VOL. 18, NO. 3 MARCH 1963

Food Drug Cosmetic Law JOURNAL

This Concludes the Presentation of the Papers Presented at the Eighteenth Annual Meeting of the New York Bar Association Section on Food, Drug and Cosmetic Law

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $20 per year. Single copies are $2 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

March, 1963
Volume 18 • Number 3

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . March, 1963

VOLUME 18 NUMBER 3

Vol. 18, No. 3 March, 1963

Food·Drug·Cosmetic Law
Journal

Fair Advertising Landmarks

By EVERETTE MacINTYRE

Mr. MacIntyre Is Federal Trade Commissioner.

IT IS FITTING that your meeting today celebrates the twenty-fifth anniversary of the enactment of the Food, Drug and Cosmetic Act and in that connection commemorates the Silver Anniversary of the Wheeler-Lea Amendment to the Federal Trade Commission Act. Indeed, it is a pleasure to participate with you here today in the celebration of the Silver Anniversary of the Wheeler-Lea Act, the Act of March 21, 1938, which so greatly strengthened the authority of the Federal Trade Commission to protect businessmen and the public from false advertising and other deceptive and unfair acts and practices. Everyone recognizes the Wheeler-Lea Act as one of the great landmarks for fair advertising.

Fair Advertising Landmarks

Perhaps the greatest fair advertising landmark of all is the Federal Trade Commission Act as it was originally approved in 1914 and interpreted in some of the early cases, such as *Winsted*[1] and *Algoma.*[2] Only when some of the guideposts of that basic statute became obscured by the events of time, as by the decision in the first *Raladam* case,[3] did it become necessary to spell out, in the Wheeler-Lea Act, what was probably intended by the Congress in the first instance, namely, that consumers as well as businessmen are entitled to be pro-

[1] *FTC v. Winsted Hosiery Company,* 258 U. S. 483 (1922).

[2] *FTC v. Algoma Lumber Company, et al.,* 1932-1939 TRADE CASES ¶ 55,041, 291 U. S. 67 (1934).

[3] *FTC v. Raladam Company,* 283 U. S. 643 (1931).

tected from unfair and deceptive advertising and other unfair acts and practices.

Prior to the Wheeler-Lea Act, the Commission's capacity to protect consumers from deceptive practices was only an incident to the businessman's protection against unfair methods of competition. Unless there were competitors and they had suffered actual or potential injury, the Commission could not prohibit a misrepresentation even though it was clearly deceptive to the public.[4]

This does not mean that the Commission was unaware of the consumer or his problem before 1938. The first two cease and desist orders ever entered by the Commission prohibited misrepresentations with regard to composition of sewing thread and textile fabrics for home use. The first cease and desist order to be reviewed by the courts involved misrepresentation of food products, sugar, coffee and tea, by one of the nation's largest retailers. The broad responsibility of the Commission to protect the public was described by the court of review in that case as follows:

> The commissioners, representing the Government as *parens patriae*, are to exercise their common sense, as informed by their knowledge of the general idea of unfair trade at common law, and stop all those trade practices that have a capacity or a tendency to injure competitors directly or through deception of purchasers, quite irrespective of whether the specific practices in question have yet been denounced in common-law cases. . . .

The court added that the advertiser's ethical standards were at least as high as those generally prevailing in the commercial world at that time, and that the Commission's order was to be taken more as a general illustration of the better methods to be required in the future rather than a criticism for past conduct.[5]

"Special Board of Investigation"

As early as 1929, it had become apparent to the Commission that misrepresentation embodied in false and misleading advertising was of such volume as to require the giving of special attention to the problem. In that year the Commission established a "special board of investigation" to conduct a continuing survey of newspaper and magazine advertising for the purpose of detecting any claims appearing to be questionable. In 1934 the survey was extended to radio advertising and in 1948 to television, when it became a significant advertising medium. The Commission has continued that survey or

[4] Case cited at footnote 3.

[5] *Sears, Roebuck & Company v. FTC*, 258 F. 307 (CA-7 1919).

monitoring of advertising up to the present day as an important part of its activity to prevent false and deceptive advertising.

It thus became established in the very beginning of the Commission's history that positive misrepresentations would be prohibited, if they tended to deceive consumers and if there were competitors likely to lose business as a result of the misrepresentations.

Consumer Protection

With the enactment of the Wheeler-Lea Amendments to the Federal Trade Commission Act in 1938, consumer protection gained new stature. He was given protection in his own right, not dependent on whether the deceptive practice also had an effect of injuring competitors.

The Wheeler-Lea Amendments to Section 5 gave the Commission jurisdiction to prevent "unfair or deceptive acts or practices in commerce," in addition to the "unfair methods of competition in commerce" which previously were unlawful. Thus, this change established another great landmark for fair advertising. It put the consumer on a par with the businessman from the standpoint of entitlement to protection from deceptive practices. At that point, *caveat emptor* or "purchaser beware" ceased to be the economic and commercial policy of the United States. From then on, consumers and businessmen could deal with each other on a basis of equality, in the knowledge that use of deceptive practice was against public policy. No longer need the consumer suspect that the businessman was likely, or any more likely than anyone else, to engage in deception. By the same token, the businessman was elevated to a new plane of public responsibility and respect. The new law proclaimed to the world an assurance that the American businessman, like every other American, is assumed to act in a manner which will be honest, nondeceptive and in the best long-run interests not only of himself but his fellow man.

An equally important contribution of the Wheeler-Lea Amendments to the Commission's arsenal was the provision that cease and desist orders entered under the Federal Trade Commission Act would become final 60 days after their issuance, whereupon civil penalties of up to $5,000 for each violation could be collected in suit brought on behalf of the United States. Prior to that, the repeat offender was allowed three bites at the apple before he could be penalized for his wrongdoing. His initial violation would lead to issuance of a cease and desist order by the Commission. His next violation would result

in a decree from a court of appeals that he comply with the Commission's order. His third violation might result in his being held in contempt of the court's decree.

Under the new procedure, he would be subject to penalties for the first violation of the order. Teeth had been put in the Commission's orders. No longer would they be treated merely as a code of ethics or an illustration of better methods required for the future. They were now a command of the government, to be respected upon first issuance.

Civil penalties were collected under that section during fiscal year 1962 in the record amount of $100,400.

New Sections Added

Probably the most important consumer protection feature of the Wheeler-Lea Amendments was the addition to the Federal Trade Commission Act of new sections, numbered from 12 through 16, giving the Commission special authority to prevent false advertising of food, drugs, therapeutic devices and cosmetics. Not only could such advertising be attacked through a conventional cease and desist proceeding, but pending the outcome of such proceeding, issuance of injunction by a United States district court could be sought, to stop use of the challenged advertisement until the cease and desist proceeding had been brought to conclusion. Additionally, if the advertisement was published with fraudulent intent or if the advertised commodity would be dangerous to health, then upon certification of the facts to the Attorney General, a criminal action could be brought to impose punishment by fine up to $5,000 or imprisonment up to six months, or both. The jurisdiction of the Commission over advertising of food, drugs, therapeutic devices and cosmetics was broadened so it would not depend upon sales of a falsely advertised product in commerce, but would extend also to the dissemination of false advertising by United States mails, or in commerce by any means, or by any means likely to induce a sale in commerce.

An interesting development under the Wheeler-Lea Amendments has been the evolution of affirmative disclosure requirements in the advertising or labeling of products.

In one of the first and most definitive of those cases, the Commission's order as affirmed by a court of appeals in 1942 required affirmative labeling of true composition on food serving trays which were made of paper that had been treated to simulate the appearance of wood. The court observed that:

The process used . . . to simulate woods does great credit to the ingenuity of . . . (the manufacturer), and is so skillfully carried out that the physical exhibits shown us in court were distinguishable from the real wooden trays only after the most careful scrutiny. The trays themselves were the best evidence of the possibility of confusion. Without some warning, the trays of themselves are almost certain to deceive the buying public . . . .[6]

The complaint as issued by the Commission in that case was couched in the language of the Wheeler-Lea Amendment to Section 5 of the Federal Trade Commission Act, charging use of "unfair and deceptive acts and practices in commerce" with no mention being made of "unfair methods of competition in commerce."

Another landmark complaint issued under Section 5 charged that because of consumer preference for domestic products, failure to disclose the foreign origin of imitation pearls constituted "unfair and deceptive acts and practices in commerce," and the order required that such products not be offered for sale or sold without clearly disclosing the foreign country of origin. In affirming the order, the reviewing court stated:

We commence our study of the instant case with the knowledge that the Commission may require affirmative disclosures where necessary to prevent deception, and that failure to disclose by mark or label material facts concerning merchandise, which, if known to prospective purchasers, would influence their decisions of whether or not to purchase, is an unfair trade practice violative of section 5 of the Federal Trade Commission Act, . . .[7]

Ultimate Consumer Protected

In another leading case, the court of review emphasized that requiring labels to contain affirmative disclosures is intended to protect the ultimate consumer and not merely the middlemen. The product involved in that instance was rayon dresses which simulated the appearance of silk. The court said that the likelihood of consumers buying the dresses in the belief they were silk justified the Commission in requiring the manufacturer to label them as rayon, "thus preventing distributors from exercising a deception of which the petitioners themselves were not guilty . . . ."[8] That case, decided in 1952, was of particular significance because it put the force of court decision behind trade practice rules which the Commission had issued in 1937 requiring affirmative disclosure of true composition respecting rayon goods. It also was a significant factor leading to enactment of the Textile Fiber Products Identification Act of 1958.

---

[6] *Haskelite Manufacturing Corporation v. FTC*, 1940-1943 TRADE CASES ¶ 56,317, 127 F. 2d 765 (CA-7 1942).

[7] *L. Heller & Son, Inc., et al. v. FTC*, 1950-1951 TRADE CASES ¶ 62,931, 191 F. 2d 954 (CA-7 1951).

[8] *Mary Muffet, Inc., et al. v. FTC*, 194 F. 2d 504 (CA-2 1952).

Other Commission orders requiring affirmative disclosures have been upheld in regard to abridgment of books, reprinting of books or stories under a new title [9] and the sale of previously used products.[10]

The Supreme Court recently denied certiorari respecting a Commission order requiring that aluminum watch cases which had been treated to simulate the appearance of gold, be marked to disclose that they were not precious metal.[11] This was another case of consequence, as it enforced trade practice rules adopted by the Commission in 1948 requiring affirmative disclosure respecting composition of watch cases deceptive in appearance.

By an action similar in principle the Commission modified an order so as to require that a debt collector not only cease misrepresenting the nature of his business, but also cease distributing written materials which did not disclose the nature of his business.

The order as thus modified was affirmed on court review, the main basis being that failure of the written materials to contain the disclosure required by the order would "cause recipients to take action they would not otherwise have taken." [12]

Consumer Protection Extended

I think it can be said, then, that the Wheeler-Lea Amendment to Section 5, by declaring deceptive acts and practices in commerce to be unlawful, extended the protection of consumers from the area of simple misrepresentation to the area of deception practiced through omission or nondisclosure. When the omission or nondisclosure involves a fact material to the consumer's decision of whether or not to engage in commercial dealings, the Commission may act to protect him. In so doing, the Commission has no desire to dictate what goods or services the consumer shall or shall not purchase. Rather, the purpose is to aid him by making sure that he gets what he thinks he is getting.

The disclosures required in the advertising of food, drugs, therapeutic devices and cosmetics under Sections 12 through 15 of the Act have had a similar evolution.

---

[9] *Hillman Periodicals, Inc. v. FTC,* 1948-1949 TRADE CASES ¶ 62,411, 174 F. 2d 122 (CA-2 1949); *Bantam Books, Inc. v. FTC,* 1960 TRADE CASES ¶ 69,640, 275 F. 2d 680 (CA-2 1960), cert. den. 364 U. S. 819.

[10] *Royal Oil Corp. et al. v. FTC,* 1959 TRADE CASES ¶ 69,234, 262 F. 2d 741 (CA-4 1959).

[11] *Theodore Kagen Corp. et al. v. FTC,* 1960 TRADE CASES ¶ 69,815, 283 F. 2d 371 (CA of DC 1960), cert. den. 365 U. S. 843.

[12] *Mohr et al. v. FTC,* 1959 TRADE CASES ¶ 69,528, 272 F. 2d 401 (CA-9 1959), cert. den. 362 U. S. 920.

Section 15, as you know, defines a false advertisement as including one which fails to reveal facts material in the light of representations made in the advertisement or in the light of possible consequences from use of the advertised product. This provision did not fare well on its first court test in 1950. The Commission had ordered a respondent, Alberty, to cease advertising a mineral preparation as having a beneficial effect upon the blood, except in cases of simple iron-deficiency anemia. The order further required that the product not be offered for tiredness unless limited to tiredness due to simple iron-deficiency anemia, and unless affirmative disclosure be made that tiredness is caused less frequently by simple iron-deficiency anemia than by other causes for which this product would not be an effective treatment or relief. The respondent refused to disclose in advertising of the product for tiredness that the product would usually not be beneficial, and the courts upheld that contention. It seemed abhorrent to the court that the Commission might have power to require an advertiser to disclose, when a fact, that in most cases his product would be useless. The court felt that the Commission had gone too far toward requiring advertisements to be "informative" and had gone beyond its function of "preventing falsity." [13]

Consumer protection activities of the Commission gained significant support from court affirmance of the order in the *Koch* case of 1953. Disclosures were not involved, but the flagrancy of claims showed a compelling need for action to protect the public. In that case, the Commission's order not only proscribed references to the advertised products' being efficacious in the treatment of cancer, coronary thrombosis, diabetes, meningitis, infantile paralysis, pneumonia, undulant fever, malaria, gonorrhea, and syphilis, but also prohibited claims that the products would be of any benefit in the treatment of any disease of the human body or in animals.[14]

Hair Grower Cases

The *Alberty* decision was specifically overcome in the *Wybrant* and other hair grower cases, where the courts of appeal beginning in 1959 upheld Commission orders requiring that products not be advertised as efficacious in growing hair or preventing baldness unless it be revealed that the products are of no value in most cases of baldness

[13] *Alberty et al. v. FTC*, 1950-1951 TRADE CASES ¶ 62,583, 182 F. 2d 36 (CA of DC 1950), cert. den. October 9, 1950.

[14] *Koch et al. v. FTC*, 1953 TRADE CASES ¶ 67,526, 206 F. 2d 311 (CA-6 1953).

or excessive hair fallout. The courts were furnished with more adequate records in support of the orders against the hair growers because, unlike the *Alberty* case, the Commission in each of the hair grower cases included a specific finding that failure to make the affirmative disclosure required by the order was in itself deceptive. The orders were affirmed by opinions in which the courts declare that the Commission's authority to require affirmative disclosures were necessary to prevent deception is clearly established.[15]

The requirement that affirmative disclosures be made when a product advertised for a designated disease or condition is of limited effectiveness has been extended to vitamin and vitamin-mineral preparations. Consent orders have been accepted requiring advertisements offering such products for tiredness and nervousness to disclose that in the great majority of persons these symptoms would be due to conditions other than vitamin or mineral deficiency, and that in such cases the product would be of no benefit.[16]

The Commission issued a similar order in a litigated case involving such a product designated "Rybutol," noting that medical testimony showed the great majority of persons experiencing tiredness and loss of happiness would have these symptoms as a result of a disease or condition other than vitamin deficiency, and that possibly serious consequences might result from continued self-treatment of such diseases and conditions.[17]

In two pending cases the question has been raised of whether advertising of vitamin-mineral preparations for iron deficiency anemia is deceptive if it fails to disclose that in women beyond the childbearing age and in men of all ages, iron deficiency anemia is almost invariably due to bleeding from some serious disease or disorder and in the absence of adequate treatment of the underlying cause of the bleeding, the use of the preparation may mask the signs and symptoms and thereby permit the progression of such disease or disorder.[18] As these cases are in process of being adjudicated by the Commission,

[15] *Wybrant System Products Corporation et al. v. FTC,* 1959 TRADE CASES ¶ 69,348, 266 F. 2d 571 (CA-2 1959), cert. den. 361 U. S. 883; *Erickson Hair and Scalp Specialists v. FTC,* 1959 TRADE CASES ¶ 69,527, 272 F. 2d 318 (CA-7 1959), cert. den. 362 U. S. 940; and *Ward Laboratories, Inc., et al. v. FTC,* 1960 TRADE CASES ¶ 69,690, 276 F. 2d 952 (CA-2 1960), cert. den. 364 U. S. 827.

[16] Docket 8151 (7/18/61), Docket 8397 (9/25/61), Docket 8398 (9/22/61), and Docket C-123 (4/19/62).

[17] Docket 8150, Lanolin Plus, Inc., order to c. and d. 9/12/62.

[18] Docket 8523, Hadacol, Inc., et al.; and Docket 8547, The J. B. Williams Company, Inc., et al.

with no conclusion as to final disposition having yet been reached, I will not comment further about them.

Affirmative Disclosure of Facts

I believe the greatest development of the law in deceptive practices before the Commission in the immediate future will entail questions of affirmative disclosure. I think you will see more and more of our cases involving the question of what omissions in advertising and labeling are material enough and deceptive enough to require an affirmative disclosure of facts. Full implementation of this authority of the Commission to prevent deception by requiring affirmative disclosures may obviate the need for a multiplicity of labeling or packaging laws or laws seeking to provide further protection to the public in the sale of particular commodities. The argument might be made that if the practice is deceptive, let the Commission correct it under present law. If no deception is involved, then it may be the practice is not of sufficient importance from the public interest standpoint to warrant its being given further attention.

The jurisdiction conferred upon the Commission by the Wheeler-Lea Amendments to prevent false advertising of food, drugs, therapeutic devices and cosmetics, regardless of whether there were sales in interstate commerce, was confirmed by court decisions in 1958. In the first case, a product designated O-Jib-Wa Bitters was advertised extensively in 35 or 40 newspapers throughout the State of Michigan as a curative treatment for arthritis, rheumatism, neuritis, sciatica and various other ailments. The advertiser was careful not to fill any order from persons located outside Michigan. The Michigan newspapers in which he advertised did have some interstate circulation, and were circulated via the United States mails. The court held that jurisdiction of the Commission to prohibit use of the advertising was warranted not only on the basis of interstate circulation of the advertisements, but also their circulation via the United States mails.[19]

In the second case, Sidney J. Mueller, advertiser of products offered to grow hair, had been operating in several states but, after order to cease and desist was issued, confined his operations within one state. However, he continued to advertise in newspapers which had some interstate circulation and were distributed via the United States mails. The court found that the order had been violated

[19] *Shafe v. FTC*, 1958 TRADE CASES ¶ 69,069, 256 F. 2d 661 (CA-6 1958).

because the advertisements had been sent via the United States mails and across state lines.[20] He was fined $8,000 for violating the order.[21]

What Is the Public Interest?

The Commission's jurisdiction to prevent false advertising or other deceptive practices under the Wheeler-Lea Amendments is still limited by the proviso in the original act that proceedings will not be undertaken except when in the public interest. The courts have interpreted that as meaning *substantial* public interest,[22] which permits the Commission to avoid becoming involved in matters that are essentially private controversies not affecting substantial numbers of the public. The Commission is sometimes criticized for concerning itself with trivial matters, especially in the exercise of its deceptive practices jurisdiction. But I believe you will find if you examine the cases that each of them is important either because of flagrancy of practice or numbers of the public affected. I suppose no one would argue that we should ignore the advertising of a mineral preparation offered as a treatment for arthritis and blindness,[23] even though sales volume may not have been very large. At the other end of the scale, we sometimes have a case in which the claims are not very deceptive, but the volume of advertising and sale of the product is so extensive that even a slight misrepresentation will have a tremendous effect upon the public and upon competition. The top 100 largest advertisers in the United States have been listed.[24] Orders prohibiting use of misrepresentation or deceptive practice have been issued by the Commission against 38, or more than one-third of those 100 companies. A total of 53 such orders have been issued, as 11 of the companies have had two or more orders issued against them. Forty-seven of those orders have been issued since the date of the Wheeler-Lea Act, including ten which were issued during the past two years. Eight of the companies are now charged with deceptive practices in nine proceedings pending before the Commission, one company being the subject of two pending actions. Thus the Commission has not overlooked the more important advertisers; neither has it overlooked the smaller advertiser when he was in effect stealing substantial amounts of money from the public.

---

[20] *Sidney J. Mueller v. United States,* 1958 TRADE CASES ¶ 69,219, 262 F. 2d 443 (CA-5 1958).

[21] *United States v. Sidney J. Mueller,* U. S. District Court, Southern District, Texas, Houston Division, April 10, 1958.

[22] *FTC v. Klesner* (*Shade Shop* case), Sup. Ct. (1929), 280 U. S. 19.

[23] Consent order accepted 10/31/61, Docket C-11.

[24] See *Advertising Age.* August 27, 1962, p. 42.

Organizational Setup

Under the present organizational setup of the Commission, as adopted July 1, 1961, the investigation and litigation of initial violations occurring under the Wheeler-Lea Amendments, especially those involving food, drugs, therapeutic devices and cosmetics, is vested in the Division of Food and Drug Advertising, Bureau of Deceptive Practices. This division also monitors radio, television and printed advertising to watch for claims which may be false and misleading. Medical and scientific advice and assistance in such cases is provided by the Division of Scientific Opinions, in the same bureau. Any field investigation needed is performed by the Bureau of Field Operations. Maintaining and enforcing compliance with cease and desist orders entered in false advertising and other deceptive practice cases, is a function of the Division of Compliance in the Bureau of Deceptive Practices. Court work arising from the deceptive practice and other Commission cases is performed by the Division of Appeals, Office of General Counsel. The Bureau of Industry Guidance endeavors to prevent deceptive and other unlawful practices on an industry-wide basis, in the field of food and drug advertising as well as other areas.

We at the Commission are grateful for the efforts at self-regulation which have been instituted by business groups, as the prevention of false advertising and other deceptive practice will always, in large measure, be dependent upon such activity.

We are also appreciative of opportunities made available by the bar associations to disseminate widely the views of administrators of the laws through meetings like this, as a possible aid to the better implementation of those laws.

Let me say again that it has been a pleasure to meet with you, and I thank you for your attention. **[The End]**

FTC Chairman Supports "Truth in Packaging" Bill

Federal Trade Commission Chairman Paul Rand Dixon told a Senate antitrust and monopoly subcommittee that a proper truth-in-packaging law would enable the FTC to protect consumers from acts and practices which it may not be able to prevent under Section 5 of the FTC Act. However, Mr. Dixon said that he felt that the division of responsibilities proposed by S. 387, which would be administered jointly by the Food and Drug Administration (as to food and drug packaging and labeling) and the FTC (as to packaging and labeling of all other products) was anomalous. The thrust of packaging and labeling problems is economic deception, he declared, not protection of health.

The Secretary of Commerce, Luther H. Hodges, and George P. Larrick, Commissioner of Food and Drugs, have also expressed support of the "Truth in Packaging" bill.

Agriculture–Food Supplier to the Nation

By DR. M. R. CLARKSON

The Author Is Associate Administrator, Agricultural Research Service, United States Department of Agriculture, Washington, D. C.

IT'S A REAL PLEASURE to join with you in paying tribute to the Food and Drug Administration and, in particular, to commemorate the twenty-fifth anniversary of the enactment of the Food, Drug and Cosmetic Act.

Passage of the 1938 Act was in itself a vote of confidence in the effectiveness, integrity and leadership of the Food and Drug Administration. The bills which eventually emerged as the new legislation were most carefully considered in an atmosphere of recognition of the good job being done by the enforcement agency, and the need to further strengthen its effectiveness. The objective of all this legislation has been to protect the American people by insuring the safety and wholesomeness of their foods.

Agriculture—Beginning of Safety and Wholesomeness

In the broad sense, the safety and wholesomeness of our foods begins with agriculture—from the time the farmer selects tested, disease-free seeds for planting, and healthy, productive animals for breeding.

Agriculture continues its concern for our foods through a long and complicated chain of growing, feeding, harvesting, storing, processing, and distribution.

The end products are the familiar items that crowd the shelves of modest neighborhood grocery stores as well as the huge, gleaming supermarkets that have become a hallmark of the American way of life. And what foods they are—varied beyond belief, plentiful, nutritious, easy to prepare, attractive and relatively inexpensive to buy compared to other products in the economy.

Even here, agriculture is concerned with how foods look and taste—how they've been affected by processing—how much nutritive value they have—and the kinds of foods that people of all ages should eat to be strong, healthy and productive.

Food has always been the main interest of the Department of Agriculture—from the time it was first organized a little over a century ago in 1862. That interest continues greater than ever today, now that our food supply is recognized as a vital national asset—the keystone of our national strength and international power—a symbol for other nations of the success that *can* be achieved in a free society.

Other nations, in fact, seem to be much more aware of our success in agriculture than our own people.

Far too few Americans realize the tremendous significance of our abundance—of just plain having enough to eat. Nor do they realize the significance of the scientific and technological revolution in agriculture that has made this abundance possible.

Increases in Farm Productivity

It has come about because millions of farmers have applied new discoveries and new methods to their own operations. They have done this so successfully that increases in farm productivity far overshadow increases in other major sectors of the economy. During the 1950's, output per manhour in agriculture increased more than three times as fast as it did in other industries.

Other figures further demonstrate this increasing productivity.

In 1900, 37 per cent of our labor force was in agriculture. Today, the figure is about 8 per cent. That 8 per cent, using only two-thirds of our cropland acres, provides all our food and plenty to spare. Last year alone, we exported a record total of $5 billion worth of agricultural products.

As farmers have become more efficient through use of research-based technology, more people have been released from agriculture to produce other goods and services. Our industrial economy could never have come into being except for the development of our efficient, specialized system of producing basic agricultural commodities.

This system gives us a tremendous advantage over nations that utilize time-consuming and unrewarding systems of farming. As Secretary Freeman said in a recent speech:

> No feudal estate, no state-owned farm, no plantation, no collective has ever achieved the productivity of the American farm. No one of these has ever

produced an agricultural economy that has contributed so much to overall economic growth. No one of these has ever equalled it in the development of a high level of citizenship and sense of personal dignity and worth.

These are facts that we should remember and bring home whenever and wherever we can. People throughout the world are not nearly as much impressed with our industrial development, as by the fact that we're able to produce more than enough food with only 8 per cent of our labor force.

We can truly be thankful for the marvelous achievements of American agriculture over the past hundred years. But we must also remember that increases in productivity cannot continue indefinitely. Simply because we have all the food we need and want doesn't automatically guarantee that future generations of Americans will have all *they* need or want.

Our ability to feed our people may well be challenged some day.

Population Growth Expected

The current rapid increase in population is expected to continue. In another 50 years, population experts say, we may have close to 400 million people in our country, more than twice our present population of 188 million. They say, too, that world population may exceed 7 billion early next century.

These are staggering prospects if we think of them only in terms of food, disregarding the great social, political and economic implications. They're even more staggering when we realize that population growth estimates are generally on the low side. And they're positively depressing when we consider that despite our present miracles of production, we are *still* living in a world where the vast majority of its 4 billion people are often hungry and always malnourished.

What this all means for our country is that we'll need at least twice as much food just to keep on eating the way we are now. In fact, by 1975, only 12 years away, it's estimated that we'll have to produce 54 per cent more soybeans than we're producing now, 47 per cent more beef, 35 per cent more corn, and 28 per cent more poultry. In all likelihood, we'll have to do it on less cropland than we're using today.

And that brings us to the important question: How are we going to do it?

How Can Larger Population Be Fed?

For one thing, we can make better use of present information. We can increase production a great deal simply by applying more fully the knowledge and the tools we already have.

Beyond that, we're going to have to apply the whole vast range of science to agriculture on a scale never known before. Given new information and tools and sufficient incentive, our farmers can do an outstanding job of farm management.

Nothing that we do to increase production will be of much value, however, if the foods we grow aren't safe, wholesome, nutritious and high in quality. Our foods must be protected at every stage from the contamination and filth of insects of every variety and description, from rodents, and many other pests.

Two National Regulatory Agencies Set Up

This need was recognized early this century. And, by coincidence, Congress on the same day set up two of the nation's major regulatory agencies to do part of the job of protecting our foods. Both the Food and Drug Administration and the Meat Inspection Service of the Department of Agriculture came into their present form from acts signed on June 30, 1906. The Food and Drug Administration was first organized as part of the Department of Agriculture. Here were forged the basic philosophy underlying the work of the Food and Drug Administration, and the machinery to put it to use.

So, for more than half a century, we in the Department of Agriculture have maintained the closest working relationships with the Food and Drug Administration in a common effort to keep our foods safe. These relationships have been built on mutual trust and confidence. The effectiveness of these efforts has been enhanced still further by close cooperation with the states.

My own career in the department has given me many opportunities to work with Food and Drug Administration officials. I began in 1930 as an inspector in the Meat Inspection Division.

Soon after coming to Washington in 1939, I became acquainted with George Larrick, present commissioner of the Food and Drug Administration. In common with others in the Department of Agriculture, I quickly developed an appreciation of his scientific competence and professional integrity. Because of the dedicated work of Commissioner Larrick and his assistants, it has been easier to meet our own responsibilities in plant, animal disease and pest control, regulation of pesticides, the inspection of meats, and our farm, utilization, human nutrition and consumer-use research.

At a time of mounting nationwide concern over the growing use of chemicals in our everyday lives, Commissioner Larrick is perform-

ing an exceedingly difficult job in an outstandingly effective and conscientious manner.

At best, a regulatory agency's job is hard and thankless. And today, those regulating the use of chemicals are very much in the spotlight. It is indeed a curious fact that the more active our regulatory agencies become, and the more knowledge we acquire about chemicals, the more apprehensive the public gets about their continued use.

Chemicals from the Standpoint of Agriculture

Let's take a long look at chemicals from the standpoint of agriculture to clear up at least one area of possible misunderstanding.

Pests cost our agricultural economy more than $13 billion every year. That's nearly one-third our potential national production. It's clear that the prosperity of our agriculture and our high standard of living are related directly to effective control of pests.

Our food supply would probably be rationed if we had no chemicals to protect our crops and livestock. Many of our major foods would be in the luxury class and available only to the wealthy. Housewives would have to buy inferior foods—when and if they were available—and pay 25 per cent more for them. We'd lose nearly a third of our protein supply. More than 80 per cent of our high-vitamin foods could not be produced.

Fortunately, we've managed to control many of nature's worst pests here in our own country. Consequently, no one is willing to take the losses from contamination by many different kinds of pests that were once considered normal. Modern housewives and food processors simply won't buy insect-infested, scabby, scaled, or blotched produce. The American public will not tolerate insect pests in their foods, or their homes or possessions.

An often-repeated belief is that we can control these insects and enable them to live in harmony with man by restoring the so-called "balance of nature."

Nature has not been "in balance" since man entered upon the scene as an aggressive and intelligent animal determined to wrest a comfortable and secure life for himself and his family at the expense of other forms of life. With the advance of civilization, man has worked continuously to tip the balance in his favor. Where he has succeeded, he lives in relative comfort and security. Where he hasn't succeeded, he lives in poverty.

Another commonly-held belief is that agriculture uses most of the chemicals in the country today.

The truth is that agriculture uses only about 165 million pounds of the 225 million pounds of chemicals applied for insect control in the United States in an average year. The rest is applied in urban areas.

Agriculture is far from satisfied that our present-day chemicals are the last word in insect control. We're deeply involved in research to show us how we can do a better job.

First of all, I want to emphasize that the intensive safety evaluations on *all* aspects of our food supply—from field to freezer—must be continued. There should be no letup on this important basic function.

New Types of Chemicals and Uses

Beyond that, our scientists are probing for new types of chemicals and new ways to use them. We are developing various baits and lures and natural and synthetic sex attractants that can be used with other chemicals right in the field to attract and kill insects. The advantage of such techniques is that only small amounts of chemicals are used and they leave no residues. In effect, we are literally harnessing bug power so the bugs can kill themselves.

Not all insects respond to chemical sex attractants. Some may be attracted by sound, chemicals and sound or by light. We're investigating all these areas of research and they all look extremely interesting and promising.

We're also developing techniques to make insects sterile so they can't reproduce and will thus die out. Our scientists got rid of screwworm flies in the Southeast, for example, by raising them in large quantities, irradiating them to make them sterile, then releasing them to mate with native flies. The eggs that resulted from these matings were infertile and the screwworm population gradually died out. We're now experimenting with chemicals that can sterilize the insects right in the field.

And finally, we're developing various biological control methods to disturb the "balance of nature" more and more in our favor. Some of the older ones include the milky-spore disease to control Japanese beetle, and an insect imported from Australia to control Klamath weeds out West. Many others are being studied, such as the use of parasites to control the alfalfa weevil in the East . . . and still other parasites imported from Israel to control brown soft scale of citrus in Texas.

In short, we're investigating any area of work that looks like it has possibilities. Many of the newer approaches are extremely complex, expensive, and time-consuming.

But we feel our efforts are amply justified when we consider the goal—to help provide a wholesome and continuing supply of food for now and the future, and to help bring about a world free of hunger and malnourishment. I know of no greater challenge in the world today.

To meet this challenge on the worldwide scale that is needed will require the fullest possible cooperation of all industries and federal and state agencies concerned with food production.

Greater Public Understanding and Support Needed

Research and regulatory activities will have to receive greater public understanding and support . . . on the part of national leaders, farm groups, commodity and trade groups, of farmers themselves, and the nonfarm public as well. It is these functions, after all, that are most closely geared to the objective of providing food for the nation and much of the world.

A great many things have combined to help our nation get where it is today. Certainly, one of them is the rule of law that governs all our activities. This is the reason we can all talk here today, while science provides the motive for our being here. The relationship between these two great forces—law and science—has already been forged in our past working experiences. It will deepen in the years ahead.

A recent editorial in *Science* refers to a book by Jacob Bronowski, *Science and Human Values*. Bronowski says that honesty and objectivity—reliance on the evidence rather than upon bias, wish, authority or personal advantage—are some of the greatest gifts that science has given to society. I am sure that you would insist, as prominent members of the New York State Bar, that your profession had already achieved these excellent qualities.

Nevertheless, let the tradition of complete honesty and objectivity that characterizes science stand as a constant challenge to each of us, whatever work we may do. Let each of us make the best use of our talents and thus contribute toward the realization of these high goals. In the final analysis, our professions, our agriculture, and the nation itself are based on the accomplishments of people, not operating as a mass, but contributing separately as individuals. **[The End]**

Administering New Food and Drug Laws

By GEORGE P. LARRICK

The Author Is Commissioner of Food and Drugs.

I PARTICULARLY APPRECIATED Mr. Depew's invitation to speak at this luncheon on the occasion of the twenty-fifth anniversary of the passage of the Food, Drug and Cosmetic Act of 1938. In administering this statute, we have had rewarding relationships with both the Food, Drug and Cosmetic Law Section of the New York State Bar Association and with the Food, Drug and Cosmetic Section of the American Bar Association. As a corollary, the Food Law Institute has played a most important part in the administration of this statute by bringing together the industries involved, the law groups to which I have referred, as well as the local and federal officials concerned with food and drug law enforcement.

The annual conferences which have been held have permitted free discussion of problems of mutual interest. They have been invaluable. The publications of the Food Law Institute have made a permanent record of the significant contributions to the interpretation of these fundamental laws. The Institute has sponsored many meetings and other activities which have lent meaning and dignity to an enterprise to which we are all so deeply dedicated.

Administration of the Act

The administration of the Federal Food, Drug and Cosmetic Act has gone through a number of phases. From a strictly legal standpoint, the statute as originally enacted was a punitive law and its terms were almost exclusively negative in the sense that they told the regulated industries what they could not do. As the law and its administration evolved, more and more the statute dealt with affirmative requirements, and in recent years the trend has been very strongly in the direction of requiring prior approval before products can be

marketed. This trend acquired more impetus through legislation enacted in the last Congress. Today the drive of the statute is predominantly preventative enforcement rather than punitive enforcement. It has been the objective of the administrators of the Food, Drug and Cosmetic Act from the very beginning to administer the statute in such a way as to prevent violations of the law rather than to punish violators after they occur. We will always, in my opinion, need to employ the sanctions of the statute to effectuate its purposes, but recent developments, both in the amendments mentioned as well as in the reviews of our administrative programs by the Citizens Advisory Committee and others, have emphasized that administrative actions designed to implement preventative enforcement should be undertaken at an accelerated pace. This we plan to do. We welcome your constructive suggestions and participation in this endeavor.

[The End]

ANIMAL RESEARCH LAB UNDER CONSTRUCTION

A $1.75 million Special Pharmacological Animal Laboratory, now under construction at Beltsville, Maryland, will upgrade the Food and Drug Administration's ability to properly house and otherwise care for the animals required for its research activities.

The new laboratory is expected to be occupied in about 12 months. Five X-shaped kennel units with quarters for 550 dogs will be included. It will also have special care areas containing a "sick bay" and other provisions to insure humane and proper treatment. Provisions are also made for housing 32 personnel. Of these, 19 will be engaged in research work in the laboratories and 13 will be assigned to caring for the animals.

The animals to be housed in the new facility are used in research to obtain scientific data necessary for the discharge of FDA's responsibilities for the safety of foods, food additives, color additives, pesticides, drugs and cosmetics. Since its establishment in 1935, the Division of Pharmacology in FDA has used dogs as experimental animals. However, the amount of this kind of research has increased in recent years with the enactment of the Pesticides, Food Additives and Color Additives Amendments to the Federal Food, Drug and Cosmetic Act. Because dogs' physiological processes are closely related to similar processes in man in many cases, dogs are especially valuable as research animals. And where it is necessary to obtain cooperation between the "patient" and the researcher, the dog may be readily trained. Thus in health research as well as in other ways, the dog is truly "man's best friend."

Products Liability—1962

By WILLIAM J. CONDON

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

NO SIGNIFICANT QUANTITATIVE CHANGE is to be noted in the 1962 list of cases. There were, however, some very interesting developments. The list of cases, grouped according to subject matter, is as follows:

Foreign Substance Beverage Cases

Tucker v. Pepsi-Cola Bottling Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,704 (Ct. App. Tenn.).

Tetreault v. Coca-Cola Bottling Company of Rhode Island, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,712 (R. I.).

Harris v. Coca-Cola Bottling Company of Chicago, Inc., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,718 (Ill. App.).

Calhoun v. Coca-Cola Bottling Company of Memphis, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,719 (Ct. App. Tenn.).

Foreign Substance and Contaminated Food Cases

Walton v. Guthrie, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,710 (Ct. App. Tenn.).

Gilbert v. Gendusa Bakery, Inc., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,722 (La. Ct. App.).

Kassouf v. Lee Bros., Inc., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,728 (Calif. Ct. App.).

Trichinosis Case

Adams v. Scheib, 184 A. 2d 700 (Pa.).

Exploding Bottle Cases

Jones v. Burgermeister Brewing Corp., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,700 (Cal. D. C. App.).

Hochgertel v. Canada Dry Corp., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,702 (Pa. Ct. Com. Pleas).

Chapman v. Redwine, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,703 (Colo. Sup. Ct.).

Selfridge Carnation Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,707 (Calif. Ct. App.).

Phillips v. Pepsi-Cola Bottling Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,709 (N. C. Sup. Ct.).

Rowe v. Oscar Ewing Distributing Company, Inc., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,713 (Ky. Ct. App.).

Boyd v. Marion Coca-Cola Bottling Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,715 (S. C. Sup. Ct.).

Hyams v. King Kullen Grocery Company, Inc., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,720 (N. Y. City Mun. Ct.); CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,721 (N. Y. Sup. Ct., App. Term).

Copher v. Barbee, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,723 (Springfield, Mo. Ct. App.).

Salzo v. Vi-She Bottling Corp., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,727 (N. Y. Sup. Ct., Queens Co.).

Drug Cases

Kaspirowitz v. Schering Corp., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,697 (N. J. App. Div.).

Kramer v. Lakeside Laboratories, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,699 (E. D. Pa. DC).

Cosmetic Cases

Baleson v. Clairol, Inc. et al., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,698 (N. C. Sup. Ct.).

Cox v. Budget Beauty Salon, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,706 (N. Y. Sup. Ct., Suffolk Co.).

Patterson v. George H. Weyer, Inc., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,708 (Kan. Sup. Ct.).

Bathory v. Procter and Gamble Distributing Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,717 (CA-6).

Ruderman v. Warner-Lambert Pharmaceutical Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,724 (Conn. Ct. Com. Pleas).

Moran v. Insurance Company of North America, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,726 (La. Ct. App.).

Exploding Dry Cell Battery Case

Cunningham v. Joseph Horne Company et al., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,696 (Pa. Sup. Ct.).

Playground Equipment Case

McBurnette v. Playground Equipment Corp., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,701 (Fla. Sup. Ct.).

"Heat Block" Case

McLaughlin v. Mine Safety Appliances Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,705 (N. Y. Ct. App.).

Cigarette Cases

Green v. American Tobacco Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,711 (CA-5); CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,716 (CA-5).

Pritchard v. Liggett & Myers Tobacco Company, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,725 (W. D. Pa. DC).

One of the areas that has given the courts considerable trouble has been concerned with the element of exclusive control in the application of *res ipsa loquitur* in the bottled beverage cases. In 1962, this problem was thoroughly aired in four different cases, two involving foreign substances and two, exploding bottles.

Foreign Substance Cases

The two foreign substance cases came out of two sections of the Court of Appeals of Tennessee. Both courts announced the Tennessee rule that control is extended in contemplation of law in cases involving sealed containers. Therefore, liability may be predicated upon the doctrine of *res ipsa loquitur* even though the product may have been out of the physical control of the defendant. In *Tucker v. Pepsi Cola Bottling Company*, the eastern section of the court pointed out that where, as in the case of bottled beverages, the seal may be removed and replaced, the plaintiff has the added burden of proving that there has been no reasonable opportunity to tamper with the bottle after it has left the physical control of the defendant. The emphasis here is on the word *reasonable*. The evidence which sufficed to entitle the plaintiff to the benefit of *res ipsa loquitur* in this case was the testimony that the cap was hard to remove in the plaintiff's home and that the contents of the bottle had the usual carbonation.

In addition, there was testimony by the retailer that the product was stacked within sight of the cash register in his store and that he had not seen anyone tampering with the product. Hence, the court concluded that the jury was entitled to infer that the mouse had been in the bottle when it left the defendant bottler's premises.

The western section of the court agreed completely with respect to the applicable law. However, in *Calhoun v. Coca Cola Bottling Co. of Memphis,* the opposite result was reached. Here, plaintiff purchased her beverage from a vending machine and took it to her place of employment which was in the basement of the nearby building. While she drank the coke with her lunch, she placed the bottle down from time to time on a table nearby. There was evidence that the basement in which plaintiff worked was infested with roaches. On this evidence, the court held that plaintiff was not entitled to an inference that the roach which she found in her beverage had been there when the bottle left the defendant bottler's premises.

Exploding Bottle Cases

The remaining two cases involved exploding bottles. In the first of these, *Hyams v. King Kullen Grocery Company, Inc.,* a municipal court judge in New York City strove valiantly to expand the doctrine of *res ipsa loquitur* to cover an action against the bottler in a case where a carbonated beverage bottle exploded in a supermarket without any handling by plaintiff. He argued that the doctrine of *res ipsa loquitur* should not be considered to be a rigid technical doctrine, but that rather it should be as the New York courts had earlier said, "a common sense appraisal of circumstantial evidence." The appellate term of the Supreme Court, in a memorandum decision, disagreed.

The final case in this group illustrates how the same result might be reached without the help of *res ipsa loquitur.* This case is *Copher v. Barbee,* which was decided by the Springfield, Missouri Court of Appeals. The facts were somewhat unusual. Plaintiff went into a supermarket and walked toward the beverage rack in order to procure a bottle of strawberry soda. As she stood before the display, looking for her flavor, she heard a rolling on the floor. Looking down, she saw two bottles of the defendant bottler's product rolling toward her. No other customers, nor any employees of the store, were near the display. Plaintiff picked up one of these rolling bottles and returned it to the rack. Then, as she was bending to pick up the second rolling bottle, it exploded and she was injured.

On the bottler's appeal from a judgment from the plaintiff, the court pointed out that *res ipsa loquitur* is not available in Missouri in a case of this kind because the Missouri view is that exclusive control means physical control. However, the court went on to say that this would not prevent the plaintiff from making a submissible case of general negligence by circumstantial evidence. In order to accomplish this, plaintiff must show first, that the bottle was not damaged nor negligently handled after leaving the bottler's possession; and second, that the bottle had not been subjected by intermediate handlers to unusual temperature change. On the evidence of the handling by the retailer in this case, plaintiff failed on both counts. However, the same evidence was sufficient to sustain her action against the retailer.

Meat Issue

Of interest to those who are concerned with meats, the Pennsylvania Supreme Court decided an issue which it described as one of first impression in that jurisdiction. In *Adams v. Scheib,* the court laid down the rule that the warranty accompanying sales of fresh pork is that the pork will be fit to eat when properly cooked. This accords with the expanding majority view in this connection.

Privity of Contract

No report of this type would be complete without some discussion of privity of contract. In light of recent activities and the discussions we have here had with respect to the effort to convert warranty actions into tort actions, privity cases in 1962 are somewhat optimistic.

McBurnette v. Playground Equipment Corporation involved an injury to a child as a result of an alleged defect in some playground equipment which his father bought for him. In an action for breach of implied warranty, the Supreme Court of Florida held the child was entitled to recover. However, the court was very careful to point out that, except in cases involving foodstuffs, an action for breach of implied warranty may not be maintained against a retailer in the absence of privity of contract. The court went on to say that implied warranty is a matter of presumed intent. Hence, when one sells playground equipment suitable to be used only by a small child, the presumed intent is that the warranty will run to the child. Hence, the court fashioned its own privity to meet the facts of this particular case.

Pennsylvania has been heralded as a jurisdiction in which privity of contract has been abolished. However, the Court of Common Pleas for Allegheny County, in *Hochgertel v. Canada Dry Corp.* indicated that this proposition is subject to severe limitations. Plaintiff in that case was a bartender who was injured when a bottle of soda water, allegedly bottled by the defendant, exploded as he was serving a customer. The court said that in the absence of a showing of some contractual relationship, a person who is injured as a result of defendant's goods is limited to his remedy in trespass. "The remedy in assumpsit has been extended only to those cases where a person has been injured in cases of unwholesome food or other articles for human consumption." The court further pointed out that the Uniform Commercial Code was of no help to plaintiff because he was neither a purchaser, a member of the household of a purchaser, a guest of a purchaser nor a member of the family of a purchaser.

These latter two cases would seem to indicate a present disposition on the part of the courts of Florida and Pennsylvania to resist extension of the food exception to other products.

Advertising Warranty Concept

In another nonfood case, New York adopted the advertising warranty concept. This was the court of appeals case of *Randy Knitwear, Inc. v. American Cyanamid Company*, 14 NEGLIGENCE CASES (2d) 781, 11 N. Y. 2d 5, 181 N. E. 2d 399 (1962). There the court permitted an action by a clothing manufacturer against a supplier of an ingredient which had been sold to the textile manufacturer. The textiles thus made bore the defendant's label and tied in with his advertising that this ingredient which had been added to the material in its manufacture would prevent shrinkage. Plaintiff was allowed to recover commercial damage and loss of profits which were occasioned to him when the products which he manufactured out of the treated textiles suffered excessive shrinkage. Although the case marks a substantial step, it should not be confused with the implied warranty privity problem. The theory underlying these advertising warranty cases is that the advertising constitutes an express representation which is aimed directly at the class of persons of which the plaintiff is a member and seeks to induce them to purchase defendant's product.

There were two other warranty cases in 1962 which are of passing interest. *Rowe v. Oscar Ewing Distributing Company, Inc.* involved an injury which plaintiff suffered when a milk bottle collapsed in his hand as he was taking in his milk from the doorstep of the trailer in

which he lived. The Kentucky Court of Appeals held that his action for breach of warranty against the milk company must fail because there was no showing that there was a sale of the bottle. Since it appeared that the bottles were merely loaned to the plaintiff as an incident to the sale of milk, there was no warranty accompanying the bottle.

Kassouf v. Lee Brothers, Inc. involved worms in a candy bar. Plaintiff bought a candy bar from defendant, took it home and ate it without looking at it while she read a newspaper. From the beginning she noticed that the bar did not "taste just right," but it was not until she had eaten a third of it that she discovered worms crawling around inside. The sole issue raised by defendants on appeal in this warranty action concerned the refusal of the trial court to instruct the jury on the doctrine of contributory negligence. Quite properly, the California Court of Appeals held that contributory negligence is not a defense to an action for breach of implied warranty. It might be wise to insert a *caveat* at this point. This case should not be taken to mean that the defendant should not attempt or be permitted to show plaintiff's negligence. However, if the plaintiff has been negligent, contributory negligence, as such, should neither be pleaded nor argued. In a proper case, the defendant may still show that plaintiff's conduct was a superseding and hence the legal proximate cause of his injuries.

Cigarette Cancer Litigation

There remains to discuss two developments in the most interesting area of cigarette cancer litigation. The case of *Green v. American Tobacco Company* was an action to recover for the suffering and death of plaintiff's intestate. In the Federal District Court in Florida written interrogatories had been submitted to the jury, the responses to which indicated that the decedent had lung cancer which caused his death and that the smoking of defendant's cigarettes was the proximate cause or one of the proximate causes of the development of that cancer. In response to the final written interrogatory, the jury found that the defendant could not, on or prior to the date of the discovery of the cancer, by the reasonable application of human skill and foresight have known that users of [Brand X] cigarettes would be endangered, by the inhalation of the main stream smoke therefrom, of contracting cancer of the lung. The jury returned general verdicts for the defendant. On appeal, the Court of Appeals for the Fifth Circuit affirmed the judgment entered on these verdicts. It is im-

portant to note that this action was submitted to the jury on the question of breach of implied warranty. No question of lack of privity of contract was raised by the defendant. After reviewing the Florida cases on warranty (and it should be noted that Florida is a liberal jurisdiction in this area) the Court of Appeals concluded that "the defendant could not be held liable as an absolute insurer against consequences of which no developed skill and human foresight could afford knowledge." The court stated that implied warranties are founded on the presumed intention of the parties and the existence or nonexistence of an implied warranty of fitness for a particular purpose depends upon the reliance of the buyer. The buyer is presumed to rely upon the skill and judgment of the seller only when the seller is thought to have superior knowledge. In applying this principle, the court divided products for human consumption into three classes:

(1) Those believed by all to be wholesome, for examples, most foods;

(2) Those known by all to be injurious to some while perhaps beneficial or pleasurable to others, for example, alcoholic beverages;

(3) Those heretofore thought by all to be wholesome or tolerable, but which constantly expanding scientific research, thought and knowledge have now proved, or at least convinced many, to be injurious, such as cigarettes in the smoke of which appear polycyclic aromatic hydrocarbons and minute quantities of arsenic, and eggs, milk and butter with their high cholestrol content—and what the future may develop the most vivid imagination cannot foretell.

Applying this doctrine, the court concluded that there is no absolute liability imposed upon the seller under the first two classes unless the product contains a foreign substance, is spoiled or differs from what it is represented to be, because the buyer knows as much about the article as the seller and relies upon his own judgment. As to products in class 3, the doctrine leaves as a question of fact for the jury whether the seller, in the estimation of the parties, had superior knowledge to the buyer and hence, whether the buyer, at the time of the purchase, relied upon the seller. One judge dissented vigorously on the ground that warranty liability is absolute liability and that knowledge or lack of it on the part of the seller is immaterial.

There is a very provocative sequel to this decision. On a petition for rehearing, the Court of Appeals certified the question of the proper application of the Florida law to the Supreme Court of Florida. This was done under a Florida statute and the Florida Appellate Rules. It is my understanding that arguments will be heard in the Florida Supreme Court within a short time. Thus, we have litigation commenced in the Federal District Court and heard by the Federal

Court of Appeals which will ultimately be determined by the Supreme Court of Florida.

Pritchard Case

Some of you may remember our discussion here last year of the case of *Pritchard v. Liggett & Myers Tobacco Company* wherein the United States Court of Appeals for the Third Circuit held that plaintiff had stated a valid case of action in both warranty and negligence and remanded the cause for a new trial. You may recall, too, that in the first trial, the complaint had been dismissed insofar as it alleged breach of warranty at the conclusion of plaintiff's case, and a verdict had been directed for the defendant on the negligence cause of action at the conclusion of all the evidence. In 1962, this case was retried in the Federal District Court for the Western District of Pennsylvania. Pursuant to the direction of the Court of Appeals, the issues were submitted to the jury on written interrogatories. In response to those interrogatories the jury found the following:

1. The smoking of [Brand X] cigarettes by the plaintiff was the cause or one of the causes of cancer in his right lung.

2. The defendant is not chargeable with negligence.

3. The plaintiff gave notice of breach of warranty within a reasonable time.

4. The defendant did not make any express warranties upon which the plaintiff relied and by which he was induced to purchase [Brand X] cigarettes.

5. There was no breach of the warranty implied by law.

6. The plaintiff assumed the risk of injury by his smoking of [Brand X] cigarettes.

Commerce Clearing House, Inc. in its FOOD DRUG COSMETIC LAW REPORTS ¶ 22,725 has reported in full the charge of the court to the jury in the *Pritchard* case. I commend it to you for your interest and edification. In particular, I call your attention to that portion of the charge relating to implied warranties wherein the court said "this means that the goods must be reasonably wholesome or fit for the purpose for which they are sold, but such an implied warranty does not cover substances in the manufactured product, the harmful effects of which no human skill or foresight could afford knowledge." You will note that this language is substantially similar to that used by the Fifth Circuit Court of Appeals in determining the warranty issue in the *Green* case.

There were several other cases which might be discussed but which would serve principally to lengthen rather than to strengthen this report. Accordingly, I shall content myself to commend them to your leisure reading if your interest in this area is sufficiently keen.

Conclusion

All in all, the year 1962 did not produce any developments which should make the problems of food, drug and cosmetic industry lawyers any more difficult than they already are. Of course, the American Law Institute did approve Section 402A in its final form, and that section is now a part of the Restatement of Torts. This was accomplished over the feeble efforts of your speaker, who went to Washington in the name of this Section of the New York State Bar Association and pleaded that the Restatements live up to their name. In this connection, my only excuse for failure is that we were outmaneuvered on strange ground. There remains, of course, the solace to be taken from the fact that it is the courts, and not the American Law Institute, which make the law. The cases in 1962 which I have cited seem to indicate that the courts are not in any hurry to adopt the runaway strict liability which Section 402A solemnly pronounces to be the law. Many of these cases, quite to the contrary, suggest that the pendulum may be slowing down in its movement in that direction. Certainly, there are clear signs that the courts have not abandoned their policy of moving forward only so far as the case at bar requires. There is nothing in this year's batch of materials to suggest that the courts are prepared to abandon the whole concept of fault in one full swoop. Rather, one can take considerable comfort from the very cautious manner in which extensions of liability were made in 1962, and by the unwillingness of many of the courts to indulge in any extension at all. In my mind, the *McBurnette, Hochgertel, Green* and *Pritchard* cases all tend further to weaken the already sandy foundation upon which Section 402A rests.

This all suggests that constant vigilance and superior effort on the part of counsel for industry may yet prove the fallacy of the prediction which is the essence of Section 402A. **[The End]**

The Drug Amendments of 1962

By JOHN T. KELLY

The Author Is Legislative Counsel, Pharmaceutical Manufacturers Association.

YOUR CHAIRMAN, Franklin Depew, was kind enough to invite me to come here and speak on various problems confronting industry as the Food and Drug Administration goes about its implementation of the 1962 Drug Amendments Act. It is my pleasure to be here with you.

This measure, you will recall, passed in the last few days of the 87th Congress, was propelled by the emotional press blitz fired up by European tragedies attributed to thalidomide. It can be safely stated that it affects every segment and operation of the prescription drug industry. Moreover, while it ostensibly legislates in the public health area, it deals as well with various economic issues. It is the first comprehensive revision of federal drug laws in a quarter century, and gives very broad new powers to the FDA. Since many of its provisions, however, do not go into effect until May, 1963, industry is yet to feel its full impact.

Meanwhile, lawyers throughout industry are culling its every word—its legislative history—trying to find out what it means and how far it goes. It is by no means the most ideally drafted law. On the contrary, it is complex and in places quite vague. Additionally, these amendments thrust on an already overworked and understaffed FDA the task of issuing new regulations in at least nine and possibly as many as fourteen different areas. To date, only one set of these regulations has been issued. With its eyes focused on the calendar, industry has repeatedly offered to assist the agency in any way possible by providing information necessary for drafting sensible sound regulations. In fact, nine industry task forces were constituted to work with the FDA in such an effort. Unfortunately, it has not fully utilized the resources of these task forces, and we are deeply concerned that it will be acting on somewhat less than the full facts and information in drafting these new regulations.

But no matter how complex or vague this law may be, it is being prepared for enforcement, and I would like to point out to you some of the more important problems that are being encountered.

Standards of Current Good Manufacturing Practice

Under an amendment to Section 501(a)(2), the FDA proposes to define what, after May 1, 1963, shall constitute per se "current good manufacturing practice." The purpose of this provision is to assure the reliability and purity of drugs and it would be accomplished by establishing controls over all phases of drug manufacturing. As a consequence, drugs would be considered adulterated if they were manufactured under nonconforming methods or controls or in nonconforming facilities. They would, therefore, be subject to the traditional enforcement provisions of the Food, Drug and Cosmetic Act. We firmly believe, however, that minimum standards should be stated in sufficiently general terms so that responsible manufacturers can freely develop and modify their methods from time to time as indicated by experience and new ideas. Rigidly imposed government standards resistant to change would place a dead hand on the pace of manufacturing progress, whereas from such manufacturers' efforts, ultimately will evolve the best manufacturing practices. It is believed that a Pharmaceutical Manufacturers Association statement entitled "General Principles of Control of Quality in the Drug Industry" will be of material assistance to the agency in its drafting of new regulations under this Section.

Whether or not FDA's authority includes the right to determine personnel qualifications presents a related question. Recent FDA statements seem to imply that it does. Clearly, a claimed and asserted federal authority in this area has far-reaching consequences. For this reason, the FDA's decision is eagerly awaited.

Together with the manufacturers' registration and factory inspection provisions, this prescription of adequate manufacturing controls should be very helpful in reaching all persons who are putting substandard drugs on the market.

Factory Inspection and Registration

By amending Section 704(a), FDA's inspection authority over establishments in which prescription drugs are made, processed, packed or held has been very considerably broadened. The new authority extends to all things "bearing on violations of the Act."

Specifically mentioned are records, files, papers, processes, controls and facilities. Since data as to qualifications of technical and professional personnel are covered, this lends further credence to the view that FDA may indeed be interested in acting in this area under its manufacturing controls authority. Excluded from scrutiny in the interest of protecting a manufacturer's competitive position were such things as financial, sales (except shipment), pricing, research and general, nonscientific personnel data. Also exempt are pharmacies, practitioners and certain other groups.

A new Section 510 requires every person who owns or operates an establishment in which drugs are manufactured or processed to register annually with the Department of Health, Education and Welfare. This provision will assist FDA in identifying and inspecting all places where drugs are made and in bringing to bear the appropriate enforcement weapons of criminal proceedings, injunctions, or seizures against those who fail to register. Moreover, a related amendment characterizing drugs from nonregistered plants as misbranded gives the FDA still another legal basis on which to proceed.

The new factory inspection and registration provisions should also be considered together in another interesting way. Section 510, as we have previously noted, spells out the broad registration requirement for persons engaged in manufacturing, preparing, propogating, processing or repackaging "drugs." Section 201(g) defines "drugs" to include their components. Consequently, the potential number of registrants may be substantially more than the FDA could hope to inspect. This is an important factor since the law is clear that whatever plant is registered must also be inspected. Due to practical considerations, therefore the factory inspection authority may act as a limitation on the scope of the registration requirement.

Effectiveness

Under the 1938 Act, the new drug provisions in Section 505 required that a drug be shown to be safe before it was marketed, but it did not have to be proven effective. In making its judgment as to the drug's safety, however, the FDA did consider effectiveness. Now, the new law specifically conditions approval of a new drug application upon *substantial evidence* that such drug is effective for its claimed uses.

There is a widespread feeling that this "substantial evidence" test is going to prove to be one of the most difficult provisions of the new law to administer. It has application to both approval and with-

drawal situations. In applying it, the FDA inevitably will have to assume the role of final arbiter in conflicts of medical opinion on matters of safety and effectiveness, and such role obviously will have a real impact on physicians. For instance, in a recent news article Dr. Kelsey pointed out that "there will be difficulties in this. . . . Opinions vary. Will a drug be 'effective' if it helps only 5 per cent of the patients?"

The importance of this test to the public health, the practice of medicine and the development of new and improved drugs cannot be overstated. If clearance of new drugs becomes increasingly difficult to obtain, there will be an inevitable sapping of the incentive and initiative of those engaged in the costly and time consuming process of searching for and developing new drugs. The task of the FDA in applying this standard will not be an easy one. Its wisdom in applying it will be widely acclaimed.

The law provides for a two-year "grace period" during which a new drug now being commercially sold cannot be challenged or ordered off the market by the FDA on grounds of lack of substantial evidence of its effectiveness. Since old drugs are not specifically regulated by Section 505 they need only comply with the law's general provisions, unless changes are made in their previously approved labeling claims or directions for use, or unless other changes, such as might affect safety, places them in the new drug category.

Industry, however, has been deeply concerned by indications that the FDA would construe the submission of all amendments and supplements to an effective new drug application in such a way as to immediately open up the question of efficacy. Our feeling is that within the "grace period" this question cannot be raised by supplements or amendments involving only minor labeling or packaging changes, and having no relevancy to efficacy. Section 107(C)(3)(a) of the new Amendments clearly shows that the new efficacy requirements in revised Sections 201(p) and 505(b) apply only to changed uses or conditions of use.

Investigational Drugs

In addition to changes in the new drug section which I have just noted, particular attention should be paid to the subject of experimental drugs dealt with in revised Subsection 505(i) and new Subsection (j). These provisions concern adequate preclinical testing, agreements by investigators on supervision of clinical trials, record-keeping and reporting on investigational drug use, advice to and consent of patients, and records and reports on adverse effects at-

tributed to previously cleared new drugs. Certainly, the impact of such requirements cannot be minimized. In terms of future drug research and the number of persons affected, they involve not only our industry but the entire medical profession and public as well.

The foregoing observation is highlighted by the overwhelming proportion of critical comments from the medical and scientific community, generated by FDA's proposed clinical regulations. These proposals have been considerably and commendably modified in the final version, effective February 7, "to allow for flexibility in design and execution of investigational programs" while at the same time "imposing only necessary restrictions on the conduct of (such) research." It appears, however, that many scientists are not yet convinced that the latter objective has been attained. How well these regulations work out in practice remains to be seen.

Foreseeable problems may well arise from the provisions requiring manufacturers or sponsors to spell out suitable criteria for selection of clinical investigators, and such investigators in turn to list their qualifications for this type of work. If present fears are well founded and these requirements, in fact, represent an indirect attempt by government to establish research qualifications with resultant blacklisting, many responsible individuals may be driven out or choose never to enter the drug research field.

A related and legitimate complaint concerns the amount of paperwork required of both manufacturers and investigators. FDA views such reporting as reasonable, but in the eyes of industry and the scientific community, it may prove sufficiently excessive to drive researchers out of the field and hence curtail necessary efforts in the development of new drugs.

Patient Consent Provision

Finally, of particular interest to the legal profession is the patient consent provision. The exemption of experimental drugs from normal (regular) new drug clearance procedures is specifically conditioned upon manufacturers or sponsors requiring clinical investigators to certify that patients or their representatives will be informed of the experimental nature of drugs to be administered and their consent obtained to such use, except where the investigator deems it not feasible or in his professional judgment contrary to the best interests of his patient. The danger here is that many doctors might interpret this provision to mean that they may use experimental drugs in any

way they consider appropriate. Only too often, obtaining informed consent from the patient-subject has been considered by physicians and clinicians as evidence for defense in a possible future malpractice suit. Admitted the practice of medicine will always involve some element of experimentation, and experiments are essential for progress, but apparently only in rare cases where there is no acceptable current therapy. Constrictive applications of the new 1962 Amendments do not change the historic fact that legally, the physician continues to experiment at his own peril.

Labels, Labeling and Advertising

The provisions relating to labels, labeling and advertising involve matters of grave concern to industry. Moreover, at the moment they present the most acute problems. It should be recognized that their very presence in a public health law, in of itself, is somewhat incongruous. They involve issues basically, if not wholly, economic in character, having little relevancy to public health.

Additionally, in the case of labels and labeling, time is of the essence, for unless extended, the effective date of these provisions is May 1, 1963. Many firms now believe that it will be impossible for them to meet this deadline date. This flows from the fact that adequate lead time is essential for the supply, purchase and printing of orders that will have to be let. In the absence of definitive regulations, few, if any, firms will chance reprinting their labels and labeling in hopes that such can comply with forthcoming regulations. Too much is at stake. If they guessed wrong, their products would be misbranded and their firm's funds unwisely expended. Executives don't last long in the business world with decisions of this kind.

Most large firms estimate that the normal average course requires about nine months to effect changes on materials involving labels, literature and cartoons. Smaller firms will, of course, need less lead time. We are now well into the fourth month prior to May 1. Time is running swiftly against the deadline date.

You may be interested in the fact that one firm between October 1, 1961 and October 30, 1962 printed the following units at the approximate costs indicated:

Labels	198,473,490	$1,321,000.00
Literature	98,523,139	$ 411,000.00
Cartoons	65,925,000	$ 902,000.00

On a crash basis the costs for these units would have been much higher, as might well be the case for any firm placed in this position. Projecting these figures across the entire industry, unofficial estimates come to about 100 million dollars. Thus far, regulations have not been issued, and as you might expect, industry's uneasiness is growing daily. Because of the importance of labels, labeling and advertising, I would like to review the known changes brought about in each of the new Amendments. Regulations will of course be required to clarify many things now uncertain.

Labels

On prescription drugs, for human or veterinary use, the new law requires that the "established name" be printed in type at least half as large as the trademark or brand name (where a brand name is used). This also applies to each ingredient in these drugs. Consequently, the label must bear the name and quantity of all active ingredients, as required by present law plus that of any inactive ingredients. Where an ingredient has a brand name, its "established name" is to be in type at least half the size of the ingredients' brand name—not half the size of the product's brand name. The law gives FDA authority to promulgate regulations and provide exemption from some of these requirements where compliance is impracticable. A judicious use of exemptions will be needed to prevent some weird looking labels and results. As to multi-ingredient products which have only carried the brand name on the label, there exists a bright ray of hope that the FDA will exempt such products from the "established name" requirement.

Labeling

The term "labeling," as you will recall, includes brochures, package inserts, direct mail and the like. The new amendments require that the "established name" (that is, the official name designated by the government under the authority of the new Act, or the official title specified by an official compendium, if an official name has not been designated, or the common or usual name, if the drug or ingredient does not have an official name or title) of a prescription drug or active ingredient must be printed on labeling "prominently and in type at least half as large as that of the proprietary name or trademark." What this amendment means, therefore, is that a firm's labeling must carry the established name properly printed and placed.

I should like to point out that the law does not expressly state that each time the trademark appears the "established name" must

appear right behind it in half size type. An HEW explanatory memorandum states, however, that "the established name for the drug and for each such ingredient must appear, both on the label and labeling, wherever a brand name for the drug or ingredient appears, . . ." Should the final regulations specify an "each time" requirement, I am inclined to feel that it would provoke a law suit.

The primary function of a trademark is to identify a particular manufacturer's brand. Physicians have long associated the trademark with the manufacturer. It is wrong in principle to use the Food, Drug and Cosmetic Act to deprive drug manufacturers of normal trademark rights and thus reduce their incentive to strive for a degree of excellence surpassing the minimum statutory standards. Since physicians are well aware of the established name, it adds little to require a manufacturer to repeat it every time he mentions his own trademark.

Advertising

The new amendments transfer jurisdiction over medical advertisements of prescription drugs from the Federal Trade Commission to the FDA. They require that all such advertisements contain a true statement of (1) the "established name" as defined in Section 502(e), printed prominently and in type at least half as large as that used for the drugs' trade or brand name; (2) the formula showing quantitatively each ingredient of the drug to the extent required under Section 502(e); and (3) such other information in "brief summary" relating to side effects, contraindications, and effectiveness as FDA shall require by regulation.

The advertising provisions become effective May 1, 1963 for drugs on the market prior to October 10, 1962. For new drugs marketed after October 10, 1962, Items 1 and 2 thereof become effective immediately. Item 3 will take effect when regulations are issued, but this will likely mean at least four months from the time when FDA calls for hearings.

The character of the regulations will have an inevitable impact on the content of drug advertising. They can hurt journal advertising, but this need not be the case. The "brief summary" requirements covering side effects, contraindications and effectiveness will not stop manufacturers from advertising if the regulations are reasonable. But if they call for information which can't be placed in half, quarter or smaller size page ads, you can imagine the effect it will have on small manufacturers. It is entirely possible that such manufacturers would

have to turn to direct mail, sampling or detailing. The existence of many medical journals is also at stake. Their disappearance from the scene would be a tragedy and a severe blow to a necessary source of information on new research.

Conclusions

All aspects of this new law contain broad new powers for FDA, with corresponding awesome responsibilties. The implementing regulations can decide the future of this country's prescription drug industry. They can encourage an expanding research effort at home, or they can provoke a flight of research abroad. They can overregulate the already most highly regulated industry, or they can perpetuate and further stimulate sound competition. They can slow down the development and marketing of new drugs or they can provide physicians with more effective weapons to fight disease.

They can overwhelm industry with inordinate requests for reports and the government with their evaluation, or they can promote the cause of good management by industry and good administration by government. Computer analysis of reports, as Dr. Kelsey has suggested, may indeed be needed at the FDA, but unfortunately report making of the kind expected of industry and clinical investigations does not lend itself to machine production.

The new law also means that FDA's staff, facilities and organization must be strengthened if the Act is to work. Further success depends in large part on the wisdom of administration and interpretation of forecoming regulations. Industry wants this law to work, raising public health standards and insuring our country's present leadership in this field. If it doesn't, we all shall be faced with great difficulties, and it is hoped that those who supported its enactment will press just as vigorously for appropriate amendments.

[The End]

Some Problems of the Food Industry Under Federal Regulatory Statutes

By EDWARD BROWN WILLIAMS

This Paper Was Delivered at the Food Update 1963 Seminar Which Was Jointly Sponsored by The Food Law Institute and the Food Science Department, Rutgers University on February 12, 1963. Mr. Williams Is the Former Principal Attorney, United States Food and Drug Administration.

OUR SUBJECT IS FOOD. When, however, we scan the pyramiding regulatory measures which Congress in its traditional wisdom has provided for consumer protection, we frequently find that in some of its aspects the regulation of food is so intertwined with the regulation of drugs that we can't even intelligently discuss the regulation of one without talking about the regulation of the other.

It has always been a basic statutory tenet of the Federal Food, Drug and Cosmetic Act that a food may be a drug and a drug may be a food, depending upon the manner of its use and the claims made for it. There is nothing new about that and the overlap was not without practical precedent. Thus, before the enactment of the Food and Drugs Act of 1906, the United States Pharmacopoeia and the National Formulary listed a number of common foods in their monographs on drugs. Today raspberry juice, raspberry syrup, saccharin and lemon oil are recognized in the United States Pharmacopoeia as drugs, and lime, orange flower water and whiskey are recognized in the National Formulary. Despite the fact that rattlesnakes are listed in the Homeopathic Pharmacopoeia I am not prepared as an individual to recognize them either as foods or drugs. Nobody would think of treating these substances (leaving out the snakes) as drugs when they are sold for food use and there seems to have been no great problem resulting from their listing in the monographs of these so-called "official compendia."

Unfortunately, this relative simplicity of classification does not carry over into the structure of some of the provisions of the Food, Drug and Cosmetic Act which have been enacted in recent years. In this area we become all tied up in statutory concepts of such

vagary and uncertainty that it is easy to see why it is so frustrating for those who want to comply with the law to try to find out how to do it in a practical manner; and when we add to the conceptual aspects the government's pressure to extend the statutory provisions to include situations which the administrator thinks ought to be subject to legal sanction, even though they do not seem to be, our confusion is compounded.

The problem exists in varying degrees under the Federal Trade Commission Act, the Meat Inspection Act, the Poultry Products Inspection Act, and state statutes in the field of food and drug regulation. At the federal level, at least, it must often be faced against the background of jurisdictional conflicts between the several agencies involved and the provisions of the statutes which they administer. But the rapid expansion of the regulatory provisions of the Federal Food, Drug and Cosmetic Act has put that statute in a class by itself.

It may be observed that it is not entirely accurate to characterize the mix-up as one between foods and drugs alone. It involves each of those articles and chemicals generally, since chemicals are the root and fiber of both foods and drugs.

Authoritative Construction of Laws Needed

There is an obvious need for authoritative constructions of these laws. The pronounced tendency of the courts is to accept government's construction of the law because of alleged impingement of the food, drug or chemical upon matters of public health. Under such circumstances it requires not much imagination to divine why so many legitimate and serious legal questions are never tested by recourse of industry to the judicial system.

Some of my remarks are going to be critical of certain aspects of federal regulation of the food and drug industries. It seems appropriate also to make a preliminary reference to other current criticisms of food and drug regulation with specific reference to the Food and Drug Administration.

These other criticisms have come in large measure from Capitol Hill in Washington, emanating from that privileged citadel, the Congress, which has all along possessed the power to deal with administrative deficiencies through its legislative power and therefore can hardly be held entirely blameless for some of the administrative inadequacies which exist, particularly those traceable to lack of sufficient money to operate effectively.

We need not examine in detail the political mechanism which triggered the newly-developed enthusiasm for lashing out at individuals, policies and alleged failures of a dedicated federal administration. It seems not unfair to observe, however, that with the exception of committees of Congress which regularly deal with food and drug matters, a real congressional interest in FDA was notable primarily for its apparent absence until recent newsworthy developments seemed to lend a certain appeal to intervention in FDA affairs by some of our federal statesmen.

The critical analysis of FDA appearing in the recent report of the second Citizens Advisory Committee,[1] which was appointed by former Secretary Ribicoff to study and make recommendations on the operations of FDA, is of an entirely different character. It is clear both from that report and from industry experience that FDA has not coddled industry and that FDA officials have not been improperly or unduly chummy with industry representatives as some people seem to think. I believe that the comments to follow will bear out that statement.

Pesticide Chemicals Amendment

Consider first the Pesticide Chemicals Amendment to the Food, Drug and Cosmetic Act, which was enacted in 1954. It provides for the establishment by FDA of tolerances (and for certain exemptions from the requirement of tolerances) for residues of pesticide chemicals on raw agricultural commodities, when the chemicals have been registered under the Federal Insecticide, Fungicide and Rodenticide Act as useful economic poisons. The Insecticide Act is administered by the Department of Agriculture.

Pesticide chemicals are not foods as such but frequently, to the dismay of Miss Rachel Carlson, some of the residue from the chemical used on the raw agricultural commodity remains in or on the food when it is consumed in its raw state or even when the commodity is used in processing other foods. A pesticide residue, although it conforms to a tolerance established under the Pesticide Chemicals Amendment, is not by reason of that fact alone out of the regulatory woods. It may be a chemical preservative and it may be a food additive in a processed food made from the raw agricultural commodity.

[1] The October, 1962 FOOD DRUG COSMETIC LAW JOURNAL contains the full text of the report.

Under the Food, Drug and Cosmetic Act a food containing a chemical preservative must bear labeling stating that fact, with certain exceptions. By a process of reasoning with which some of us have never been able to make mental contact, FDA has insisted that, although an insecticide applied either before or after harvest or a fungicide applied before harvest, is not a chemical preservative, a *fungicide* applied *after* harvest *is* a chemical preservative. Until a modifying amendment to the statute was obtained, FDA wanted the chemical preservative label declaration to be placed, not only on the shipping container but also on fresh fruits and vegetables being displayed for sale in retail stores or on a placard placed in the immediate vicinity of the fruits and vegetables—all this despite the fact that the fungicide was cleared for safety and its residue limited by a tolerance established under the Pesticide Chemicals Amendment. The fact that the requirement was of dubious legal validity made a great impression upon the industries concerned, but nobody wanted to submit to legal action by FDA to vindicate his position, at the risk of proceedings in which there might be talk about the effect of the chemical on consumers, even though its use had been authorized by both the Department of Agriculture and FDA.

Pesticide Residues in Processed Foods

There is a somewhat different rule when the pesticide is carried into processed food. Then, it will not be deemed unsafe under the statute "if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity." But suppose that the commodity is apples which are dried, thereby increasing the concentration of the residue. In that case the chain of regulation would continue under another section of the statute, probably that dealing with food additives, which will be discussed later.

If the chemical used was a fungicide applied after harvest, the question arises, as I have indicated, whether the processed food will be required to bear a label declaration that it contains a chemical preservative. I anticipate that under some circumstances the contention will be made that it must, with what advantage to the public is not evident. Indeed, the utility to the consumer of many of the kind of interpretations of the law of which I have been talking is

unclear to me and I know to many others concerned. The expenditure of the time and resources devoted by both FDA and industry to the solution of matters of so little apparent import to the public seems difficult to justify, when judged in the light of the really serious and basic problems facing FDA and industry.

Legal and Administrative Maze

Let us now attempt to penetrate just a small segment of the truly formidable legal and administrative maze of FDA's world of food additives, antibiotics, color additives and food standards. Here we meet a series of marvelous and sometimes distressing concepts and requirements which have been created in part by the Congress and in part by administrative regulations and interpretations of the statute. In this remarkable administrative and legal structure there is not even a uniform method of establishing regulations which have the force and effect of law; nor is there consistency in the provisions for challenging in the courts the regulations which have been adopted by the agency.

The conditions of uncertainty and the interrelation of the provisions of the law and the regulations involved are a challenge to the ingenuity of the administrative agency, but they sometimes approach the shadowy status of a nightmare for those who are regulated. They say that all of this is delectable fare for the lawyers, but perhaps it is sometimes forgotten that conditions which may preclude turning out a successful job are not regarded with any more favor by the lawyer than by the client.

Example of Animal Feeds Cited

A striking example of the intricacies and hardships created by the present food and drug laws and regulations is readily at hand in the case of animal feeds, which of course are subject to regulation as foods under the Federal Food, Drug and Cosmetic Act.

The widespread use of antibiotics and other drugs in animal feed concentrates which go into the finished feed, is known to you. The bulk of manufactured feed now contains drugs in minute amounts for disease prevention and growth promotion. This, under the act makes the feed itself a drug. It may be a new drug and therefore subject to the premarketing clearance procedures of the new drug provisions of the Act, unless it is an antibiotic drug, in which event it may be subject to the provisions requiring certification of each batch of the

feed, if it is not exempted from certification by FDA. But if it is a certifiable antibiotic, it is not a new drug. Regardless of whether it is a new drug or an antibiotic, it may be a food additive and therefore subject to an entirely different premarketing clearance provision made applicable to food additives by the Food Additive Amendments of 1958.

Before the addition to the act of the Drug Amendments of 1962, only five antibiotics and their derivatives were subject to certification. Consequently, some antibiotics were new drugs—those not in the certifiable class—and others were not—the five which were certifiable. Some therefore passed through the new drug clearance procedure, others through the antibiotic certification procedure.

Here are some of the results, as described by Mr. D. L. Bruner, Executive Secretary of the Animal Health Institute, before the House Interstate Foreign Commerce Committee, on one of the bills which led to the Drug Amendments of 1962:

> One of the basic criteria for the clearance of a new drug application is the control commitments which will insure that the marketable finished dosage form would be identical to that which was tested clinically. This is justified in the case of human pharmaceuticals. However, this concept was carried over into drugs incorporated in animal feeds by requiring that each feed manufacturer submit and obtain an effective new drug application for his medicated feed. This over and above the requirement that the basic drug manufacturer establish the safety of the drug in the first instance. Thus, FDA saw fit to exercise controls going beyond the establishment of safety of drugs for use in animal feeds, a result which was never contemplated by Congress.

Now, suppose the feed contains an antibiotic which is certificable and is therefore not a new drug. Again I quote from the testimony:

> . . . once the safety and efficacy of an antibiotic drug intended for use in animal feeds has been established it would have been appropriate for FDA to have exempted such a use of these drugs from any further requirement of the antibiotic section [as FDA is authorized to do by law].
>
> However, following a line of reasoning similar to that adopted under the new drug section, the FDA actually promulgated regulations which on the one hand exempted these drugs from batch certification and on the other hand established conditions [upon the exemption] which served to control the ultimate use of such drugs in animal feeds, reaching as far as individual feed formulations.

Since any feed containing an antibiotic drug is subject to control as an antibiotic, the many feeds containing both certifiable antibiotic and other drugs, as well as the other drugs themselves, are subject to clearance and control under the antibiotic regulations.

The Food Additives Amendment, enacted in 1958 establishes an elaborate clearance procedure for substances added to food which, in terms of the largely subjective jurisdictional test adopted are not

"generally recognized as safe" by qualified experts for use in foods. Since an animal feed is a "food" under the act, the drugs used in feed are food additives which must run the gamut of the premarketing clearance procedure for such substances. Mr. Bruner and animal feed and drug manufacturers therefore were all duly horrified to find that yet a third obstacle had been created to the expeditious clearance of beneficent drugs in feeds.

A final quotation from the witness:

> . . ., animal drugs are subject to three separate statutory procedures, involving three separate regulatory divisions of FDA.
>
> The situation is further complicated by the fact that these sections of the law have differing provisions, are subject to differing interpretations, and the actions taken under one are not always consistent with the actions taken under the others . . .
>
> These regulations go beyond the establishment of the safety of drugs in animal feeds and actually undertake the policing of feed manufacturing industry practices.

Color Additives Interpretation

Mr. Bruner called this "triplification of controls." He did not mention what problems may have been added by the Color Additive Amendments of 1960, which establish other and further rules for the clearance of color additives for use in foods, drugs and cosmetics. A color additive is defined to include just about anything added or applied to a food, drug or cosmetic or the human body, which is "capable of imparting color thereto," unless FDA exempts it on the ground that it is used solely for a purpose other than coloring. Under this definition FDA proposes to interpret the statute to mean that:

> An ingredient of an animal feed which by its action through the biological process of the animal is capable of imparting color to the meat, milk or eggs of the animal, whether or not the ingredient has additional nutritional functions, is a color additive and is not exempt from the requirements of the statute.

FDA has already held that a xanthophyll product fed to chickens to add yellowness to portions of their anatomy and to the yolks of eggs produced by them, is a color additive. This must be upon the theory that the live fowl is a "food" under the act, a construction which could lead to some situations which would be as hilarious as they would be irksome, such as the seizure of a flock of chickens or of beef cattle on the hoof, because they contain a color additive which has not been listed by FDA for such use—let us say in the case of the chickens, corn or alfalfa which had been fed them to enhance the yellow color of their shanks or eggs. If a living beast is a food within

the meaning of the act it is subject to seizure as being adulterated if it "contains" an uncleared color additive. This result might conceivably shock the legislative committees who handled the color additive bills.

Revision Needed

I am not sure whether the time has yet arrived, but it seems apparent that in the course of the development of the federal food and drugs laws and regulations, it will become necessary in the interest of some kind of uniformity of administration of these laws and of predictability of their effect, that a basic revision be undertaken by Congress and the executive. It is not enough just to have laws, particularly when, in some of their more extreme aspects they have been hurriedly enacted on the heels of flamboyant and grossly exaggerated newspaper versions of the deficiencies of the then existing statutes—as occurred in the instance of the Drug Amendments of 1962. We do not yet know just how fortunate or unfortunate these *ad hoc* alleged cures for a situation which was to a large degree nonexistent may ultimately turn out to be.

In any event the day will come, I think, when there will be a revamping of the maze of federal food and drug laws and regulations. There are others yet to be enacted—for example, the cosmetic control legislation—and they can be counted upon to add not only to the need for a re-evaluation and revision of the whole poorly-meshing structure, but also to the frustration of those who are regulated. Perhaps the demand for this will come both from harrassed regulators as well as from the regulated.

Identity Standards

One of the troublesome aspects of food regulation, as it has developed in both federal and state jurisdictions, is the artificiality, as applied, of some of the prime concepts upon which such regulation relies. One of these concepts is that of identity. It has been applied in such a manner that the function and the actual nutritive character and qualities of acceptability of the food seem to be relegated to a place of secondary importance. Thus identity has become a vehicle for the invocation of the sanctions of enforcement, in some instances almost in the nature of a fetish.

One good example is a food which simulates another traditional product but is made from different materials. It must, in the view of FDA be labeled as an imitation and no amount of disclaimers on the

label that it is not the simulated food will satisfy enforcement officials. Nor does it matter that a coined name is used or that the food is just as good or better for the purposes for which it is sold as the traditional article. I have searched in vain for any substantive reason why a food which is honestly labeled and honestly sold for what it is, should be subjected to restrictions more onerous than those imposed upon its traditional counterpart. If it is fraudulently marketed and the passing off can be eliminated by a requirement that it be sold as an imitation, the requirement would be justified. This, indeed, is the approach once followed by FDA but it has been abandoned in favor of the technical and, to my way of thinking, superficial point of view which I have described.

Identity is a useful concept in food regulation, but it should I think be keyed more to function and performance than to tradition and words than it is today.

Both complexity and technicalities increase when we consider the area of food standards. Standards tie up a bunch of ingredients into a tight little bundle which is designated by an official name and any departure from the composition of the bundle stated in the standard is ground for enforcement action, if the officially adopted name is used or, even where a new or fanciful name is employed, if it can be said that the food "purports" to be that for which the standard was established. Again, it is immaterial what disclaimers may be included in the label.

At first FDA insisted that a departure from the standard banned the food from commerce even if it was designated as an imitation. The Supreme Court disagreed.[2] It is still FDA's view, however, in effect, that if the food is not an imitation and so labeled, it is banned from commerce if it contains an ingredient or ingredients not authorized by the standard, even though it is honestly marketed under a name other than that adopted in the standard. I am satisfied that this was not the intended effect of the legislation except in cases where it can be said that the article is sold *as* the standardized food.

Basic Purpose of the Statute Obscured

Here again, the formal concept of identity is permitted to obscure the *basic* purpose of the statute—to promote honesty and fair dealing —and the function and performance of the food seems to be ignored. It would not be so bad if standards constituted basic outlines of food

[2] *62 Cases of Jam v. United States,* 340 U. S. 593 (1951).

composition, but instead, they specify each ingredient down to the last pinch of salt.

The FDA concept of identity, as applied in the food standards field, which results in this detailed specification of ingredients, has also borne interesting progeny in the food additive and pesticide chemical operations of FDA.

It has been noted that a fungicide applied after harvest to inhibit deterioration of raw agricultural commodities is regarded by FDA as a chemical preservative whose presence must be declared on the label of the raw agricultural commodity and, presumably, under some circumstances, on the labels of foods processed from that commodity. If the processed food containing the pesticide residue is standardized, the same requirement of label declaration would be applicable. Yet no provision for the presence of pesticide residues is made in food standards and surely there is no intention that such residues shall be treated as ingredients for the purposes of standards. The result seems to be that, despite the insistence upon detailed specification of ingredients in formulation of food standard regulations, the pesticide residue would have to be declared as a chemical preservative under the official construction of one section of the law, although the same residue is not authorized as an ingredient in the food standard regulation.

Here again this logical dilemma would not be present were the notion of identity not carried so far as to demand that everything that goes into the standardized food must be singled out and approved by the regulation and that the slightest departure from the prescribed formula will result in an illegal product.

It is my understanding that the presence of an incidental additive in foods resulting from its use (in accordance with a regulation) as, for example, a container component or an equipment lubricant, is not regarded as excluded by definitions and standards of identity for such foods if the additive is in fact used for one or more of these purposes. Under such circumstances the additive is not regarded as an "ingredient" or "optional ingredient" for the purposes of the food standards provisions of the statute. This is obviously a practical and necessary rationale for a difficult legal and logical conceptual problem; but if the additive is a chemical preservative (as some post-harvest fungicidal residues are held to be) and must therefore be declared on the label, it is not apparent how the problem can be convincingly resolved without some kind of compromise with the strict idea of food identity which seems to be its principal root.

I am not forgetful of the formidable complex of legal tools with which FDA has been provided, particularly in recent years, and of the massive problems of administration which have resulted. I know that the Administration is trying hard and I applaud its achievements under sometimes exceedingly difficult conditions. I am forced to wonder, however, whether an excessive zeal for protection and preservation of concepts which antedated the new tools is not impairing their effectiveness and the ability of industry to use its developing technology in its own and the public interest. If, for example, an additive—even a direct additive—has been found to be safe and does not change the basic character of a food for which a standard has been established, it is difficult to see why the standard should not be sufficiently resilient to permit its use without resort to administrative proceedings for its amendment, which, if they reach the public hearing stage, may and probably will be costly and time-consuming—in some cases only because of a contest among competing suppliers rather than because of any basic public interest.

In the same direction perhaps more attention to the merits of the case would dictate a policy *against* overlapping food additive, new drug and antibiotic regulations, avoiding a multiplication of controls which seems to be without basic justification from the standpoint of the interest of industry and the public.

In *Fortune* magazine for February, 1963, there is an editorial which is of interest in this context. Application of the principle stated in the editorial is of broader significance than our problems under the laws regulating the food industry. It is nevertheless applicable in connection with the complexities and uncertainties of application of those laws and the broad discretion given to the administrative agency by their provisions. I quote the following excerpt:

> When government discretion is substituted for the rule of law, officials inevitably become entangled in the detailed activities of private individuals and organizations; confusion, suspicion, and a decrease of social energy are bound to follow from the confusion of responsibilities.

The regulation of the food industry is, of course, based upon a rule of law but the confusing nature of the law and the wide discretion given to its administrators, with the resultant unpredictability of application in many areas, create a truly basic and formidable problem for the regulated industries. This problem deserves continuing close attention and thought of government and industry alike.

[The End]

The Scientists' Forum

By BERNARD L. OSER

President and Director, Food and Drug Research Laboratories, Inc.

The Following Is a Report on the Seventh Session of the Joint Expert Committee on the Food and Agriculture Organization and the World Health Organization of the United Nations. Dr. Oser Is This Magazine's Scientific Editor.

THE SEVENTH SESSION of the Joint Expert Committee of the Food and Agriculture Organization and the World Health Organization of the United Nations met in Rome, February 18 to 25. The meeting was devoted to the establishment of specifications for identity and purity and to evaluating the available toxicological data in support of the safety-in-use, of a series of food additives, principally in the categories of emulsifiers, stabilizers and flour-bleaching and maturing agents.

The 12 members of the Expert Committee were drawn from Denmark, England, France, Germany, Netherlands and the United States; in addition, seven specialists served as consultants or observers. The Chairman of the Committee was Professor A. C. Frazer of the University of Birmingham, England, who has acted in this capacity at previous sessions, and the Vice-Chairman was Professor J. F. Reith of the University of Utrecht.

The technical information about which discussions were centered and decisions reached were obtained from industrial sources, as well as from the scientific literature. Prior to the meeting a list of substances selected for consideration by WHO and FAO was distributed to the committee members and to manufacturers in various countries, with the view toward assembling as much data as possible. Because of

the lack of adequate information concerning several of the additives (principally the absence of published toxicological reports) it was necessary to delete them from the list. However it is intended to evaluate them at a subsequent session of the Committee should adequate information be made available. The substances whose consideration was thus deferred included certain emulsifiers (sulphoacetate, phosphate and acetyl tartrate esters of mono- and di-glycerides), and flour oxidizing agents (nitrosyl chloride, acetone peroxide, calcium peroxide and ammonium persulfate).

Monographs describing the chemical identity, criteria for purity, assays, and toxicological evaluations (including ranges of conditional and unconditional acceptance for food use) were drafted for the following additives:

agar
alginic acid and alginates of ammonium, calcium, potassium and sodium
benzoyl peroxide
calcium acetate
calcium chloride
citrates of calcium, potassium and sodium
chlorine dioxide
methyl cellulose
mono- and di-glycerides
mono-, di-, and tri-phosphates
polyoxyethylene (8) and (40) stearates
polyoxyethylene (20) sorbitan laurate, palmitate, oleate, mono- and tristearate
potassium bromate
propylene glucol
sodium carboxymethylcellulose
sodium pyrophosphates
sodium tartrate and potassium sodium tartrate
sorbitan palmitate and mono- and tristearate
sorbitol

It should be noted that the foundation for these assessments by the Joint Expert Committee were laid at its Third and Sixth Sessions, held in 1959 and 1961, respectively. The report of the former session has been published in two parts by FAO under the general title "Specifications for the Identity and Purity of Food Additives, Part I: General Considerations; Part II: Provisional Specifications." It includes monographs on physical and chemical specifications for the following series of antimicrobial preservatives and antioxidants:

benzoic acid and sodium bonzoate
methyl, ethyl, and propyl p-hydroxybenzoates
calcium and sodium propionates
sorbic acid
sulfur dioxide
sodium and sodium-hydrogen sulfite
sodium metabisulfite
ethylene and propylene oxides
sodium diacetate
ascorbic acid and sodium ascorbate
isoascorbic acid and sodium isoascorbate
ascorbyl palmitate
butylated hydroxyanisole
butylated hydroxytoluene
nordihydroguaiaretic acid
propyl, octyl, and dodecyl gallates
alpha-tocopherol
mixed tocopherols concentrate
citric, tartaric and phosphoric acids

The toxicological evaluation of these substances was the subject of the Sixth Report of the Committee which was published recently

by WHO under the title "Evaluation of the Toxicity of the Number of Antimicrobials and Antioxidants." Barring unforeseen delays, it is hoped to issue the report of the Seventh Session before the middle of 1963.

These reports are available from the Columbia University Press, 2960 Broadway, New York, New York.

The Committee has recognized the need for reliable data from as many sources as possible and has particularly emphasized the importance of publication of toxicological evidence. Information of this kind which rests in company files, or is reported in obscure or difficultly accessible places (for example, in official transcripts of FDA hearings) contributes little toward the international recognition of the safety of food additives.

It is planned to convene the Eighth Session of the Joint Expert Committee early in 1964 when the subject will be the specifications and toxicological evaluation of color additives for food use.

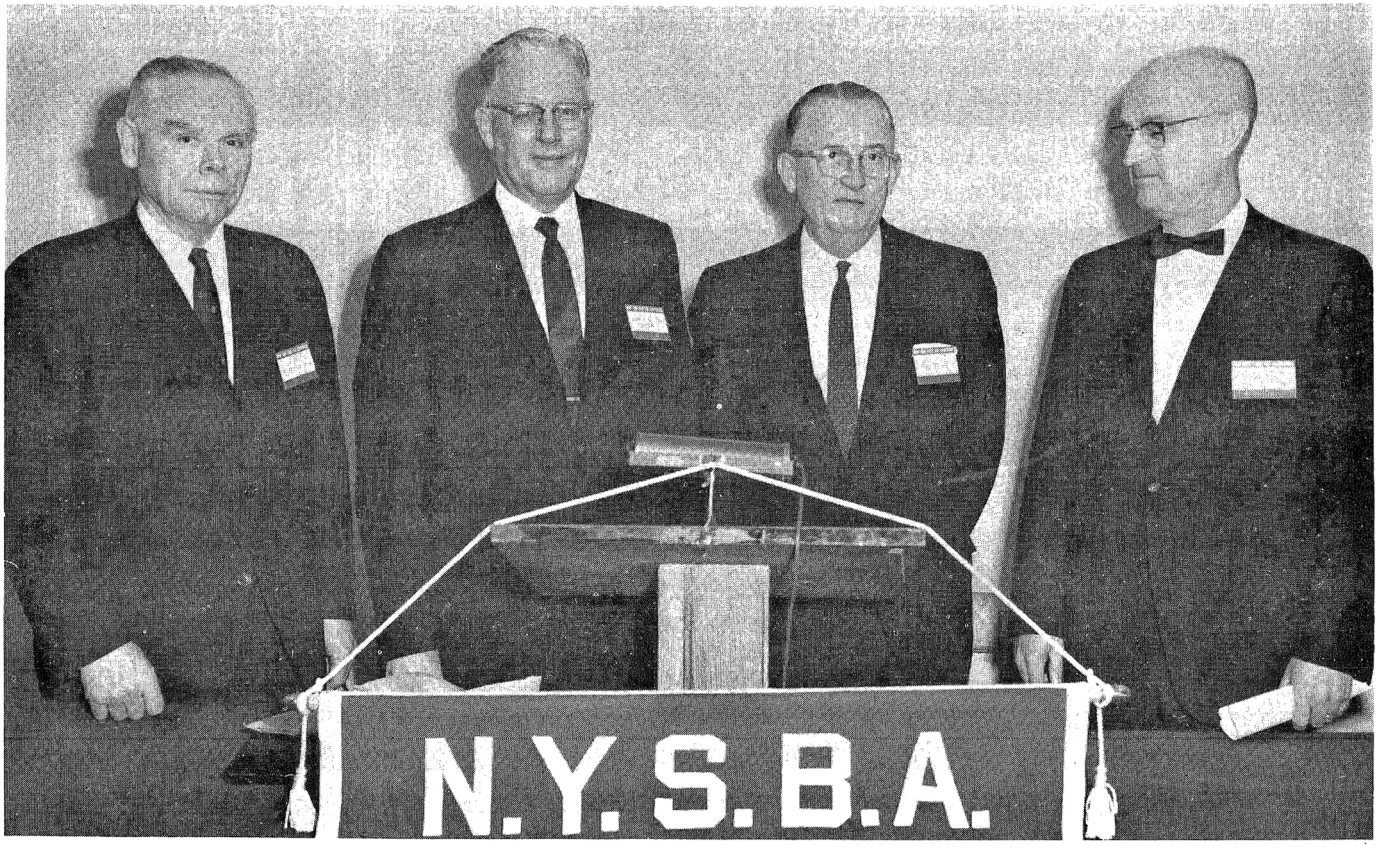
[The End]

PRESIDENT OF THE FOOD LAW INSTITUTE TO DELIVER CHARLES WESLEY DUNN LECTURE

Franklin M. Depew, President of The Food Law Institute, will deliver the Charles Wesley Dunn lecture on food and drug law at 11:15 a. m. on Thursday, April 4, in the Lecture Hall at the University of Southern California Law School. Mr. Depew will speak on "The Philosophy of Enforcement of the Federal Food, Drug and Cosmetic Act."

The Charles Wesley Dunn lectures are made possible through the generosity of the Pharmaceutical Manufacturers Association which has provided funds for this purpose at five American law schools. They were created in honor of the late Charles Wesley Dunn who was one of the founders and first president of The Food Law Institute, Inc., which sponsors research and education in food law at a number of law schools, schools of public health, and food science schools throughout the country.

The lecture is open to the public without charge.



Among those who participated in the eighteenth annual meeting of the New York Bar Association Section on Food, Drug and Cosmetic Law are the following (from left to right): **Everette MacIntyre,** member of the Federal Trade Commission; **Franklin M. Depew,** Chairman of the Section; **George P. Larrick,** Commissioner of Food and Drugs; and **Dr. M. R. Clarkson,** Associate Administrator, Agricultural Research Service, United States Department of Agriculture.

BUSINESS REPLY MAIL

No Postage Stamp Necessary if Mailed in the United States

POSTAGE WILL BE PAID BY—

CCH PRODUCTS COMPANY

4025 W. PETERSON AVE.

CHICAGO 46, ILL.

FOOD LAW

INSTITUTE SERIES

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.

ORDER CARD

Detach and Mail This Card Today
To Order Additional Books
For Your Food and Drug Law Library

CCH PRODUCTS COMPANY
4025 W. Peterson Ave.,
Chicago 46, Ill.

Send the copies of CCH books indicated below at prices quoted. (Remittance with order saves postage and packing charge.)

Fill in Amt.

1. ... General State Food and Drug Laws —Annotated (4436). Price: $17.50 a copy.
2. ... Constitutional Questions in Food and Drug Laws (0226). Prices: 1-4 copies, $3.50 ea.; 5-9, $3.20 ea.; 10-24, $3.00 ea.; 25-49, $2.80 ea.
3. Federal Food, Drug, and Cosmetic Act—Judicial and Administrative Record:
   ... 1938-1949 Edition (1446). Price: $17.50 a copy.
   ... 1949-1950 Edition (1329). Price: $10.25 a copy.
   ... 1951-1952 Edition (3228). Price: $12.00 a copy.
   ... 1953-1957 Edition (8224). Price: $25.00 a copy.
   ... 1958-1960 Edition (2233). Price: $17.50
4. ... Legislative Record of 1958 Food Additives Amendment (8445). Prices: 1-4 copies, $3 ea.; 5-9, $2.70 ea.; 10-24, $2.40 ea.; 25-49, $2 ea.
5. ... Product Liability Cases (4118). Price: $12 a copy.
6. ... Canada's Food and Drug Laws (3334). Price: $19.50 a copy.

☐ Remittance herewith ☐ Send bill

Signature & Title .....

Firm .....

Attention .....

Number & Street .....

City, Zone & State .....

(If ordering by letter or purchase order, please attach this card for our records.)

4436—313

Use This Check List to Add to Your Permanent Food and Drug Law Library

Wherever things happen of importance to Food and Drug Men, you'll find CCH there with handy desk helps on food, drug and cosmetic law. Each of these books was written by an outstanding authority in the field and published by Commerce Clearing House, Inc., for The Food Law Institute. They serve as a chronicle of the development of food law, including the associated drug and cosmetic laws; provide an adequate library for everyone concerned.

Some BOOKS IN THE FOOD LAW INSTITUTE SERIES:*

- ✓ General State Food and Drug Laws—Annotated, by David H. Vernon and Franklin M. Depew. Table of contents; 816 pages. Price: $17.50 a copy.
- ✓ Constitutional Questions in Food and Drug Laws, by Thomas W. Christopher. Topical index; 128 pages, 6" x 9", heavy paper covers. Price: $3.50 a copy.
- ✓ Federal Food, Drug, and Cosmetic Act—Judicial and Administrative Record. All these publications include indexes and case tables.
  - 1958-1960, (Kleinfeld & Kaplan), 528 pages. Price: $17.50 a copy.
  - 1953-1957, (Kleinfeld & Dunn), 1,444 pages. Price: $25.00 a copy.
  - 1951-1952, (Kleinfeld & Dunn), 588 pages. Price: $12.00 a copy.
  - 1949-1950, (Kleinfeld & Dunn), 543 pages. Price: $10.25 a copy.
  - 1938-1949, (Kleinfeld & Dunn), 922 pages. Price: $17.50 a copy.
- ✓ Legislative Record of 1958 Food Additives Amendment to Federal Food, Drug, and Cosmetic Act. Topical index; 160 pages, 6" x 9", heavy paper covers. Price: $3 a copy.
- ✓ Product Liability Cases, by Frank T. Dierson and Charles Wesley Dunn. Table of contents; 1,182 pages. Price: $12 a copy.
- ✓ Canada's Food and Drug Laws, by Robert E. Curran, Q. C. Topical index, case table; 1,138 pages. Price: $19.50 a copy.

** Unless otherwise noted, books come in hard bound covers, red and black with gold stamping, size 6⅝ x 9⅞ inches.*

YOURS—FOR 15 DAYS' FREE EXAMINATION

Any of these authoritative books can be yours for 15 days' free examination. Just fill out the handy tear-off Order Card at the right. If not completely satisfied after looking them over, return the books for full credit.

CCH PRODUCTS COMPANY

4025 W. PETERSON AVE., CHICAGO 46, ILL.

A COMMERCE CLEARING HOUSE PUBLICATION