Manual*, cited at footnote 14 (quoting from letter to the Congress from the Department of Health, Education and Welfare), p. 14.

[74] Winton B. Rankin, "Color Additives," a paper presented at Washington Conference to Discuss 1958 Food Additives Amendment of Federal Food, Drug and Cosmetic Act, November 24-25, 1958, published in 13 FOOD DRUG COSMETIC LAW JOURNAL 774 (1958).

a greater amount were unsafe.[75] The Color Additive Amendments provide for regulation of all food, drug and cosmetic colorants and for regulations of acceptance. To the producer of paper and paperboard food packaging, the colors used in paper dyes or in printing inks that might transfer to packaged food should be selected from colors approved for use as a color additive.

Ice Cream Labeling Regulations

Under its authority[76] to promulgate regulations for standards of identity and labeling, the FDA in 1960 issued regulations[77] for the labeling of ice cream, ice milk, sherbets, water ices and quiescently frozen dessert products. These regulations had been under consideration for over 18 years, during which public hearings were occasionally held. Of concern for the producer of ice cream packages, the regulations, as issued, provided for label statements of the presence of artificial flavoring or coloring in at least as large type as the name of the product (that is, "Vanilla, artificial flavoring added, ice cream" to be in the same type size).[78]

These regulations brought forth an immediate response from the ice cream industry in the filing of four lawsuits[79] challenging the reasonableness of the regulations. Pending the outcome of this challenge, the FDA suspended[80] the effective date of the more burdensome provisions of the regulations. Negotiations have been under way between representatives of the International Association of Ice Cream Manufacturers and FDA in which some of the practical problems of carton design and printing have been brought out.

Many ice cream cartons are produced for a specific customer and carry labeling specified by that customer, so that the labeling regulations are principally the ice cream producers' concern. However, the

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[75] John L. Harvey, "Food Additives and Regulations," a paper presented at the Food Industry Science School of Rutgers University, January 18, 1962, published in 17 FOOD DRUG COSMETIC LAW JOURNAL 272 (1962).

[76] Food, Drug and Cosmetic Act, Sec. 401.

[77] *Federal Register,* July 27, 1960, pp. 7125-41 (effective October 25, 1960).

[78] *Federal Register,* July 27, 1960, at p. 7139.

[79] *International Association of Ice Cream Manufacturers and High's Dairy Products Corporation v. Commissioner of Food and Drugs,* (CA of DC); *Food Adjuncts Association, Inc. v. Commissioner of Food and Drugs,* (CA of DC); *National Dairy Products Corporation v. Secretary, Department of Health, Education and Welfare,* (CA-2) filed October 14, 1960; *Foremost Dairies, Inc. v. Secretary, Department of Health, Education and Welfare* (CA-9) filed October 10, 1960.

[80] *Federal Register,* November 3, 1960, p. 10532.

larger carton makers preprint cartons in a variety of what are termed "stock designs" which are sold to small ice cream producers who do not have their own carton designs. These stock design cartons are usually in series of compatible designs for the more common flavors. When ordered they are then rerun through a job press (usually one-color) to print the customer's name and address. Since the labeling under the proposed regulations might vary tremendously for even the same basic flavor of ice cream because of the ingredients used, the present practices of stock design cartons would be altered severely. It now appears that a compromise set of regulations will be adopted acceptable to both FDA and the ice cream manufacturers.[81]

Other Labeling Requirements

Although not concerned with food items, packaging producers should be aware of the existence of the Federal Insecticide, Fungicide, and Rodenticide Act[82] and the Federal Hazardous Substances Labeling Act.[83] The former, administered by the Department of Agriculture, relates to the label declaration of ingredients, claims for the product and caution notices on certain products such as insecticides often found on the shelves of food markets. The latter, adopted in 1960, relates to labeling of products commonly found in the home which contain toxic or flammable substances, irritants, sensitizers or whose containers generate pressure. Such products include waxes, cleansers, and household items sold in pressure cans.[84]

Labeling has been a major area of concern for food producers for some time and is a subject in itself for extensive review if one is interested, more as a producer of foods than as a producer of packaging material. In addition to those mentioned, there are both federal and state laws, establishing food standards and the labeling to appear on foods meeting these standards and also, to prevent misbranding and deception, spelling out what a label must show, what it may not contain and what may optionally appear thereon.[85]

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[81] *Food Chemical News,* July 2, 1962, p. 8.

[82] Public Law 104, 80th Cong., as amended by Public Law 86-139, 74 USC 135.

[83] Cited at footnote 29.

[84] George T. Scriba, "The Federal Hazardous Substances Labeling Act," a paper presented before the Division of Food Drug and Cosmetic Law, Section of Corporation, Banking and Business Law of the American Bar Association, August 9, 1961, published in 16 Food Drug Cosmetic Law Journal 615 (1961).

[85] Robert M. Rubenstein, "Your Label, Labeling and the Law," a talk given at the Forty-fourth Annual Convention of the National Fruit and Syrup Manufacturers Association in New York City, April 2, 1961, published in 16 Food Drug Cosmetic Law Journal 366 (1961).

CHAPTER IV

EFFECT ON FOOD PACKAGING MATERIALS, THEIR COMPOSITION AND USE

To say that the Food Additives Amendment of 1958 created a large amount of confusion, uncertainty and apprehension throughout the food and food packaging industry is a gross understatement. Industry trade journals predicted ruinously expensive and other drastic results from this legislation.[86]

The amendment was to become fully effective on March 6, 1960, 18 months after its enactment, and the Commissioner of Food and Drugs was given discretionary powers to grant further extensions up to an additional 12 months.[87] When it became evident that many testing programs could not be completed within these time limits, Congress passed the Food Additives Transitional Provisions Amendment of 1961 [88] to permit further extensions to June 30, 1964 by FDA under circumstances where testing programs were underway and there was no undue risk to the public health.

The paper and paperboard industries, in common with other segments of the packaging industry, found a number of new and confusing problems as a result of the new law. Paper and paperboard were early pioneers in the prepackaging of food and were instrumental in making the old cracker barrel obsolete. Over a long span of years in which billions of packages have been sold, there had been no instances of injury to health attributable to paper or paperboard packaging material.[89]

As Kaufman [90] observed, a prime function of a food package is to combat the destructive forces of the many chemical, microbiological, climatic and physical abuses at work to render food either useless or at least unappetizing. The secondary function of a food package he states,

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[86] "Crisis: The New Food Law," a series of three articles in *Modern Packaging*, Vol. 32, Nos. 9, 10, 11, May, June and July, 1959.

[87] Sec. 6(c)(1).

[88] Public Law 87-19, 75 Stat. 42.

[89] *Modern Converter*, August 5, 1962, commenting on speech by E. B. Brookbank, Jr., before Packaging Institutes' 23rd Annual Forum.

[90] Charles W. Kaufman, "Food Packaging and the 1958 Food Additives Amendment," an address to the 1959 American Bar Association meeting at Miami Beach, Florida, August 24, 1959, published in 14 FOOD DRUG COSMETIC LAW JOURNAL 649 (1959).

. . . is to provide a measure of convenience, such as easy storage or means of carrying, and a means of identification, such as ingredient clauses, weights or measures, and manufacturer identity. In other words, a food package is food protection, food economy and food convenience all rolled into one.

Although paper is the most common packaging material of all, chemically speaking, it is one of the most complex. As Kaufman [91] describes the papermaking process,

> Wood is digested in a chemical bath of sulfides or sulfites, to free the cellulose for use in making paper. Fungicidal treatments may then be added to prevent the build-up of slime in the piping system of the paper-mill equipment. Any one of a dozen chemicals may then be added to bleach the paper or still other chemicals may be added to impart the "whiter than white" effect, as we do with various laundry preparations. Later on are added the resins, rosins, starches, gums, waxes, rubbers, plasticizers of both natural and synthetic varieties, which are the sizes that make the paper printable or receptive to the additional coatings and treatments that will impart grease-proofing, gas-proofing and moisture-proofing properties to the paper. There are at least a hundred chemicals involved here which have been used and accepted for decades, conservatively speaking, almost all of which have no significant past toxicological history at this time.[92]

As pointed out by Brookbank,[93] the packaging industry is self-policing. Misapplications are not accepted by the buying public. If a food item stains its container evidencing a transfer of food ingredients to the packaging material, or if the coloring matter (ink or dyestuff) from a package is visible on the contents, the esthetic appearance of the package or the contents is a deterrent to the continued use of that particular packaging material. This consumer veto power is strong enough to insure properly selected materials and properly designed packages.

To meet the problems posed by the new enactment and with encouragement from the Food and Drug Administration, the Biological and Chemical Research Committee of the National Paper Board Association joined with the Chemical Additives Committee of the American Paper and Pulp Association, forming a Joint Liaison Committee. This brought together the top technical and legal personnel of every major producer of paper and paperboard in the country in a unified attempt to comply with the new law.

The Liaison Committee did the major job of preparing lists and, in consultation with FDA officials, classifying the 350 principal chemical components used in manufacturing grades of paper and paperboard.

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[91] Cited at footnote 90, at p. 652.

[92] An excellent survey of food packaging materials in nontechnical language may be found in the booklet *Food Packaging Materials Their Composition and Uses,* a report of the Food Protection Committee, Food and Nutrition Board, publication 645, Washington, D. C., National Academy of Sciences-National Research Council, November, 1958.

[93] Cited at footnote 89.

Considerable confusion followed the flood of petitions for approvals of materials used in proprietary mixtures (for example, coatings and adhesives). The problem was further complicated by the fact that low-volume, low-profit ingredients might require safety evaluation at a disproportionate cost. To preserve the confidential nature of some proprietary mixtures, independent laboratories were used in some of the studies. Other chemical suppliers cooperated in this program and a big portion of the biological testing, testing for transfer or migration of ingredients from one material to another, and development of analytical methods was handled by suppliers and their associations.

Although the cellulose fibers which are basic to any sheet of paper were given almost immediate clearance, the many papermaking chemicals, such as wax and rosin sizes, starches, defoamers, slimicides, and so forth, in various grades, produced by several concerns, had to be listed and classified as to their safety.

To some extent papermaking today is still an art and papermaking formulas will vary from mill to mill and even from machine to machine in the same mill, which made the problem one of listing those chemicals used by several firms rather than considering every last item used by each producer. It also required, in some instances, new measuring techniques to meet new standards of precision.[94]

Reused Fibers

Among paperboard producers, a very significant problem was that of reclaimed or reused fibers. A large number of packaging grades of paperboard have traditionally used reclaimed fiber from wastepaper as the major, if not the sole, component of the fiber furnished. Such paperboard grades as chip, jute liner, patent coated, folding boxboard, bleached manila, cracker shell, and many specialties are based largely on reclaimed fibers.[95]

The reclaimed fibers are obtained by repulping wastepaper. Wastepaper dealers sort and grade this waste into some 42[96] grades such as news, soft white shavings, hard white shavings, boxboard clippings, and so forth. Paper mills using reclaimed fibers select grades of wastepaper in accordance with the required properties

[94] E. B. Brookbank, Jr. "Paper Chemicals and the FDA," *Paper Mill News,* December 25, 1961, p. 32.

[95] Cited at footnote 89.

[96] National Association of Waste Material Dealers, Inc., *Paper Stock Standards and Practices,* Circular PS-59.

of the board to be produced. With cylinder machines which produce paperboard built up of several layers, the inner plies may be a waste grade while the outer plies in contact with food are made from virgin pulp.

In practice food boards are made from lighter colored, better grades of wastepaper or from new pulp. Also, in the manufacture of paperboard, the selected waste is defibered in water, washed and screened before being made into paperboard on the board machine. Nevertheless, the Food and Drug Administration was concerned about the chemical content of paperboard made from wastepaper and particularly the heavy metal content and possible bacterial contamination that might be present.

This last point (bacterial contamination) was fully answered to the satisfaction of FDA officials from projects conducted by the Institute of Paper Chemistry and from work conducted in Germany.[97] These had shown complete destruction of pathogenic bacteria in the dryer section of the paper machine, even when the wet web was inoculated with copious quantities of pathogenic cultures.[98] As pointed out to FDA officials,[99]

> Vast quantities of water (approximately 12,000 gallons per ton of paperboard) and extremely high temperatures (280-300°F) are used in making paperboard. Under these conditions, bacteria are killed and contaminants washed out.

However, there was no data available on the presence in paperboard or migratory characteristics of such metals as lead, mercury and arsenic.

To provide the scientific data required before FDA would clear reclaimed fibers for direct contact with food, the National Paper Board Association sponsored three different research projects which are described in the August 5, 1962, issue of *Modern Converter*.[100]

The first of these projects, conducted by Syracuse University Research Corporation, was a heavy metals analysis of paperboard. Methods for digestion, separation and analysis, with sensitivities in the microgram range, were adapted and developed. Then 87 different samples of various types of paperboard were analyzed for arsenic, cadmium, cobalt, copper, mercury and molybdenum. The work showed

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[97] Cited at footnote 89.

[98] Fred W. Tanner, "Paper and Paper Board in the Food Industry-Public Health Aspects," *Journal of Public Health*, vol. 38, December, 1948, pp. 1690-91.

[99] Letter from National Paperboard Association to Dr. Arnold Lehman, Food and Drug Administration, Washington, D. C., December 3, 1959.

[100] Cited at footnote 89.

that the quantities of arsenic, cadmium, cobalt, copper, mercury and molybdenum present in paperboard made from reused or reclaimed fibers are, in general, about the same as found in agricultural commodities and in water supplies. While the lead content varied, further work on migration indicated the presence of lead to be of no practical significance.

A second project carried out by Hazelton Laboratories, Inc. investigated the possible leaching and migration of heavy metals from paperboard. In this work, standard FDA solvents were used in contact with the paperboard under investigation and also samples of lean beef and chocolate were exposed to surfaces of each of the test boards for 7 and 14 days. The tests indicated no detectable transfer of lead and mercury to moist or fatty foods even under exaggerated use conditions.

The third project, carried out by the Institute of Paper Chemistry, involved abrasion studies to determine the amount of paperboard which might enter the packaged food under severe shipping conditions. In this study, cartons were filled with either a purified sand or special reagent grade sodium chloride and shipped by rail on round trips from Appleton, Wisconsin, to Kansas City and to Seattle, Washington. After shipment, analysis of the salt and sand for paperboard fragments showed that no detectable amount of paperboard enters the test material under ordinary conditions of handling even though the traveling distance is greatly exaggerated.

When the three research programs were completed, a petition proposing the issuance of a regulation to provide for the safe use of pulp from reclaimed fibers in the manufacture of paper and paperboard for food packaging was filed jointly by the National Paperboard Association and the American Paper and Pulp Association. The petition was accepted by FDA on May 13, 1961, and on August 9, 1961, a notice of the filing was released for publication. After several extensions to allow for further consideration of the submitted data, the FDA on July 4, 1962 [101] published its regulation covering the use of pulp from reclaimed fiber as a component for containers for food.[102] To date, (November, 1962) the only adverse reaction to this regulation has been a letter from a consulting engineer in the packaging field [103] criticizing FDA for approving pulp from reclaimed fiber. There are no indications that his views are finding any support in Congress, in the Food and Drug Administration or elsewhere.

[101] *Federal Register,* Wednesday, July 4, 1962, p. 6328.

[102] Reprinted in full in Appendix.

[103] *Food Chemical News,* July 9, 1962, p. 16; August 6, 1962, p. 13.

Other Ingredients

Although the regulation answered the questions concerning the base paperboard, further work was done on the dyes and pigments used to color paperboard. One can take the position that in the use of colored packaging materials, where there is no intent to color the food product contained in the package, the Food Additives Amendment, rather than the Color Additives Amendment, controls. FDA has taken a practical approach and accepted in principle the test that absence of visible transfer of color to food is sufficient evidence of no significant transfer, provided a migration test or dye solubility data is used to evaluate materials used with colored food.

In addition to colors in paperboard and paper, many different chemicals are used in coatings for paper and paperboard, in inks for printing them, and are present in materials, such as cellophane, polyethylene, polypropylene and foil, used in combination with paper and paperboard to produce a functional and esthetically pleasing appearance in the final package.

As of September 1, 1962,[104] some 230 substances, including coatings, remained to be cleared. The Joint Liaison Committee is continuing its work with FDA officials to establish regulations for their use.

Many questions asked by food packagers, according to Brookbank,[105] involve the use of paper and paperboard where the direct contact of the paper and board with the food product is not involved. The food product is frequently prepacked in another material or there is an impervious layer, such as wax or polyethylene, between the food and the surface of the paper or paperboard. The provisions of the Food Additives Amendment certainly do not apply to corrugated shipping containers for products packed in metal cans or glass bottles. Nor do they apply, under present FDA interpretation,[106] to paper cups and plates sold without food items packaged therein. Since cups and plates are not food containers, when moving in interstate commerce, they cannot contain food additives.

Other questions are not so easily answered. Can a substance migrate from paperboard into dry tea packed in porous tea bags? Not

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[104] Letter from Food Additives Subcommittee to Einar T. Wulfsberg, Food and Drug Administration, Washington, D. C., September 1, 1962.

[105] Cited at footnote 94.

[106] "FDA Answers to Questions Submitted at Washington Conference on November 24-25, 1958, to Discuss Food-Additives Amendment," reprinted in 14 FOOD DRUG COSMETIC LAW JOURNAL 13 (1959).

if the package remains dry and a wet package of tea bags is not normally a saleable product.[107]

It will be obvious that to establish compliance with the Food Additives Amendment of 1958, it is necessary to examine each packaging application individually. Not only is it necessary to know the components of the paperboard and other package components, but it is also necessary to know what food products are involved, and, in some cases, conditions of temperatures and humidity and time periods to which the packaged food will be subjected before it is consumed.

As one FDA official [108] explained:

> . . . whenever a new wrapping material is developed, even though it be composed entirely of substances which have been tested and found to be safe individually or in other combinations, extraction studies should be made and the extractables looked at from the standpoint of the food-additives amendment. Unless the substances which may migrate to food are generally recognized as safe for their intended use or their presence conforms with a pre-existing approval or order under the amendment, a petition seeking an order authorizing their addition to food is necessary.

Labeling and Deceptive Packaging

Although the Food Additives Amendment caused the biggest stir in packaging and the most concentrated effort to insure compliance, there has been renewed interest in the labeling provisions of the Act. In this area common sense and the exercise of judgment play an important part in decisions as to the conspicuousness and prominence of label declarations as well as the intent to deceive.[109]

The food packaging producers are watching very closely the labeling requirements proposed by FDA and opposed by the International Association of Ice Cream Manufacturers. Another potential area of legislative difficulty is the outcome of the hearing on deceptive packaging. For example, if fractional weights of food are outlawed, package sizes will have to be adjusted to some standard weight. On the other hand, if an attempt is made to regulate package size, such as "small," "large," "economy," the weights will be adjusted to size.

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[107] Cited at footnote 89.

[108] Arthur A. Checchi, "Developments under the National Pure-Food Law Affecting the Packaging Industry," an address to the meeting of the National Flexible Packaging Institute in New York City, January 20, 1959, published in 14 FOOD DRUG COSMETIC LAW JOURNAL 531 (1959).

[109] Joseph M. Creed, "How the Federal Food, Drug and Cosmetic Act Affects Labeling Requirements for Bakery Products," a paper presented before the Bakery Division of the Institute for Better Packaging in Chicago, Illinois, February 7, 1962.

Guaranties

As mentioned in Chapter II, the basic Food, Drug and Cosmetic Act provides for the use of guaranties to avoid the criminal penalties of the Act.

Many food processors, including some of the major chains, requested guaranties from their suppliers of packaging materials immediately after the Act was passed. This put suppliers in a nearly untenable position. They did not have guaranties from the manufacturers of the various ingredients used in their own products, but were sometimes threatened with loss of orders if they did not give a guaranty. The penalty for giving a false guaranty is the same as for a violation of the Act for adulteration of food, misbranding, and so forth.[110]

Further, the legal counsel of the National Paperboard Association, stated his opinion [111] that a written guaranty from a packaging producer is of no practical benefit to protect the food processor from the penalty provisions of the Federal Food, Drug and Cosmetic Act. To use his example, the written guaranty is designed to protect a box broker or wholesaler who doesn't do anything to the product or make it into some final article for sale. When the product is made into a box, is filled with an item or is otherwise changed and then sold, it is not the same article which is purchased.

This view was supported by the Assistant General Counsel for Food and Drugs [112] and others.[113]

The requests for guaranties have nearly stopped since the efforts of the paper and paperboard packaging industries in gaining approval for their products and their ingredients are far more meaningful in giving to food packers, the government and the public the assurance of a safe food supply. The warranty provisions of the Uniform Commercial Code referred to in Chapter I will, when given greater recognition, undoubtedly make guaranties unnecessary.

CHAPTER V

PROPOSED LEGISLATION AFFECTING PACKAGING

Any person who reads the newspaper, with a little reflection, will realize that our federal government in Washington is concerning

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[110] Secs. 301, 303(a).

[111] National Paperboard Association, Releases No. 1 and 3 on Legal Matters, January 7, 1960 and April 15, 1960.

[112] William W. Goodrich, "Guaranties for Food Additives," a paper presented at the Joint National Conference of the Food and Drug Administration and the Food Law Institute, 14 FOOD DRUG COSMETIC LAW JOURNAL 760 (1959).

[113] *Modern Converter*, December 15, 1960, commenting on a speech by John Kuniholm before Laminated Foil Manufacturers' Association.

itself more and more with the care and protection of our people. This is evident in not only proposals for increased Social Security benefits and medical care for the aged, but the Senate investigations of drug prices and deceptive packaging. Proposals have been put forth to provide a consumer representative adviser on the White House staff of the President. Another proposal has been the creation of a new cabinet level post to concern itself with consumer affairs. On July 11, 1962, the Secretary of Health, Education and Welfare announced the formation of a Departmental Committee for Consumer Protection to carry forward the consumers' rights to safety, to be informed, to choose and to be heard.[114] This is indeed a fertile field for government extension and regulation and, since everyone buys food, this particular area can easily become, if it hasn't already, a battleground of emotional propaganda, charges and counter-charges.

The government's position as to its role was made very clear recently by the Commissioner of Food and Drugs,[115] who said:

> As our society becomes more complex, the evolution of technology requires more safeguards for the consumer. As much as we admire the rugged individualist, when you have 90,000 firms dealing in over $82 billion worth of food each year, you can't have each going his own merry way. Processors who are hundreds of miles from the point at which their product will be consumed have to have standards of operation to live up to and somebody has to see that the processor does in fact live up to them. We believe that you and we together have to do the job the individual housewife would do if she were preparing a product in her own kitchen. And really the food plant is just an extension of the home kitchen. Since the housewife can't go several hundred miles or more to assure herself of the quality of raw products used, the sanitary conditions of the commercial kitchen, the methods of handling and preparing the food, and the additives that are employed in its preparation, *we are supposed to do this job for her.* (Italics added.)

Factory Inspection Amendment

One way in which the FDA hopes to pursue its goal is by increased authority for factory inspections.[116] To this end, a bill [117] was introduced before the Congress in May, 1962, by Representative Oren Harris to broaden the investigatory powers of FDA inspectors, to inspect not only the factory premises, but any consulting laboratory, including,

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[114] United States Department of Health, Education and Welfare, *Press Release*, U 48, July 11, 1962.

[115] George P. Larrick, "The FDA and Consumer Protection," a paper presented at the Fifty-fifth Annual Convention of the National Canners Association, Bal Harbour, Florida, January 23, 1962, published in 17 FOOD DRUG COSMETIC LAW JOURNAL 270 (1962).

[116] Cited at footnote 115.

[117] U. S. House of Representatives, H. R. 11581, 87th Cong., 2d Sess., May 3, 1962.

. . . all pertinent equipment, finished and unfinished materials, containers, and labeling therein, and all things therein (including records, files, papers, processes, controls and facilities) . . .

The National Canners Association [118] and others [119] have opposed this legislation as being an unwarranted expansion of FDA's inspection powers with no demonstrated need to go beyond the present inspection provisions. One of the principal objections is the opening up of trade secrets and financial information to FDA agents.[120] Although "killed" in 1962, it can be expected to be reintroduced in 1963.[121]

Senate "Truth in Packaging" Bill

Either the FDA or the Federal Trade Commission will likely be given further authority to regulate food and food packaging [122] as the result of the recently concluded investigation conducted by a Senate sub-committee headed by Michigan's Senator Philip A. Hart and the so-called "Truth in Packaging" bill [123] introduced in the 1962 session of the 87th Congress.

FDA is aiming at what it calls "the problem of inconspicuous display of required label information and the related problems of slack-fill and short weight of package contents." [124] It sees this as a problem due to the fact that the public, in its opinion, is buying "by the package" instead of the pound, pint or peck as it used to.[125]

During the period from 1938 to 1949, four or five charges of deceptive packaging reached the courts.[126] These cases basically concerned packages in which the food content occupied 33 to 60 per cent of the space in the package. If there were laudable reasons (for example, protection of the contents) for the package design, the courts generally found no deception.

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[118] National Canners Association "Statement of the N. C. A. before the House Committee on Interstate and Foreign Commerce in Opposition to Title II of H. R. 11581" June 21, 1962 (Reprinted in Information Letter of N. C. A. No. 1880, June 23, 1962).

[119] *Food Chemical News,* June 11, 1962, p. 14.

[120] National Canners Association, cited at footnote 118.

[121] *Food Chemical News,* September 17, 1962, p. 7.

[122] *Food Chemical News,* September 17, 1962, p. 7; June 11, 1962, p. 7; September 24, 1962, p. 3.

[123] U. S. Senate, S-3745, 87th Cong., 2d Sess., introduced September 24, 1962. The revised bill, introduced in the 88th Congress, January 21, 1963, is S. 387, by Senator Hart and others.

[124] George P. Larrick "Some Comments on Packaging," a talk to The Food Group meeting in Washington, D. C., February 14, 1962, published in 17 FOOD DRUG COSMETIC LAW JOURNAL 442 (1962).

[125] Cited at footnote 124.

[126] Vincent A. Kleinfeld and Charles Wesley Dunn, *Federal Food, Drug and Cosmetic Act 1938-1949.* Commerce Clearing House, Chicago, Illinois, 1949.

More recently, the Food and Drug Administration seized 174 cases of chocolate thin mints, alleging that containers in which chocolate thin mints occupied only 45 per cent of the interior space, the rest being largely occupied by hollow dividers, were misleading to the public. The federal district court for New Jersey ordered the seized goods returned [127] holding that the dividers protected the contents and that the case was lacking in proof that the average adult would be deceived. FDA appealed to the court of appeals and the case was remanded to the district court for further findings of fact.[128] The district court again found the accused package was not misbranded or misleading [129] and again the FDA appealed. The court of appeals this time affirmed the district court.[130]

It is the writer's personal opinion that the final decision of this case was a blow to the FDA and has much to do with the present pressure for new legislation on deceptive packaging.

Senator Hart described his legislative plans outlining a three step approach, to the National Conference on Weights and Measures in Washington: [131]

> First: A ban across the board of practices which by their nature are subject to a high degree of abuse because the manufacturer has no control over the final pricing of his product. Such practices, of course, include "cents off promotions" and "economy size" designations.
>
> Second: Establishment of standards applicable to all products regardless of their particular problems and differences. This would include guides requiring the net weight or content designation to be in a specific type size and face in proportion to the main panel of the package, positioned in a location where it can easily be seen, unadorned by qualifying phrases.
>
> Third: Promulgation of standards on a product line basis in those categories of practices which require separate and individual treatment. The areas where this may be necessary . . . include serving designations; meaningful size designations; product efficiency measurement where net weight or content is not meaningful in this regard; undue proliferation of weights and sizes (this would necessitate some modified kind of standardization); distorted package proportions; relationship between package size and package contents.

One authority has warned [132] that standardized packaging legislation proposals, if passed, will cause the demise of some products unless customers are willing to pay a higher price to cover the cost of new equipment or altering existing operations.

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[127] *United States v. 174 Cases . . . Delson Thin Mints,* 180 F. Supp. 863 (DC N. J. 1960).

[128] 287 F. 2d 246 (CA-3 1961).

[129] 195 F. Supp. 326 (DC N. J. 1961).

[130] 302 F. 2d 724 (CA-3 1962).

[131] *Food Chemical News,* June 11, 1962, p. 7.

[132] Institute for Better Packaging, "News Briefs," No. 33, July 13, 1962, commenting on article in *Packaging, U. S. A.* (July 9, 1962).

This promises to be a controversial subject since economical packaging requires some uniformity of package size. As foods vary in bulk or density, it is necessary to either vary the percentage of fill, use fractional weights, or use nonuniform sizes of packages.

Labeling of Dietary Foods

Recently, FDA published[133] its proposed rules for labeling of dietary foods. According to an FDA release:[134]

> The regulations would cover vitamin, mineral, and other dietary supplements, baby foods, foods for the elderly, low sodium foods, low calorie and artificially sweetened foods, protein supplements, hypoallergenic foods, foods for use in dietary management of disease, and all other foods represented as having special dietary properties.

According to Commissioner Larrick:

> The proposed regulations are designed to provide the consumer with complete and reliable labeling information which will enable him to select and purchase special dietary foods of all kinds. This will help to eliminate false and misleading claims.

The increasing popularity of low calorie food substitute type products, vitaminized cereals and so-called low calorie breads and desserts probably prompted the Food and Drug Administration to up-date the regulations in this area.

Comments on the impact these regulations will have on the packaging and package designs for this large group of food items have not been extensive. However, there are no provisions in these regulations comparable to those in the Ice Cream Labeling Regulations requiring any particular size of type or conspicuous placement of the required information. The only provisions are that the information be set forth on a separate part of the label, in easily readable style of type on a contrasting background and no information not required by the regulations is to be comingled with required information.[135]

CHAPTER VI

CONCLUSIONS

In this paper, an attempt has been made to collect and collate the principal laws affecting food packaging materials made from

[133] *Federal Register,* June 20, 1962, pp. 5815-5818.

[134] United States Department of Health, Education, and Welfare, Food and Drug Administration, *Press Release,* No. HEW-U 21, June 20, 1962.

[135] *Federal Register,* June 20, 1962, p. 5818 (Reg. Sec. 125.12).

paper and paperboard. To more thoroughly dissect and examine each law or subject would be a monumental task and would serve no useful purpose since interpretations and regulations are forever changing and any particular point would have to be re-examined in the light of the facts involved and the law current at that time. No attempt is made here to make legal experts out of the readers of these pages, but rather to give those interested in the subject the "feel" of what laws are involved, what they attempt to prescribe or regulate and when to seek legal or technical advice.

In Chapter I, the early enactments leading up to the passage of the Wiley Act in 1906 were noted. The provisions of this original federal food and drug act affecting packaging were discussed. The major revisions of 1938 in the Copeland Act were compared, as they related to packaging, with the earlier law. Parallel, and in some ways over-lapping, laws such as the Federal Meat Inspection Act and the Federal Poultry Products Inspection Act were described and recognition given to state laws and products liability decisions.

In Chapter II, the Food Additives Amendment of 1958 was more thoroughly considered as to its origin, its provisions and the way in which packaging materials were very suddenly brought under the strict surveillance of the Food and Drug Administration.

Chapter III deals with the response of the paper and paperboard industries to the 1958 legislation. The attempt is made to give some insight into the complex technical problems created in obtaining regulations approving the many chemicals used in paper and paperboard production and conversion.

Since 1958, additional legislation (for example, the Color Additive Amendments and the Federal Hazardous Substances Labeling Act) have been passed and further regulations issued under existing laws. These are covered in Chapter IV and Chapter V follows with proposals for further laws now before the Congress (Factory Inspection and "Truth in Packaging") from which it can be expected new laws will be enacted.

The great increase in federal activity since 1958 in the regulation of the food industry and those that serve it will be apparent. Producers and converters of paper and paperboard can no longer hide behind the excuses that they produce only what their customers order and label copy is not of concern to those who merely act as printers. Today, between requests for guaranties of compliance with federal, state and local law and the warranties attaching to any sale of goods,

anyone producing merchandise without knowledge of the ingredients used in his products and their suitability for the intended use of those products is exposing his company to liability.

As in the case of stock ice cream cartons, some converters offer their products in a way that they must warrant their safety and that they meet legal requirements. In other cases, small food processors look to their larger suppliers for information as to what can be used. Although no supplier concern can put itself in the position of rendering legal advice to its customers, as a practical matter it has a moral duty to point out that certain packaging materials have limitations as to the foods with which they be appropriately used.

The thrust of this increasing regulation by federal agencies in this area alone will undoubtedly be less than pleasing to contemplate by advocates of states' rights, less government control of business and balanced budgets. However, at the same time, it is obvious that with the interstate traffic in the food industry and in food containers that 50 different state laws and untold local ordinances cannot be known, much less observed, to the national enterprises that are a part of this huge part of our economy.

But we can and should ask if the federal activities are steps in the right direction. The President of the Food Law Institute observed recently: [136]

> The problem of safety clearance of incidental additives resulting from chemical residues in packaging materials (fibre or otherwise) has taken up the bulk of FDA's time and effort in the food additive field. Petitions for food additives regulations for such additives involved approximately 1,675 chemicals as of March, 1961. . . . It has also required large expenditures and intensive studies by industry which have not produced any evidence that any old or new packaging material would have been a serious hazard to health if the Food Additives Amendment had not been enacted. It has even been suggested that a vigorous effort be made to secure FDA's support for Congressional reconsideration of the Act insofar as it relates to incidental additives. These problems might possibly have been solved by expert panel determinations that the various substances were generally recognized as safe.

One writer [137] suggested that "the food and associated industries are being over-regulated in fields where not even a remote possibility

[136] Franklin M. Depew, "Regulatory and Developmental Problems Attendant Chemical Residues and Additives in Food and Fibre," an introductory statement to the Third Session of the American Chemical Society Symposium on the Role of Chemicals in Modern Food and Fibre Production, March 21, 1962, published in 17 FOOD DRUG COSMETIC LAW JOURNAL 252 (1962).

[137] Kenneth E. Mulford, "The Food Additives Amendment of 1958," a lecture delivered at a symposium on Current Developments in Food Law at Stanford University on April 27, 1962, published in 17 FOOD DRUG COSMETIC LAW JOURNAL 304 (1962).

of hazard to public health has existed in fact." However, he goes on to point out that "details of the composition and production of packaging materials, can lining and other like materials are now known to FDA and their approval by this governmental agency should alleviate public fears about the unknown."

Another writer[138] after reviewing events since 1958 expressed the view that "the present regulatory plan is imprudent when applied to incidental packaging additives" and urged Congressional reconsideration.

Unless the urgings of industry spokesmen are heeded by Congress, those in the paper and paperboard industry can look forward only to increased regulation and control. The managers, technical and legal personnel charged with the responsibility of compliance with these laws have a big task ahead of them and one which cannot be ignored. The praise for keeping one's company out of trouble will be scant compared to the scorn that will befall the adviser who overlooks a federal requirement resulting in the seizure of the customers' goods and the notoriety that will result.

As Miller[139] observed, those associated with industries close to the consumer must expect additional legislation of this nature and must develop the means for adjusting to it as it arises. One way he suggests is working together in technical areas. He also suggests trying to anticipate what future legislation might cover and making such changes within the business "to obviate the need, real or apparent, for the passage of this legislation."

APPENDIX
Regulation Covering Use of Pulp from Reclaimed Fiber

(*Federal Register,* Wednesday July 4, 1962, p. 6328)

Sec. 121.2546 Pulp from reclaimed fiber.

(a) Pulp from reclaimed fiber may be safely used as a component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of paragraph (b) of this section.

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[138] Richard C. Nelson, "Incidental Additives to Food: Have We Made a Prudent Judgment?" 16 FOOD DRUG COSMETIC LAW JOURNAL 614 (1951).

[139] Cited at footnote 71, at p. 43.

(b) Pulp from reclaimed fiber is prepared from the paper and paperboard products described in sub-paragraphs (1) and (2) of this paragraph, by repulping with water to recover the fiber with the least possible amount of nonfibrous substances.

(1) Industrial waste from the manufacture of paper and paperboard products.

(2) Salvage from used paper and paperboard excluding that which bears or contains, or has been used for shipping or handling any poisonous or deleterious substance which may have contaminated the paper or paperboard and which may reasonably be expected to be retained in the recovered pulp.

BIBLIOGRAPHY

PUBLIC DOCUMENTS

United States Constitution, Article I.

United States Department of Health, Education and Welfare, Food and Drug Administration, *Federal Food, Drug and Cosmetic Act, as Amended,* F. D. C. Act, June, 1958 Revision.

————. *Food and Drug Administration,* reprint from the Annual Report of the U. S. Department of Health, Education and Welfare, 1960.

————. *General Regulations for the Enforcement of the Federal Food, Drug and Cosmetic Act Title 21, Part 1,* F. D. A. Regs., Part 1 of Act, June 1958 Revision.

————. *Press Release.* HEW-421, June 20, 1962; U 48, July 11, 1962.

————. *Requirement of the United States Food, Drug and Cosmetic Act, A Guide for Foreign Manufacturers and Shippers,* FDA Publication No. 2, 1958 Revision.

————. *What Consumers Should Know About Food Additives,* Leaflet No. 10, 1961.

United States Federal Register, July 27, 1960; November 3, 1960; June 20, 1962; July 4, 1962.

United States House of Representatives, *H. R. 11581.* 87th Cong., 2d Sess., May 3, 1962.

————. *H. R. 11582.* 87th Cong., 2d Sess., May 3, 1962.

United States Senate. *S. 3745.* 87th Cong., 2d Sess., September 24, 1962.

United States Statutes, Chapters 29, 34, 38, 42, 44, 46, 52, 72, 74, 75.

United States v. 174 Cases . . . Delson Thin Mints, 180 F. Supp. 863, 287 F. 2d 246; 195 F. Supp. 326, 302 F. 2d 724.

MacPherson v. Buick, PRODUCT LIABILITY CASES 827, 217 N. Y. 382, 111 N. E. 1050 (1916).

BOOKS

Black, Henry Campbell. *Black's Law Dictionary.* 4th ed. St. Paul, Minnesota, West Publishing Company, 1951.

Darby, William J. and Lam, Gwen. *Food and Science . . . Today and Tomorrow.* Public Affairs Committee, Inc., New York, 1961.

Dunn, Charles Wesley. *The Food and Drug Law in the United States.* Commerce Clearing House, Inc., Chicago, 1955.

———— (ed). *Legislative Record of 1958 Amendment to the Federal Food, Drug and Cosmetic Act.* Commerce Clearing House, Inc., Chicago, 1958.

Kleinfeld, Vincent A. and Dunn, Charles Wesley. *Federal Food, Drug and Cosmetic Act 1938-1949.* Commerce Clearing House, Inc., Chicago, 1949.

Uniform Commercial Code (U. L. A.) Edward Thompson Company, Brooklyn, N. Y., 1962.

Wilson, Stephen. *Food and Drug Regulation.* American Council on Public Affairs, Washington, D. C., 1942.

ARTICLES AND PERIODICALS

Brookbank, E. B., Jr. "Paper Chemicals and the FDA." *Paper Mill News,* December 25, 1961.

Checchi, Arthur A. "Developments under the National Pure Food Law Affecting the Packaging Industry." An address to the meeting of the National Flexible Packaging Institute in New York City, January 20, 1959. Published in 14 FOOD DRUG COSMETIC LAW JOURNAL 527 (1959).

Creed, Joseph M. "What FDA Requires on Baked Foods' Product Labels." Reprinted from *Bakers Weekly.*

"Crisis: The New Food Law." A series of three articles in *Modern Packaging,* Vol. 32, Nos. 9, 10, 11; May, June and July 1959.

Depew, Franklin M. "Regulatory and Developmental Problems Attendant Chemical Residues and Additives in Food and Fibre." An introductory statement to the Third Session of the American

Chemical Society Symposium on the Role of Chemicals in Modern Food and Fibre Production, March 21, 1962. Published in 17 FOOD DRUG COSMETIC LAW JOURNAL 249 (1962).

Dickerson, Reed. "The Basis of Strict Products Liability." A paper presented before the Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law of the American Bar Association, St. Louis, Missouri, August 9, 1961. Published in 16 FOOD DRUG COSMETIC LAW JOURNAL 585 (1961).

"FDA Answers to Questions Submitted at Washington Conference on November 24-25, 1958, to Discuss Food Additives Amendment." Reprinted in 14 FOOD DRUG COSMETIC LAW JOURNAL 5 (1959).

Food Chemical News, 1960-62.

FOOD DRUG COSMETIC LAW REPORTS. Topical law reports in four loose leaf volumes. Commerce Clearing House, Inc., Chicago.

Goodrich, William W. "Rule-Making Under the Food Additives Amendment." A paper delivered at the Washington Conference to Discuss the 1958 Food Additives Amendment, November 24-25, 1958. Published in 13 FOOD DRUG COSMETIC LAW JOURNAL 761 (1958).

————. "Guaranties for Food Additives." A paper presented at the Joint National Conference of the Food and Drug Administration and the Food Law Institute. Published in 14 FOOD DRUG COSMETIC LAW JOURNAL 760 (1959).

Harvey, John L. "Food Additives and Regulations." A paper presented at the Food Industry Science School of Rutgers University, January 18, 1962. Published in 14 FOOD DRUG COSMETIC LAW JOURNAL 272 (1962).

Hollander, Stanley C. "Problems and Puzzles in Trade Regulation." *Business Topics,* Michigan State University, Graduate School of Business Administration, Vol. 10, No. 3, Summer, 1962, 23-35.

Kaufman, Charles W. "Food Packaging and the 1958 Food Additives Amendment." An address to the 1959 American Bar Association meeting at Miami Beach, Florida, August 24, 1959. Published in 14 FOOD DRUG COSMETIC LAW JOURNAL 649 (1959).

Kleinfeld, Vincent A. "Conflicts in Legislation and Regulations." A paper delivered at the Annual Meeting of the Institute of Food Technologists, Miami Beach, Florida, June 11, 1962. Published in 17 FOOD DRUG COSMETIC LAW JOURNAL 523 (1962).

Kirk, J. Kenneth. "Safety of Packaging Materials." An address presented to Twenty-first Annual Packaging Institute in New York City, November 18, 1959. Published in 15 FOOD DRUG COSMETIC LAW JOURNAL 263 (1960).

Larrick, George P. "Scope and Responsibility of Government in Development and Regulation of Chemical Additives for Food." Paper read before American Chemical Society Symposium on "Role of Chemicals in Modern Food and Fiber Production," Washington D. C., March 22, 1962. Published in 17 FOOD DRUG COSMETIC LAW JOURNAL 548 (1962).

————. "Some Comments on Packaging." A talk to The Food Group meeting in Washington, D. C., February 14, 1962. Published in 17 FOOD DRUG COSMETIC LAW JOURNAL 442 (1962).

————. "The FDA and Consumer Protection." A paper presented at the Fifty-fifth Annual Convention of the National Canners Association, Bal Harbour, Florida, January 23, 1962. Published in 17 FOOD DRUG COSMETIC LAW JOURNAL 266 (1962).

Markel, Michael F. "Federal Pre-emption." A paper presented to the P. M. A. Law Section meeting in White Sulphur Springs, West Virginia, May 7-9, 1962. Published in 17 FOOD DRUG COSMETIC LAW JOURNAL 453 (1962).

Miller, Adolf. "The Effect of the Food Law on Packaging Materials." An address to the 1961 Joint National Conference of Food and Drug Administration and the Food Law Institute, in Washington, D. C., November 27-28, 1961. Published in 17 FOOD DRUG COSMETIC LAW JOURNAL 38 (1962).

Modern Converter, December 15, 1960; August 5, 1962.

Mulford, Kenneth E. "The Food Additives Amendment of 1958." A lecture delivered at a symposium on Current Developments in Food Law at Stanford University on April 27, 1962. Published in 17 FOOD DRUG COSMETIC LAW JOURNAL 292 (1962).

National Association of Waste Material Dealers, Inc., *Paper Stock Standards and Practices,* Circular PS-59.

National Research Council, Food and Nutrition Board, National Academy of Sciences. "Cancer and Food Additives." Published in *Public Health Reports,* Vol. 72, No. 5, May 1957, 449-450.

————. "Chemical Additives in Food." A statement by the Food Protection Committee in *Chemical and Engineering News,* Vol. 30, No. 2, January 14, 1952, 150-154.

Nelson, Richard C. "Incidental Additives to Food: Have We Made a Prudent Judgment?" 16 FOOD DRUG COSMETIC LAW JOURNAL 597 (1961).

New York Times. August 5, 1962; October 26, 1962.

Ramsey, L. L. "Progress Under the Food Additives Amendment of Interest to the Cereal Chemist." Paper read before the annual meeting of the American Association of Cereal Chemists, St. Louis, May 20-24, 1962. Published in 17 FOOD COSMETIC LAW JOURNAL 485 (1962).

Rankin, Winton B. "Color Additives." A paper presented at Washington Conference to Discuss 1958 Food Additives Amendment of Federal Food, Drug, and Cosmetic Act, November 24-25, 1958. Published in 13 FOOD DRUG COSMETIC LAW JOURNAL 772 (1958).

Rubenstein, Robert M. "Your Label, Labeling and the Law." A talk given at the Forty-fourth annual Convention of the National Fruit and Syrup Manufacturers Association in New York City April 2, 1961. Published in 16 FOOD DRUG COSMETIC LAW JOURNAL 366 (1961).

Scriba, George T. "The Federal Hazardous Substances Labeling Act." A paper presented before the Division of Food Drug and Cosmetic Law, Section of Corporation, Banking and Business Law of the American Bar Association, August 9, 1961. Published in 16 FOOD DRUG COSMETIC LAW JOURNAL 615-635 (1961).

Shema, B. F. "Further Studies on the Lethal Effect of Drier Roll Temperature upon Bacteria in Paperboard." TAPPI Vol. 33, No. 2, February 1950, 81-83.

Tanner, Fred W. "Paper and Paper Board in the Food Industry—Public Health Aspects." *Journal of Public Health,* Vol. 38, December 1948, 1688-1693.

The Washington Post. October 4-5, 1962; October 26, 1962.

REPORTS

Citizens Advisory Committee. *Report* to the Secretary of Health, Education and Welfare on the Food and Drug Administration, October 1962. 17 FOOD DRUG COSMETIC LAW JOURNAL 581.

Manufacturing Chemists' Association, Inc. *Food Additives Manual,* Parts One, Two and Three. Washington, D. C., Manufacturing Chemists' Association, Inc., 1962.

Food Additives, What They Are/How They Are Used. Washington, D. C., Manufacturing Chemists' Association, Inc., 1961.

National Academy of Sciences—National Research Council. *Food Packaging Materials Their Composition and Uses.* A Report of the Food Protection Committee, Food and Nutrition Board, Publication 645. Washington, D. C., National Academy of Sciences—National Research Council, November 1958.

UNPUBLISHED MATERIAL

Creed, Joseph M. "How the Federal Food, Drug and Cosmetic Act Affects Labeling Requirements for Bakery Products." A paper presented before the Bakery Division of the Institute for Better Packaging, Chicago, Illinois, February 7, 1962. (Mimeographed.)

Institute for Better Packaging "News Briefs", 1960-62.

Larrick, George P. "Progress and Policies of the Food and Drug Administration." Paper delivered at 1961 Meeting of Food Industries Advisory Committee, The Nutrition Foundation, Inc., Skytop, Pennsylvania, May 4, 1961. (Mimeographed.)

National Canners Association. "Statement of the NCA before the House Committee on Interstate and Foreign Commerce in Opposition to Title II of H. R. 11581." June 21, 1962. (Reprinted in Information Letter of NCA No. 1880, June 23, 1962).

National Paperboard Association. Letter to Dr. Arnold Lehman, Food and Drug Administration, Washington, D. C., December 3, 1959.

————————and American Pulp and Paper Association. Food Additives Sub-Committee. Letter to Mr. Einar T. Wulfsberg, Food and Drug Administration, Washington, D. C., September 1, 1962.

————————. Releases No. 1 and 3 on Legal Matters, January 7, 1960, and April 15, 1960.

Ramsey, L. L. "Chemical Data Required for Evaluation of Food Packaging Materials Under the Food Additives Amendment." Paper presented at meeting of Safety of Packaging Materials Committee of Food Packaging Institute, New York City, March 3, 1959.

Wulfsberg, Einar T. "Food Packaging and Processing Equipment Under the Food Additives Amendment." Paper presented to the meeting of the Manufacturing Chemists' Association, Washington, D. C., January 5, 1961. (Mimeographed.) **[The End]**

Food Laws, Regulations and Technology—The Government View

By ORAL L. KLINE

This Paper Was Presented at the Third Food Industry Science School Sponsored by the Food Law Institute and Conducted by the Department of Food Science at Rutgers University, February 11-15. Mr. Kline Is Assistant Commissioner for Science for the Food and Drug Administration. In That Position, He Represents the Food and Drug Administration in Scientific Matters and Is Responsible for the Coordination of the Scientific Program.

WE ARE HERE TO DISCUSS FOOD LAWS, regulations and technology. I leave the discussion of legal aspects of laws and regulations to others. It is my purpose to show how technology and scientific research and methodology are an integral part of the enforcement of food laws and regulations promulgated under those laws.

The Food, Drug and Cosmetic Act is consumer protective legislation. This Act prohibits the movement in interstate commerce of adulterated and misbranded food, drugs, devices and cosmetics. In it, the term "food" means articles used for food and drink for man or other animals. In the chapter on food, provision is made for the establishment of definitions and standards for foods, and authority is given for promulgation of regulations fixing tolerances for poisonous ingredients in food, tolerances for pesticide chemicals in or on raw agricultural commodities and regulations with respect to petitions to establish safety of food and color additives. There is authority for fixing regulations for other purposes as well, for example, for the labeling of foods for special dietary use which are necessary to fully inform purchasers as to their value for such uses.

The Pure Food and Drug Law of 1906 was initially useful and effective in the control of foods and drugs until it was shown to be clearly out of date. An outstanding example occurred in 1938 when the sulfonamide tragedy made it clear that for public health protection, new drugs must first be tested for safety before being marketed.

The Food, Drug and Cosmetic Act of 1938 provided the new legislation that required pretesting of drugs to show safety before marketing and for the pretesting and certification of coal tar colors that may be used safely in foods, drugs, and cosmetics. In 1954 the use of pesticides had advanced to the point that better control of food residues was essential. This resulted in the Miller Amendment of that year. As the complexity of food manufacturing and technology increased with the use of greater and greater varieties of chemical substances for technological and nutritional purposes, the requirement for pretesting for safety of many of these substances became the subject of the 1958 food additive amendment. Not long thereafter, in 1960, there was legislation requiring the establishment of safe amounts of colors that may be used in foods, drugs and cosmetics. Also in 1960, we were given responsibility for labeling of hazardous household substances. Now, out of the atmosphere surrounding the thalidomide incident, we have the Kefauver-Harris Drug Amendments of 1962, increasing the authority of the enforcement agency over interstate commerce in drugs. This is all testimony to the fact that as scientific discoveries and developments change the technology and the manufacture and distribution of foods, drugs, cosmetics and devices, the consumer must have added protection because of his inability to understand and thereby choose wisely between those products that are useful and safe and those which are ineffectual and possibly hazardous.

A Strong Scientific Organization

The Food and Drug Administration began as an enforcement agency with attached analytical laboratories which dealt primarily with the composition and labeling of foods and drugs. From that relationship evolved, in keeping with the advancement of science, a strong scientific organization with an effective research program which requires a large force of scientifically trained people both for laboratory and for inspectional functions. To discuss the very problems of enforcement in the area of public health now requires some understanding of scientific terminology and scientific understanding in all categories of the sequence of enforcement activities.

Chief Justice Earl Warren, speaking recently before the University of Pennsylvania Law School was quoted as saying, "It is not the scientists who are the ogres of our time and it is not science that is running away and endangering civilization. The danger lies in the lack of a logical world and the absence of a world ordered under law

which will avoid the pressures to use scientific knowledge for destructive rather than peaceful purposes." Undoubtedly the Chief Justice was thinking of the misuse of science for destructive purposes at an international level. Nevertheless, in its use for peaceful purposes, we must have controls of those developments and changes in technology the misuse of which may be harmful to the public health.

From the standpoint of our enforcement needs, we must develop the kind of scientific program and organization which will best cope with the problems that seem to spring from everywhere to confront us almost daily. Food and Drug Laboratories have graduated from a group of versatile chemists who are ready to "put out fires" at each alarm, to a well-ordered research organization with a program that has continuity. A pattern of research in such a program must include a group devoted to long-term project research which may continue without interruption to a useful conclusion. The program must include another group assigned to shorter term projects particularly in the area of methodology, method development, and method improvement. It must have also a group concerned with the phase of methodology in which validation of methods is established through application to a series of sample situations. As background for this over-all program, there must be those who are well versed in the development and use of constantly changing instrumentation. It is clear to all of us that an essential part of present day analytical chemistry is the use of the newer developments in instrumentation which provide the sensitivity and the speed necessary to modern day methods. Validation of accuracy and precision of methods involving such instrumentation is of particular concern to those with enforcement responsibility.

In this complex scientific era environmental hazards have been introduced, some of which are related to food use. The vast array of synthetic chemicals, new products, new processes, and new packaging materials present a host of new problems. An enforcement agency must now have a broad spectrum of research to provide the scientific expertise necessary for developing the policy, regulatory programs, methods and interpretation of analysis, and the evaluation of all the scientific facts.

Food Standards

Let us take food standards for consideration of the impact of our complex technology. Food standards are important alike to consumers, to manufacturers and to the enforcement agency. They serve to condemn certain debasement, thus preventing unfair competi-

tion and are essential in maintaining integrity of staple food products. They further serve as yardsticks for the enforcement agency in evaluating market samples. Standards must, therefore, be scientifically sound and must provide adequate methods of analysis. In their promulgation under the law, food and drug scientists have a responsibility to develop needed facts. This may require studies on the composition of natural products to determine the normal range of constituents and the seasonal and geographical variations. It may require research on the chemistry of constituents before analytical methods can be devised. It may involve studies of the effects of manufacturing processes and new technological applications. A recent example concerns canned tuna.

Some years ago canned tuna supplanted canned salmon as the leading pack of canned seafood, and as a result, the price of tuna fish increased markedly. Our laboratories in Los Angeles and Seattle reported to us that they were encountering slack filling of fish in the cans. Whereas the so-called "½ flat" can could easily hold 6 ounces of cooked tuna before the vegetable oil packing medium was added, they found packers were putting in only 5½ ounces—some were adding even less. We considered this a consumer problem—an industry-wide problem—and one which could be dealt with by a fill-of-container standard. There was need for a method of measurement. Our food scientists found that drained weights of cans of tuna did not correlate well with the fill-in weight of the cooked meat of the tuna fish. The trouble was caused by the vegetable oil retained in the tuna meat. They found the oil retention higher for grated tuna and the flake style pack than for chunk and solid pack. After some experimentation, a testing machine was developed. Our instrument maker turned out a strong cylindrical cup, with a piston which had precisely 0.025 inches clearance. Both covers of the sample cans were cut out and the contents were placed in the cylinder. With the piston above the sample, the assembly was turned to a horizontal position, and pressure applied with an eight ton hydraulic jack. Pressing at 384 pounds per square inch for two minutes produced a dry cake from which substantially all the packing medium oil had been expressed. The weight of these press-cakes correlated very well with the fill-in weight of the tuna fish.

In connection with our fill-of-container investigations, we became convinced that it would be advisable to develop not only a standard of fill for canned tuna, but also a definition and standard of identity. The identity standard was an appropriate regulation for prescribing

the particular species of fish which were entitled to be named tuna when canned. We encountered imports of canned fish labeled tuna which were packed from nontuna species. Also, we learned from over 4,000 responses to a questionnaire that housewives were often disappointed to find, when they opened cans labeled white tuna or light tuna, that the fish in the cans was dark in color. Another one of our food scientists invented an optical color comparator to solve this problem.

Standards Committee on Tuna Established

Through the National Canners Association, the tuna producers established a standards committee, which worked with us in validating the press-cake method for fill of container and the color readings on a very large number of authentic samples. These data were all assembled and copies were shared by the tuna canners standards committee and our Administration. When the notice of the proposed standards was published, there was rather general agreement between the industry and government that the proposed standards were reasonable and workable.

Although the fill-of-container standard did not have to go to a hearing, there were objections filed which raised two issues, each concerned with labeling, for resolution at a public hearing. There was objection to the use of the description "dark tuna" for the pack that exceeded a specific color value. Another objection related to the use in the label "packed in water" for the water-packed product. Witnesses from the Food and Drug Administration and from the industry standards committee defended the Commissioner's order. Both issues were resolved against the objectors, and the standards, as published in the Commissioner's order, were sustained. In January of this year the time for appealing the order to the courts ended and no appeals were taken.

With recent technological developments, frozen seafood has become an important item in commerce. It was necessary to develop methods that would preclude the substitution of a variety of fish fillets inferior to that named in the label. Such a problem was solved recently by laboratory studies on the electrophoresis of proteins. Extracts of the fish solids in starch gel media yield electrophoretic patterns that are species specific and permit a differentiation of closely related species.

From the standpoint of sanitation and the application of bacteriologic studies, we have as an example, a recently developed ability

to identify the enterotoxin of certain staphlococci by scientists in our Division of Microbiology. Enterotoxin has been produced and measured and means of differentiation have been developed. This is accomplished in a thin layer diffusion system with anti-sera embedded in a semi-solid phase with measurement of an antigen-antibody type reaction. We are now involved in developing methods to measure the presence of enterotoxin in food products suspected of being produced under unsanitary conditions but preserved by sterilization. Under these conditions, the enterotoxin is not destroyed.

Pesticide Residues

Pesticide residues which may legally be present on raw agricultural products used for food have demanded much of our attention during recent years. The best seller "Silent Spring" has made the public aware, and highly critical of, the use of pesticide compounds, but without complete understanding of the efforts of regulatory agencies in protecting against excessive amounts of these pesticides in the food supply. A group of our food chemists have developed highly sensitive methods for approximately 20 of the chlorinated pesticide compounds. These methods are used daily in our district laboratories throughout the country. A similar effort is made with respect to organic phosphate compounds. Through surveys of the pesticide residue content of total diets collected in various parts of the country, along with field work and other spot sampling and analysis, we maintain a constant check on the proper use of pesticides.

Safe Tolerances for Pesticide Residues Fixed

An important part of our effort in the enforcement of the Miller Amendment has to do with the fixing of safe tolerances for residues of pesticides. This involves the evaluation of the toxic potential of each pesticide substance approved as useful by the United States Department of Agriculture, and may require extensive toxological studies. Our pharmacologists and chemists must evaluate such data and in doing so, must answer these questions. Has the identity of the pesticide been established? Is the chemistry completely described, and are the residues remaining on or in the food identical with the compound added? Or, have there been oxidative or metabolic changes? Have the data established the safety of the proposed uses? Those assigned to evaluate the data in a petition proposing a tolerance for a pesticide chemical and to advise the Commissioner as to the safety of the proposed tolerance must be knowledgeable in

their field of science in order to have intelligent discussion with industry scientists who have prepared the data. This is possible only when our scientists are actively engaged in similar research and in the application of methods, procedures and instrumentation involved or are members of a scientific team engaged in such research.

At the present time, we are analyzing for pesticide residues, food samples taken from the market place at the rate of about 25,000 a year. The preliminary information has already indicated that certain categories of foods are of lesser concern, first because of the improbability of contamination, second, because of removal of residues in food preparation, or third, because of the fact that pesticides are not used directly in their production. This survey may reveal that we have underestimated the residue potential of certain practices and that some revisions in directions for use will be necessary. It also will point out the areas of misuse.

In dealing with the safety of color additives, we must develop new scientific facts with respect to the tolerances that may be applied for such substances. This is a relatively new area and will require as well the development of new methods of analysis, new ways of identifying and separating color components, and new pharmacological information with respect to the toxicity of these compounds. The limited commerce in color additives tends to limit the amount of research that can be supported by the manufacturer. Nevertheless, we must require full knowledge of the safety of these compounds as a safeguard to the public health.

Labeling Regulations

In 1941, regulations pertaining to the labeling of foods for special dietary use were promulgated. These regulations require, in products offered for their nutritional value, the listing of the nutrients upon which such value is based. For the vitamins and minerals, the amounts must be stated in terms of the minimum daily requirement established for each of the nutrients. These regulations were promulgated under the authority of Section 403(j) of the Act which includes the term "Necessary in order fully to inform purchasers as to its value for such uses." There is a question as to whether the listing of nutrients not shown to be essential in human nutrition may not be in violation of this section of the Act on the basis that such listing is misleading to the purchaser. We are in the process of developing revisions and modifications of the regulations now in effect. When our proposals were published last June, comments were invited, to be

filed not later than October 18, 1962. Many of you know that we have received a large number of comments and must soon evaluate the constructive and helpful responses.

Trace Minerals with Nutritive Value

The Food and Drug Administration has a laboratory research program in nutrition to develop and provide facts upon which we may more effectively evaluate the labeling of foods offered as of nutritional value. At the present time, an important aspect of our research program is a study of the interrelationships and the antagonisms of those trace minerals that have nutritive value. You may know of the antagonistic interrelationships between molybdenum, copper and sulfate. Anemia in cattle has been observed on Florida pastures because of the high molybdenum content of the forage crops. This is overcome by the addition of small amounts of copper to the animal feeds used in that region. The high molybdate interferes with the absorption of copper in the intestinal tract, resulting in a copper deficiency. You know that in some areas of the west and in certain other parts of the world, soils are so devoid of available selenium that animals pastured in these regions develop a muscular degeneration which is prevented by dietary selenium. Recent studies by our biochemists have demonstrated that zinc is an essential nutrient for the Japanese Quail. This bird becomes deficient in zinc upon a diet devoid of this element, showing poor growth and feathering and changed pigmentation. The condition is prevented and treated by the addition of zinc. It has been reported that zinc deficiency in the human has recently been observed in Egypt, associated with dwarfism and anemia. In view of the many interrelationships possible, we must examine more closely in our diets, the effects of varying levels of trace minerals and the possible antagonistic effect of one upon the other before we can safely say that supplementation of the ordinary diet with these trace minerals is in the interest of the public health.

The developments in chromatography with the use of gas liquid, thin layer and payer systems have provided great sensitivity in the measurement of small amounts of food additives. Solvents, for example, used in extraction procedures may leave residues, small amounts of which are detected by these means. This development has given us a new insight into the extent of absorbed or adsorbed solvent material removed only with difficulty, and has made necessary further evaluation from a safety standpoint.

We have not hesitated to place on the list of substances generally recognized as safe those fats and fatty acids that are common to our food supply or are prepared by a simple process of fat splitting. However, changes in technology of fats require re-evaluation. Three or four years ago, when some 25 million poultry were lost as a result of inclusion of certain fat residues in poultry feeds, it was necessary to reconsider the GRAS listing of fatty acids offered for use in foods. It is now necessary to require a showing that such fatty acids are free of the chick edema factor. This substance has been crystallized and identified as a chlorinated phenanthrene. Its origin or source in fatty materials is still a mystery. Its potency as a toxic agent is sufficiently alarming that we must be alert to keep our foods free of it. It has a toxicity at a level of .05 p. p. m. and causes excessive edema in the chick. Although we have no direct information as to its effect in the human, there is some evidence that it causes a toxic reaction in the monkey.

Migration of Substances from Food Container Materials

An interesting development with respect to the nature of food additives and the extent to which compounds may appear in our food supply is that of the migration of substances from food container materials. Methods for detecting migration of food-wrap components involve simulated conditions but, they are, nevertheless, regarded as satisfactory for the measurement of a migratory substance. Sensitive methods can detect the presence of migratory substances in extremely small amounts.

We have been concerned with the use of mineral oil in the preparation of certain foods and in view of its probable absorption through the intestinal tract have found it necessary to consider tolerances for food content of this substance. Our preliminary studies on animals indicate that mineral oil is absorbed and tends to be deposited in such tissues as the liver. As a foreign body, it may well cause reactions that are biochemically insulting to the tissue. We have suggested that a sensitive means of determining the extent of absorption and the route of deposit, degradation, or excretion, would be the use of tagged hydrocarbons synthesized to simulate the food grade mineral oil in biological studies.

I have related a number of illustrations of scientific information or methodology developed to meet requirements of one or another regulation promulgated under the food sections of the Food, Drug and Cosmetic Act. Our research program and the scientific research

developments in many industry, academic, and consulting laboratories provide exciting new information continually. A balance between new technological uses and procedures, and the means of assuring safety and informative labeling of such uses and procedures is of great importance to all of us. A regulatory agency must have the cooperation of all parts of the scientific community in maintaining such a balance. We are fortunate with the interest and cooperation from many quarters in our enforcement efforts. [The End]

PROTECTION FOR MILK PURITY ADVANCED

The continued purity of market milk is the objective of a new test method developed by FDA research scientists. The method is for detecting minute residues of sulfanilamide and other sulfonamide drugs in milk from cows treated for mastitis, a disease which hampers milk production, and causes large financial losses in the dairy industry.

Major treatment is by infusing antibiotics, often combined with sulfonamides and other drugs, into the cow's udder. Milk from cows treated must be discarded for some time after the last treatment to avoid residues in the milk sent to market. The new test measures how long sulfonamide drugs remain in milk after the last treatment of the cow. During this period, the dairy farmer must discard his milk or otherwise keep it from the market. This is particularly necessary when penicillin is used because of the possibility of dangerous reactions in persons who have been or may become sensitized to the drug. With residues of the sulfonamides and other drugs there is a danger that bacteria may become resistant to their action or that people may suffer toxic effects from them. Therefore, there is no allowable tolerance for such chemicals in milk. Labels of mastitis preparations must bear adequate directions for proper use, as well as warnings to discard milk from treated animals for the specified period, to assure that no residue will remain in milk to be consumed.

In July, 1962, FDA advised manufacturers of mastitis preparations that they must devise suitable methods of analysis to determine sulfonamide residues in milk. After October, 1962, FDA withheld certification from a number of mastitis preparations because information concerning such procedures had not been submitted, and at the same time FDA decided to develop its own method to double check results that were submitted.

The test known as a colorimetric method was then developed for the detection and estimation of sulfonamide residues in milk, by the FDA's Division of Antibiotics. In the test, the drug combines with an added chemical to produce a pink color. The amount of pink color produced is proportional to the amount of sulfonamide drug present. One man can do eight samples in a single working day.

FDA scientists under the direction of Dr. William Wright, Research Director of the Division of Antibiotics, examined samples of the milk produced by four dairies in the metropolitan Washington, D. C., area. The new test showed no evidence of sulfonamides in the market milk.

Extension of Benefits of Warranty: A Rebirth of Privity of Contract in New York

By WARREN FREEDMAN

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UNDER SECTION 2-318 of the Uniform Commercial Code, (Chapter 553, Laws of 1962 in New York) a seller's warranty is extended to any natural person who is in the family or in the household of the buyer, or who is a guest in his home, if it is reasonable to expect that such person may use, consume, or be affected by the product and who is injured in person by breach of the warranty.* Although this statutory provision will not become effective in New York, until September 27, 1964 (at which time at least 18 other states will have the provision in force), it is of interest today to ascertain the status in New York of decisions on the extension of the benefits of warranty, or in other words, how successful, if at all, has been the assault upon the citadel of privity of contract. Unfortunately, there has been much confusion precipitated in part by over zealous plaintiff's advocates who have mistaken any extension of the benefits of a warranty as a repudiation of the time-honored doctrine of privity of contract. Today, at least 60 per cent of all jurisdictions adhere to the privity of contract requirement.

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* See *Hochgertel v. Canada Dry Corporation*, 14 NEGLIGENCE CASES (2d) 1549, 187 A. 2d 575, decided by the Pennsylvania Supreme Court on January 21, 1963: "Pennsylvania was the first state to adopt the Uniform Commercial Code. . . . Clearly the Code gives no basis for the extension of the existing warranty to an employee of the purchaser." Judge Eagen points out that Pennsylvania courts "did not outrightly reject the privity of contract rule. . . . In no case in Pennsylvania has recovery against the manufacturer for breach of implied warranty been extended beyond a purchaser in the distributive chain."

Applicability of Privity of Contract Necessary Today

While privity of contract had its origin in face-to-face bargaining among commercial dealers and merchants, its applicability today is still necessary, not only to discourage rash litigation, including those instances in which the product was improperly and negligently used, but even more important, to put the plaintiff to his proof that the defendant had erred or committed a fault in relation to him. Judge Cardozo's famous "assault upon the citadel of privity" delineates a negligence action where clearly "fault" makes for "liability." However, in a breach of warranty or contract action, the retention of the privity requirement compels the plaintiff to prove that the defendant's "fault" was indeed the proximate cause of the plaintiff's injury or property loss. See *Chysky v. Drake Brothers Company,* 235 N. Y. 468, 139 N. E. 576 (decided by New York Court of Appeals in 1923). Yet, in an effort to ease the burden of the plaintiff in proof of negligence, some courts have allowed the privity of contract doctrine to become dissipated by engrafting upon the principle such exceptions as "agency," "third party beneficiary" and the like. In truth, these courts were merely seeking to extend the benefits of the warranty to those persons who were actually within the zone of foreseeability with respect to the use of the product. Under no circumstance would these same courts have blindly overthrown the accepted doctrine of privity of contract.

Extension of Benefits of Warranty

When the New York Court of Appeals on March 2, 1961, in *Greenberg v. Lorenz,* 12 NEGLIGENCE CASES (2d) 683, 9 N. Y. 2d 195, 213 N. Y. S. 2d 39, extended the protection of the warranty beyond the immediate purchaser to his daughter who allegedly broke her tooth on a piece of metal imbedded in the salmon, the court did not eliminate the privity requirement. The court simply extended the benefits of warranty for "food and household goods" to "all the members of the household." The action, it must be noted, was against the retailer, *not* against the manufacturer or distributor of the product. Subsequently, on February 22, 1962, in *Randy Knitwear, Inc. v. American Cyanamid Company,* 14 NEGLIGENCE CASES (2d) 781, 11 N. Y. 2d 5, 181 N. E. 2d 399, the same court by a 4-3 decision, permitted a remote purchaser to recover against process manufacturer for property damages upon breach of an express warranty. In fact, the defendant manufacturer had allegedly falsely represented its textile finishing process for making a fabric unshrinkable. The plaintiff's own fabrics

had been treated with this process by intermediate, independent licensees of the defendant with the result that the plaintiff's fabric was not unshrinkable. The court seemingly dispensed with the privity of contract requirement, although Judge Froessel in his concurring opinion disagreed, and declared that the requirement of privity had not been dispensed with "[w]ithout limitation . . . . We decide cases as they arise." Furthermore, the majority of the court, it is submitted, failed to appreciate the basic prerequisite of a "sale" of a product from which transaction a warranty, whether express or implied, can only arise. Judge Fuld admitted that "the article sold by the appellant, *resin,* is different from that purchased by the plaintiff, *fabric,*" but he did not pursue the next logical step of determining what warranty, if any, the defendant resin manufacturer had made to the plaintiff with respect to the *fabric* which the defendant resin manufacturer had *not* sold the plaintiff! Indeed, only the product utilizing the Cyana process (a chemical resin) was sold by its licensees to the plaintiff. Hence, the court was in error in assuming that privity applied in the absence of a sale of a product. Judge Fuld also skirted the issue of contributory negligence in the use of the process by Fairtex and Apex, although he proclaimed that Cyanamid had *subsequently* an "appropriate recourse" against them. But why should the resin manufacturer be in the direct line of fire from the purchaser of a fabric which the resin manufacturer did not manufacture?

The rationale of the *Randy Knitwear* decision is understandable only in terms of a tort, not a contract or warranty action; for it may indeed be argued that the defendant resin manufacturer had perhaps misrepresented his process upon which misrepresentation the plaintiff had relied to his detriment. (Such view is expressed by Judge Froessel in whose opinion Judges Dye and Van Voorhis concurred.) Surely the court could have affirmed judgment for the plaintiff without dispensing with the privity requirement, especially in face of its 1961 decision in *Greenberg v. Lorenz,* because "fabrics" are *not* included within the limitation of "food and household goods."

Since 1962, the decisions of the lower courts in New York have, for the most part, reflected the desire to extend the benefits of warranty, but not at the expense of eliminating the privity of contract requirement. The New York Appellate Division, 4th Department, in a 4-1 decision on February 22, 1962 in *Thomas v. Leary,* 15 App. Div. 2d 438, 225 N. Y. S. 2d 137, appreciated the necessity for not entirely eliminating the privity requirement: "By our determination we do not intend to hold that such warranty would necessarily extend

to any person, who might use the article involved. We are fully aware that any extension of the existing principles of privity will add to the present burden on retailer and others." Mr. Justice McClusky's dissent ably pointed out that the court of appeals decision in *Greenberg v. Lorenz* had merely "extended the obligation to the members of a householder's family in the case of foods. But, that Court, by its very language of extension, was careful to limit its applicability beyond the point mentioned. If the statutory doctrine of an implied warranty is to be further extended, it should be by legislative action rather than by judicial erosion of the legislative pronouncement."

Decisions Upholding Privity Doctrine

A survey of the leading New York decisions in the past three years (and especially those decisions since February 22, 1962), should make it abundantly clear that if recovery is afforded the injured plaintiff such recovery upon breach of warranty is only against the immediate seller and not against the remote manufacturer or distributor who, after all, is not in privity with the injured party. In practice, therefore, the doctrine of privity of contract is still very much a living personality within the State of New York. The following 23 recent decisions all precluded recovery against the manufacturer upon the alleged breach of warranty and in express terms upheld the dignity of the privity doctrine:

Sanchez-Lopez v. Fedco Food Corporation, 211 N. Y. S. 2d 953, (1961), involved an alleged explosion of a Coca-Cola bottle which injured a retail customer. The New York City Court, Bronx County, expressly cited both *Chysky v. Drake Brothers Company* and *Greenberg v. Lorenz*, cited above. Recovery against retailer on warranty.

McDonald v. Blue Jeans Corporation, 12 NEGLIGENCE CASES (2d) 900, 183 F. Supp. 149 (1960), involved an allegedly inflammable *cowboy suit* which injured a customer. Suit was brought by the retailer against the manufacturer, even though the material had been purchased from an intermediate distributor. No recovery.

Canter v. American Cyanamid Company, 12 Negligence Cases (2d) 53, 207 N. Y. S. 2d 745, N. Y. Sup. Ct., App. Div., 3rd Dept. Dec. 1960, involved an allegedly defective *dust vaccine* for immunization of plaintiff's chickens. Plaintiff had purchased the product from an intermediate supplier. No recovery.

Freedman v. Jacqueline Cochran, Inc., N. Y. Sup. Ct., App. Div., 2nd Dept., decided February 2, 1960.

Bolle v. Seligman & Latz, Inc., 205 N. Y. S. 2d 638, N. Y. Sup. Ct., Queens Co., decision by Mr. Justice J. I. Shapiro, on Aug. 15, 1960, involved a *hair tint* applied to plaintiff's hair by defendant beauty salon. Warranty action dismissed against manufacturer.

Colonial Boiler Service, Inc. v. Blau, N. Y. Sup. Ct., Bronx Co., decision by Mr. Justice Fine on April 19, 1961. Complaint dismissed.

Drakos v. Ace High Ladder Company, Inc., N. Y. Sup. Ct., Bronx Co., decision by Mr. Justice Capozzoli on April 13, 1961, involved an allegedly defective *plank*. Complaint dismissed.

Deeves v. Fabrics Fire Hose Company, 210 N. Y. S. 2d 903, 29 Misc. 2d 136, N. Y. Sup. Ct., Westchester Co., decision by Mr. Justice Hopkins on January 16, 1961, involved an allegedly defective *fire hose* purchased by City of New Rochelle for its employees:

> . . . A cause of action for breach of warranty ordinarily depends on a contractual relation between the parties to the action. A personal injury suffered by one not a party to the contract, even though an employee or agent of the buyer, may not be recompensed by suit against the seller based on breach of the contract. . . . Reasons of public policy underlie this denial of the right to enforce the contract, which is sometimes referred to as the absence of privity of contract. Parties to contracts bargain with an objective in view as between themselves; burdens or benefits to others are generally not within their contemplation; and the process of bargaining would be complicated if the contract could be enforced by third parties. . . . The rule refusing recovery to a non-party to a contract for personal injury arising from a breach of warranty, whether express or implied has been reiterated time and again. . . . Two exceptions to the general rule have appeared: (1) a right of recovery has been permitted in cases involving breach of warranty arising out of sales of foodstuffs, where the injured person stood in close family relationship to the buyer: (2) the class of cases characterized by the third party beneficiary principle. It is to the last exception that the plaintiff appeals to justify his cause of action. The third party beneficiary doctrine has not been thus far extended to the facts at bar. . . . If any change in the rule in favor of an employee of the buyer is to be made, it should be announced by the Legislature or the Appellate Courts.

Simpson v. Eichenbrunner, 217 N. Y. S. 2d 678, N. Y. Sup. Ct., N. Y. Co., App. Term, 1st Dept., decision by P. J. Hofstadter, J. Hecht and J. Aurelio on July 14, 1961, involved an allegedly defective *machine* upon which employee of purchaser was injured. The action was successful only against the immediate seller, and *not* against the manufacturer.

Reilly v. Newark Ladder & Bracket Company, Inc., N. Y. Sup. Ct., N. Y. Co., decision by Mr. Justice Nunez, on May 11, 1962, involving an allegedly defective *platform* sold to employer of the plaintiff.

Serrano v. Riverside Dinette Products Company, 222 N. Y. S. 2d 537, N. Y. Sup. Ct., Kings Co., decision by Mr. Justice McDonald on

Nov. 24, 1961, involving a casual social guest in the home of the purchaser who was injured by an allegedly defective *chair*:

. . . The plaintiff in his memorandum in opposition to the motion evinces a penchant for literary phrases and Horacean purple patches and Biblical quotations, and constitutes himself in the role of a joyous participant at the funeral rites of the "doctrine of privity." However, one need not, in the words of the plaintiff's brief, be guilty of "judicial myopia" to ascertain that the doctrine of privity is not yet moribund and that one would be guilty of impropriety if he attempted to conduct a funeral without a corpse. . . . It is to be noted that this action was brought against the seller, not against the manufacturer, as in the instant case, nor was the doctrine extended to cover a casual social guest of the purchaser.

Waful v. Contractors Syracuse Sales Company, 219 N. Y. S. 2d 1004, N. Y. Sup. Ct., Onondaga Co. (1961), involving the leasing of allegedly defective *construction equipment*:

. . . It is true that implicit in the *Greenberg* case is the recognition that the law will be called upon in the future, as it has in the past, to adapt itself to the changing realities of social conditions. This is not, however, a clarion call to revolution. . . . The case at bar involves construction equipment and any analogy regarding the necessity of public protection between that field and the field of food and household goods is strained.

Raymer Cont. Corporation v. Brama-Weber & Company, Inc., N. Y. Sup. Ct., Queens Co., decision by Mr. Justice Farley on April 17, 1961, involving a *bridle sling* purchased from a distributor. Complaint dismissed against manufacturer.

Rypins v. Rowan, 219 N. Y. S. 2d 288, N. Y. Sup. Ct., Nassau Co., decision by Mr. Justice Pittoni on Sept. 6, 1961, involving a *combination storm glass door*:

. . . While the rule with respect to privity of contract has been relaxed, the relaxation thus far is only with respect to food and household goods, where according to *Greenberg v. Lorenz* [cited above, at p. 200] ". . . presumption should be that the purchase was made for all the members of the household." Here the article involved is a combination storm door which was affixed to the home by Harold F. Rowan. Not only does such article not come within the category specified in the *Greenberg* case, but it also does not appear in the complaint that the agent, Harold F. Rowan, who allegedly purchased the article, purchased it from Excelum Aluminum Products Company, the movant herein.

Anderson v. Radio Corporation of America, 211 N. Y. S. 2d 337, N. Y. Sup. Ct., Nassau Co., decision by Mr. Justice Suozzi on Oct. 26, 1961, involving an allegedly defective *gas range* purchased by plaintiff's husband:

. . . Although recently in *Greenberg v. Lorenz* [cited above], it was held that not merely the individual buyer but all the members of a household benefit by a warranty as to food and household goods, it has not been held that a buyer or the members of his household may sue a manufacturer with whom the buyer has no contract.

Levitt v. Ford Motor Company, 215 N. Y. S. 2d 677, 28 Misc. 2d 599, N. Y. Sup. Ct., Queens Co., 1961, involving an allegedly defective

automobile tire which injured the plaintiff purchaser and his wife. No recovery on warranty was allowed against either the tire manufacturer or the automobile manufacturer.

Monaco v. Chrysler Sales Corporation, 191 F. Supp. 648, DCNY, 1961, involving a defective *automobile gas pedal* which automobile has been loaned to plaintiff's employer by the automobile dealer to whom the automobile manufacturer had sold the auto. No recovery against manufacturer.

Egan v. Kollsman Instrument Corporation, 7 AVIATION CASES 17,292, 145 N. Y. L. J. 40-15, N. Y. Sup. Ct., Kings Co., decided March 1, 1961, involving a faulty *airplane altimeter* which caused the death of an airplane passenger. Suit was brought against the manufacturer of the airplane:

> . . . There is no authority anywhere in the New York courts for holding that a passenger in an airplane may recover in an action based upon implied warranty against a manufacturer who sold the craft to a third party operating the same at the time of the accident. Any action by a passenger against the manufacturer has always been based in negligence, based on tort and where no contractual relation exists between the parties and their agents. . . . This cause of action is without merit since no privity of contract existed between plaintiffs' decedent and Lockheed Aircraft Corporation. Motion to dismiss the second cause of action based on breach of implied warranty against the Lockheed Aircraft Corporation is granted as no cause of action is stated therein.

General Aniline & Film Corporation v. A. Schrader & Son., Inc., 215 N. Y. S. 2d 861, 13 App. Div. 2d 359, involving an employee of the purchaser.

Samet v. Bretone, New York City Court, Queens Co., decision by Mr. Justice Hockert on May 8, 1961, involving a defective *cold water valve* in a house:

> . . . There must be a warranty or there is no basis for this action. Neither of these defendants did any wrong. The only privity of contract is between the plaintiff and the plumber. There is no privity between the plaintiff and the supplier Pomeroy The plumber bought and paid for the nipple in the regular course of business. The recent case of *Greenberg v. Lorenz* (N. Y. L. J., April 2, 1961) has no application. . . . As far as the facts in this case are concerned the law has not been changed. Warranty does not run with the chattel. . . .

Puder v. Shore Rambler, Inc., N. Y. Sup. Ct., Nassau Co., decision by Mr. Justice Brennan on Feb. 21, 1963, involving property damages of a purchaser of an *automobile* which had an oil leak:

> . . . The agreement clearly discloses that there was no privity of contract between the plaintiff and the movant. The action is based upon an express warranty contained in the agreement and that warranty was made by the dealer. Reliance is placed by the plaintiff upon the recent case, *Randy Knitwear v. American Cyanamid Company* [cited above], but that case is clearly distinguishable.

Mull v. Colt Company, 26 AUTOMOBILE CASES (2d) 1334, 31 FRD 154, DCSDNY, 1962, involving a bystander who was allegedly injured by a defective *automobile*. It was determined that there was no cause of action against the manufacturer or the dealer of the automobile.

Fortunato v. Craft, N. Y. Sup. Ct., Suffolk Co. on Oct. 8, 1962, by Mr. Justice Munder, involving purchaser of a *recapped auto tire*. Plaintiff was injured while inflating an inner tube of a second-hand recapped tire. He sued Craft who sold him the tire for breach of warranty; and he sued Ranger Tires (from whom Craft purchased the tire) for breach of warranty. Ranger Tires, the distributor, moved to dismiss the complaint upon the grounds of lack of privity of contract between plaintiff and Ranger Tires. Mr. Justice Munder granted the motion to dismiss: (1) Ranger Tires was in the tire recapping business, and cannot be held to impliedly warrant a used, second-hand tire, (2) "Plaintiff was fully aware that he was purchasing a used product," and therefore contributory negligence was a defense to warranty and (3) furthermore, no express warranty was in fact made to plaintiff by Ranger Tires. Mr. Justice Munder distinguished *Williams* (230 N. Y. S. 2d 476, 17 App. Div. 2d 661, 1962, implied warranty ran to employee of purchaser from retailer), *Greenberg* [cited above] (implied warranty ran to daughter of purchaser from retailer), and *Randy Knitwear* [cited above] (express warranty case): "To dispense with the requirement of contractual privity in this case would in my opinion be carrying the assault upon the citadel of privity too far!"

Decisions Applying Implied Warranty of Fitness

On the other hand, the following recent decisions have adhered to the holdings of *Randy Knitwear* and *Greenberg* cases, and the implied warranty of fitness for particular purpose has been extended to:

An infant whose father purchased for him an allegedly defective pair of *roller skates (Donadio v. F. W. Woolworth Company*, N. Y. Civ. Ct., Queens Co., decision by Judge Fink on Feb. 28, 1963). Recovery against retailer.

The child of the purchaser of an allegedly defective *bicycle (Outwater v. Miller*, 3 App. Div. 2d 670). Recovery against retailer.

The employee of a dentist who purchased an allegedly defective *dental chair (Thomas v. Leary*, cited above.) Recovery in his action against the furniture dealer.

The employee of the purchaser of an allegedly defective *safety mask* (*Williams v. Union Carbide Corp.*, cited above). Recovery in his action against the retailer.

An infant whose mother purchased for her a highly inflammable *dress* (*Fournier v. R. H. Macy & Company, Inc.*, N. Y. Sup. Ct., Kings Co., decision by Mr. Justice Benjamin on Mar. 27, 1961). Recovery against retailer.

The purchaser of a power-driven *riveting machine* from a local distributor; recovery was from manufacturer. (*Hoffman v. Cox*, 229 N. Y. S. 2d 485, 35 Misc. 2d 103, N. Y. Sup. Ct., Nassau Co., decision by Mr. Justice Pittoni on June 19, 1962.) Cf. the decision by Mr. Justice Wecht of the New York Sup. Ct., Kings Co., in *Cervo v. American Products Corporation*, N. Y. S. 2d (Sept. 10, 1962), permitting an amendment to the complaint for breach of express warranty but refusing an amendment for implied warranty citing the *Randy Knitwear* case.

The passenger aboard an allegedly defective *helicopter* sued the manufacturer in a wrongful death action. (*Middlleton v. United Aircraft Corporation*, 6 AVIATION CASES 17,975, DCSDNY, 1960.)

The passenger aboard an allegedly defective *airplane* sued the manufacturer in a wrongful death action. (*Hinton v. Republic Aviation Corporation*, 6 AVIATION CASES 17,802, 180 F. Supp. 31, 1959, DCSDNY.)

A gentleman friend of the mother bought the child *ice cream* which contained a screw. (*Walker v. Hot Shoppes of New York, Inc.*, 200 N. Y. S. 2d 742, Albany Co. Ct., 1960.) Jury verdict had exonerated ice cream manufacturer.

The employee of purchaser (also defendant) of the *auto tire*; the warranty was held to run from the retailer to the employee of the purchaser but *not* against the manufacturer of tire. (*Davis v. U. S. Rubber Company*, N. Y. Sup. Ct., Bronx Co., decision by Mr. Justice Lyman, on Nov. 23, 1962.)

Conclusion

In summary, it must be noted again that recovery was generally against the immediate seller and *not* against the remote product manufacturer, thus attesting to the fact that, despite a few decisions to the contrary, there has been a rebirth in New York of the privity of contract doctrine under decisions extending the benefits of the warranty to persons other than the purchaser. Indeed, Section 2-318 of the Uniform Commercial Code which will become effective in New York on September 27, 1964, will certainly strengthen the hand of advocates for retention of the privity of contract doctrine. **[The End]**

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

May Food Seizures Report.—Over 654 tons (1,309,985 pounds) of adulterated food were seized in 24 actions during April on charges of filth, spoilage and insanitary handling. Included in the "health protection" category were seizures of wheat (54 tons) contaminated with a poisonous mercury compound, rice accidently contaminated with formaldehyde, products containing nonpermitted food additives, and low potency vitamin products. Eleven seizures were made on "pocketbook protection" charges.

Drug and Device Seizures.—Twenty-two seizures resulted from charges of misbranding with false and misleading therapeutic claims, substandard quality and failure to bear adequate labeling information or warnings required by law. Included were vitamins with false and misleading labeling claims; a human use drug and medicated feed containing antibiotics not certified by FDA as required by law; a "new drug" marketed without prior safety clearance; defective prophylactics; and devices falsely promoted for diagnosis and treatment.

Cosmetic Seizures.—A deodorant and a shampoo were seized on charges that theye were not labeled as required by law. A "magic youth" cream and a series of cosmetics, including "ageless" hormone oil, were charged to be labeled with false and misleading claims.

Hazardous Substances.—An extremely flammable water repellant (seven actions), a soldering and tinning product, an oil polish, a drain cleaner, turpentine, and an engine fuel (three actions) were seized because of failure to bear precautionary labeling required by the Federal Hazardous Substances Labeling Act.

Voluntary Actions by Industry.—The food industries voluntarily destroyed or denatured a total of 1,589,629 pounds of unfit foods to prevent their consumption in the month of April. Some of the largest voluntary food actions involved 592,970 pounds of moldy barley and wheat, and 110,000 pounds of fire-damaged wheat which were converted into animal feed. Short-weight canned pork and beans (72,000 pounds) were voluntarily relabeled. Spoiled pork shoulder picnics (30,984 pounds) and oleomargarine (12,840 pounds) unfit for human consumption were rendered for use in the manufacture of soap.

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