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Food Drug Cosmetic Law JOURNAL

Papers Presented at the Seventeenth Annual Meeting of the New York Bar Association Section on Food, Drug and Cosmetic Law on January 24, 1962

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

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REPORTS

TO THE READER

About This Issue.—The seventeenth annual meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association was held January 24 at the Commodore Hotel in New York City. *Franklin M. Depew,* Chairman of the Section presided at the meeting. Following is his introductory statement:

"I am happy to welcome all of you to the Seventeenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association. I hope you like our new meeting place, the Commodore Hotel, and that you will enjoy our informal luncheon. We will have as our honored guests at this luncheon, in addition to our speakers of this morning, *Honorable J. Boyd Mullan,* President of our Association, and *William Roy Vallance,* Secretary-General of the Inter-American Bar Association.

"Because of our full program we are convening at 9:30 so that we will have time to hear our speakers, question them, hold our business meeting and adjourn not later than 4 p.m.

"Our program today consists of ten timely papers of important interest to those attorneys practicing in the field of food, drug and cosmetic law. I am confident that you will find these papers and the subsequent discussion most helpful in advising your clients. Some problems may even be resolved in your minds after hearing them, but I do not promise this. It was my privilege to present a paper at the first meeting of this Section entitled "The Slack-Filled Package Law." The problems discussed in that paper still continue unsolved and vex the Food and Drug Administration and industry sixteen years later.

"On behalf of our entire membership I wish to express our appreciation to our speakers for giving of their valuable time to prepare and present these papers to us. Before introducing them I would like to make a few brief comments on developments since our last meeting. At that time the effective date of the food additives amendment was rapidly approaching, and we all knew it would be impossible to secure food additive orders for all needed substances in time. A resolution was adopted by the Section that a committee be appointed to collaborate with representatives of the FDA relative to suitable amendments to the extension bill. In accordance with the resolution I appointed a Committee consisting of *Michael F. Markel,* Chairman, *Kenneth E. Mulford,* and *Frank T. Dierson.* FDA representatives gave sympathetic consideration to the recommendations of this Committee with the result that a satisfactory extension law was passed. This action was in accordance with the tradition of FDA. Its staff has been quite consistent in acting in the public interest to protect the public health and other consumer interests but with a reasonable regard

for procedures that are fair to those whom they affect.

"If the FDA is to continue to properly carry on its multiple duties, which are growing greater with each passing day, it needs to fill new positions with competent and devoted people. To do this it needs increased budgets. This Section and our American Bar counterpart have always advocated increases in the budget that are adequate to enable FDA to fulfill its obligations. Despite the hope expressed last year by our Chairman, *A. M. Gilbert*, that the Congress would not cut the President's budget request, it was subsequently cut from $23,580,000 to $23,000.000. I am sure we all hope that the President's budget request for the fiscal year 1963, which calls for $28,400,000, an increase of almost 25 per cent, will not be cut this year.

"A new Citizens Advisory Committee has been appointed and may be expected to make its report to the Secretary later this year. It seems to me that among important considerations this Section can urge upon this Committee are that the Committee should recommend (1) that the traditional FDA policy of adhering to the career system be maintained, (2) that adequate funds be made available to the agency and (3) that the agency expand its educational and informational program. The carrying out of such recommendations would represent a contribution toward the solution of many current problems of the consumer and industry.

"This year another law may be expected to go into effect shortly after we adjourn. The Federal Hazardous Substances Labeling Act will become effective on February 1, 1962. The promulgation of regulations under this Act has not been without controversy, and industry has felt that more time was needed to comply with them. FDA has recognized the problem to the extent they have found that more time is necessary for full compliance with the regulation's requirements with respect to the main panel placement and increased conspicuousness and contrast. The parts of the regulations covering these subjects have been suspended until August 1, 1962. I believe we can expect our speakers from FDA to give us their latest thinking in regard to this law."

This month's JOURNAL presents five of the papers that were delivered at the meeting. Two papers from the meeting were included in last month's magazine.

The chief attorney in the New York office of the Federal Trade Commission, *Albert G. Seidman,* presents an interesting and timely summary of the FTC's actions in the past year in an article which begins on page 181.

Six laws under which the food inspection services are administered are discussed in an article aimed mainly at the meat inspection division and other mandatory inspection services which appears at page 188. *M. R. Clarkson,* associate administrator of the Agricultural Research Service of the Department of Agriculture feels that inspection must be "tandem—not random."

William J. Condon, an attorney for Swift & Company, discusses developments in the field of product liability, including cases concerning foods, beverages, bottles, drugs and cosmetics. It appears on page 195.

Suggestions for amendments to strengthen the factory inspection law's power both from the standpoint of enforcement and from the standpoint of constitutionality are found in a paper by *Samuel McCain,* Vice President and of Counsel, Corn Products Company.

The Uniform State Food, Drug and Cosmetic Bill is "the cornerstone of any effort to promote uniformity of interpretation, administration and enforcement of food and drug law at the state and local level." A report on the revision of this bill is found on page 218 in an article by *O. J. Wiemann,* chairman of the Association of Food and Drug Officials' committee on this subject.

Vol. 17, No. 3 March, 1962

Food·Drug·Cosmetic Law
Journal

What's New—What's on Top at the Federal Trade Commission?

By ALBERT G. SEIDMAN

The Author Is the Chief Attorney in the New York Office of the Federal Trade Commission. This Address Was Presented Before the New York State Bar Association, Food, Drug and Cosmetic Section at the Hotel Commodore in New York City on January 24, 1962.

YOUR CHAIRMAN has asked "What's new—what's on top—at the Federal Trade Commission?"

Perhaps the major item of news since your last annual meeting is "Who's on top." This past year has seen the appointment by President Kennedy of a new chairman, the Honorable Paul Rand Dixon, and the naming of the Honorable Philip Elman and the Honorable A. Everette MacIntyre to fill two additional vacancies on the commission.

Under the vigorous leadership of Chairman Dixon, the commission has directed a substantial part of its efforts towards the reduction of the "regulatory lag" to the minimum consistent with the observance of due process. It has approached this task with boldness and imagination in the revised Rules of Practice. The major changes in procedure are:

(1) Before a formal complaint is served, a copy of the proposed complaint and order are mailed to the respondent. It is given ten

days within which to indicate its willingness to enter into negotiations for a consent settlement. If respondent so indicates, it has 30 days within which to negotiate such settlement with a special division to the Office of the General Counsel established for that purpose.

Should respondent be unwilling to negotiate or should the negotiations fail to produce an acceptable agreement within the prescribed time limit, the privilege of such a consent settlement, embodying no admission by respondent that it has committed acts in violation of law, will be withdrawn.

Should a consent settlement be reached, there will be but one public announcement of the proceeding, thus saving respondent from a succession of press releases relating to the service of a complaint, the filing of an answer, hearings, if any, the initial decision of the hearing examiner and the ultimate order of the commission. The new procedure will also avoid the assignment of a hearing examiner to the proceeding and his participation in the negotiations for consent settlement. It will deter respondents from interposing answers and allowing hearings to be scheduled and held merely to gain time, since once a complaint has been served any order will embody findings of violation of law. This fact, as well as the saving in procedural steps, will produce an effective and enforceable order at a much earlier date than under the old rules.

(2) In proceedings where issue has been joined, the new rules provide for the hearing to be held at one central location and in a continuous manner, the same as in a court of law. The trial attorney in support of the complaint must be prepared to present his case at one time, and respondent's counsel will be required to immediately proceed upon completion of the government's case. Appropriate pretrial procedures have been established to protect both counsel and avoid the necessity for requesting adjournments in order to prepare for cross-examination or based upon a plea of surprise.

Thus, you can no longer anticipate leisurely transcontinental tours with frequent and prolonged adjournments to suit the convenience of the hearing examiner, counsel on both sides, witnesses and the respondent itself. The saving in time and expense to both the government and respondents will be substantial and, of even greater importance, illegal practices will be inhibited more expeditiously.

Organization Revision

The organizational structure of the staff has been revised in an effort to more efficiently accomplish the commission's objectives. The commission is also taking advantage of the Reorganization Plan promulgated by President Kennedy in delegating some of its administrative functions to members of its staff. In the coming year there may be further changes for the commission as constituted at present is determined to fulfill its statutory obligation to protect business and the public from unfair methods of competition and unfair or deceptive acts or practices in commerce.

Despite the fact that so much of the commission's attention has been focused upon an over-all revision of procedures and organizational structure, transgressions in the food, drug and cosmetic industries, with which you are especially concerned, have not gone unnoticed. In fact, in August, the commission served orders pursuant to Section 6 of the Federal Trade Commission Act upon 37 major manufacturers and distributors of prescription drugs. The information sought by the special reports required will, among other things, reveal advertising which makes exaggerated claims of therapeutic benefits or fails to adequately disclose side effects. Should any of your clients be the recipient of such order and have any hesitancy in complying, I respectfully suggest that you call their attention to the recent decision of the Supreme Court in *St. Regis Paper Company v. United States,* as well as the earlier decision in the Court of Appeals for the Second Circuit.

FTC Proceedings

During the past year proceedings involving foods, drugs, cosmetics and therapeutic devices followed the more or less traditional pattern. There were three orders to cease and desist issued against manufacturers or distributors of vitamin preparation. The orders inhibited representations that the products were of benefit in the treatment of fatigue, restlessness, irritability, or loss of appetite, except in the small minority of cases resulting from established deficiencies in nutrients supplied by the advertised products. They also prevented misrepresentations as to the products having any value in the treatment of cardiac or liver conditions or in lowering the cholesterol level of the blood. Fictitious price saving claims and deceptive offers of "free" goods were also covered by the orders.

In the same category is the order issued against Carlson Pharmaceuticals, Inc. (D. 8432) relating to "Arthrite" capsules. The manufacturer was ordered to cease and desist from representing that they were an adequate, effective and reliable treatment and will arrest, correct and cure all kinds of arthritis and rheumatism, that they afford immediate, complete and permanent relief of their symptoms and manifestations and that they contain sleep-inducing ingredients. The product contained vitamins, minerals and extract of alfalfa of no therapeutic value in the treatment of arthritis, rheumatism or their symptoms.

A product supplying calcium and iodine was represented as being beneficial in treating blindness, arthritis, rheumatism, constipation, indigestion, weakness, nervousness, insomnia, depression and aches and pains. Its distributor entered into a consent order under the new rules.

Two manufacturers and distributors of sedatives containing ingredients dangerous when taken by some individuals were ordered to stop representing their products "harmless," "safe" or "new medical or scientific discoveries." Another offered a preparation containing the emetic Syrup of Ipecac as a new discovery in the treatment of alcoholism that would not interfere with a normal social life. Its effect was to produce violent nausea and vomiting when alcohol was imbibed, an effect hardly likely to enhance one's social standing or to make him the life of the party. An order was issued.

Finally, there was "Livigen," "a super-powerful skin food concentrate" providing "natural nourishment to undernourished skins" guaranteeing youthful-looking beauty. The commission failed to find any beneficial results from its application.

In two proceedings the commission found that manufacturers and distributors of drugs did not exercise "quality control" of their products as claimed in advertisements. The advertisements gave rise to the false implication that respondents possessed laboratory facilities and a technical staff enabling them to routinely assay qualitatively and quantitatively all preparations.

Public preoccupation with obesity has always attracted the interest of promoters. During the past year orders were issued against two distributors of vibrators and vibrating furniture for misrepresenting their products as helping to reduce weight and restore muscle tone. The most interesting proceeding was that against

Baker's Franchise Corporation. It had licensed 110 bakeries in 42 states and Canada to market "Lite Diet" bread. In four and one-half years it spent $2.5 million in advertising employing such statements as "It could help you control your weight," and "Who'd ever think such delicious bread could help you keep slim."

The bread contained 45 calories per slice of 17 grams. Ordinary enriched white bread contains 62 calories per slice of 23 grams. Thus, the lower calorie content was the result of slicing the bread a little thinner than usual. Writing for the full commission, Commissioner Secrest said:

> Of course, this is much the same as saying a small pat of butter has less calories than a large pat or that a thin slice of pie has less calories than a thick one. . . .
>
> There is no panacea or magic shrinking potion tasting like . . . "mixed flavor of cherry tart, custard, pineapple, roast turkey, toffee and hot buttered toast" such as Alice found in the Never-Never Land of Lewis Carroll's imagination. To become thin or stay thin in this practical world, one must consume a true light diet. Respondent's bread is neither more nor less suited to be an ingredient of a light diet than any other equally enriched bread and respondent's representations to the contrary constitute "false advertising."

The commission's order not only inhibited representations of lower caloric content or less fattening but directed that respondent no longer use the words "Lite Diet" as a trade name.

The so called "orthopedic" shoe which offers only comfort was also the subject of corrective action. Even the molded or "space shoe" was found to have no therapeutic qualities other than to give relief from pains and disorders caused by ill-fitting shoes. The commission specifically found false representations that they will correct, prevent or relieve arthritis or high blood pressure.

Distributors of contact lenses have continued to misrepresent an admittedly useful product. Orders have been issued forbidding representations that they can be worn all day in complete comfort, can be successfully worn by everyone, will correct all defects in vision and will permit all users to discard their eyeglasses.

Manufacturers of trusses have likewise sought to give extra support to their sales efforts by exaggerating the support given by their respective products. The commission has repeatedly held that trusses will retain and hold only reducible hernias, that they will not cure ruptures, are not more effective than surgery, will not cause tissue to form nor restore the hernial ring to its normal status nor will they hold ruptures or hernias under all conditions of activity and strain.

There have been the usual number of orders forbidding misrepresentation of price and foreign origin of perfume. The new twist has been the rebottling of cologne in one dram bottles similar to traditional perfume bottles. These have been enclosed in cartons bearing the name of a well known perfume. Exorbitant profits were made by selling the cologne for $1, the consumer being led to believe she was getting $10 worth of perfume. The commission issued orders prohibiting such deception in two proceedings.

Television Commercials

Public interest seems to have been particularly stirred by commission proceedings involving rigged television commercials. Mennen attempted to visually demonstrate the superiority of its "Sof Stroke" shaving cream by having a skin diver perform the "cream richness test" under water. A leading competitive brand quickly dissolved but the "Sof Stroke," actually a judicious mixture of shaving cream and toothpaste, adhered to the skin diver's face.

The television commercial for "Rise" shaving cream also took a fall. Ordinary shaving cream was depicted by a specially prepared mixture of 90 per cent water and 10 per cent "ultra-wet 60L," a foaming agent. It contained no soap or fatty acid salts usually found in shaving cream lathers. Naturally, it disappeared rapidly and appeared to dry out immediately upon application to the face of the actor. So, too, did the commercial after the commission's "hand was on respondent's shoulder."

Finally, we have the recent order in the Colgate-Palmolive case. I recommend that you carefully read the opinion of Commissioner Elman. You no doubt recall the advertisement for "Palmolive Rapid Shave" in which the picture shows the product applied to sandpaper, immediately followed by shots of a razor shaving a clean path through the lather and gritty surface of the sandpaper. The audio accompaniment stated, "To prove Rapid Shave's super moisturizing power, we put it right from the can onto this tough, dry sandpaper. It was apply . . . soak . . . and off in a stroke. . . . In this sandpaper test . . . or on your sandpaper beard, you just apply Rapid Shave . . . then . . . take your razor . . . and shave clean with a fast, smooth stroke."

Actually, what was represented as sandpaper was a mock-up of plexiglass to which sand had been applied. It was found as a fact that

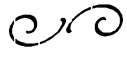
sandpaper of the coarse variety depicted not only could not be successfully shaved in the abbreviated time available during the commercial, but could not be shaved genuinely clean despite the allowance of up to an hour for soaking. I particularly call your attention to this statement in the opinion:

> As to the asserted technical limitations of the medium, the commission is inclined to be somewhat skeptical. . . . However, assuming it to be the fact that there are indeed such limitations in television photography, the Commission can appreciate that these "technical" difficulties could give rise to problems for sponsors and agencies in determining how most effectively to use television in advertising their products. The limitations of the medium may present a challenge to the creative ingenuity and resourcefulness of copywriters; but surely they could not constitute lawful justification for resort to falsehoods and deception of the public. The argument to the contrary would seem to be based on the wholly untenable assumption that the primary or dominant function of television is to sell goods and that the Commission should not make any ruling which would impair the ability of sponsors and agencies to use television with maximum effectiveness as a sales or advertising medium.

The commission is well aware of the vital role of advertising in the development of our free enterprise competitive economy. Does this justify copywriters exercising their imagination unfettered by the truth? Surely with respect to food, drugs and cosmetics the protection of the physical well-being of the public would seem to impose an essential obligation upon advertisers, and you who counsel them, not to mislead and deceive.

Important as is the physical health of the public, there is far more at stake. Faith in the essential honesty and decency of our fellow beings is the very cornerstone of our economic, social and political freedom. We cannot accelerate the growth rate of our economy by introducing the carcinogenic agent of fraud and deceit. It can only stimulate the spread of a malignancy which in metastasizing will ultimately destroy the body economic.

Let me urge that as members of the food, drug and cosmetic bar you fulfill your responsibility as counsellors as well as advocates to the end that your clients lend strength to the moral and ethical fibre of our economy. **[The End]**



Food Laws and the Department of Agriculture

By M. R. CLARKSON

The Author Is Associate Administrator, Agricultural Research Service, United States Department of Agriculture. This Speech Was Presented to the Food, Drug, and Cosmetic Law Section of the New York State Bar Association on January 24, 1962.

JUSTICE HOLMES once said, "The life of the law has not been logic: it has been experience." I would suggest that the development of the food law activities of the Department of Agriculture grew out of the wisdom of experience of the American people, for surely we enjoy the safest, the most wholesome and plentiful supply of high quality food of any country in the world.

I am limiting my discussion to comments on six laws—laws concerned with the wholesomeness of food—the laws under which our food inspection services are administered.

I shall direct most of my remarks to activities of the Meat Inspection Division and other mandatory inspection services. These services are covered by five of the six laws on my list.

However, before turning to these laws, I shall review briefly the voluntary inspection services covered by the sixth law—the Agricultural Marketing Act of 1946.

The difficulties that this act was designed to correct began to rise about 75 years ago. They were closely tied in with long-distance shipments of fresh fruits and vegetables under refrigeration. You might say they came in with the man-made "Ice Age."

Voluntary Inspection

At the beginning of this century, transcontinental shipments of fresh produce, particularly fruits and vegetables, had become commonplace. But administrative machinery for handling these shipments

lagged far behind the transportation system that moved them from coast to coast.

There were no nationally recognized grades and standards for measuring quality, for making contracts, or for settling disputes and claims.

The transactions had become a game of chance for both shipper and buyer. And as time went on, the market became chaotic.

The first attempt to deal with the problem at the national level was made in 1913. Congress directed the Secretary of Agriculture to set up a widespread educational program on marketing practices. This stimulated the investigations in department research that led to the development of United States grades and standards for agricultural commodities in commerce.

The machinery for voluntary inspection began to take shape during that same period. The Food Production Act of 1917 authorized the Secretary of Agriculture to investigate the condition of products—fresh fruits and vegetables—as they were received at markets. He was authorized to certify the condition of the products and to designate the markets where certification would be made.

Next the service was extended to cover inspection at shipping points as well as at terminal markets. And as grades and standards were established, inspectors checked quality along with condition of products.

The inspection service at shipping points evolved into a cooperative federal-state enterprise. It is administered in most states jointly by the United States Department of Agriculture and a state agency—usually the state department of agriculture.

The inspectors, as a rule, are local men, recruited and paid by the state agency. The federal role is that of training and licensing the inspectors and issuing the certificates. The operation is financed by inspection fees paid by shippers, handlers and processors. In general, these activities are administered by the Agricultural Marketing Service with only a few handled by the Agricultural Research Service.

The Agricultural Marketing Act of 1946 placed the machinery—built up through the years—on a firm, legal base. It gave the Secretary of Agriculture broad powers to develop, establish and administer standards for farm products.

Last year about half of the fruits and vegetables eaten in the United States were graded in this voluntary inspection program.

Now a point to keep in mind about this service is that it is designed primarily to build confidence in the market . . . through better products for the consumer, more stable business for wholesalers and retailers and more sales for growers.

The Food and Drug Administration has general responsibility for the wholesomeness of these products. The Department of Agriculture makes every effort to give meaning to the requirements of FDA through the voluntary inspection programs to improve the quality of foods.

Mandatory Inspection

Turning next to mandatory inspection, I shall comment first on three laws that are rather limited in scope.

Two of them set up export standards for specified fruits. The act establishing these standards for apples and pears was passed in 1933, that for grapes and plums in 1960. These food laws were designed to build confidence abroad in the quality of our exports and to strengthen the demand for these products.

The laws make it an offense to ship the specified fruits abroad without inspection and proper certification. The carrier is required to hold the certificate for a shipment on file for three years. Prosecutions under these acts are handled by the United States attorneys in the districts where the cases arise.

The fruit industry helps the government enforce these acts and compliance is good. The cases that do come up usually arise in this fashion. An industry representative on a market tour abroad will bear a buyer's complaint about poor quality fruit. He reports the complaint to us. We turn the action over to the United States attorney when we find the shipment has not been inspected and properly certified.

A third law—among the five requiring mandatory inspection—is designed to protect consumers—candy makers and others—who buy renovated butter.

When this law was enacted in 1946, there were five firms processing surplus farm butter and marketing it under a variety of trade names. None of the factories met the standards prescribed by the new regulations, and two of them discontinued operations immediately. Two others closed later. The one firm still in business processes between 40 and 50 thousand pounds of renovated butter a month under

continuing federal inspection. Inspectors turn down an average of one out of every 100 pounds of butter offered for processing because it does not meet standards of wholesomeness.

Tandem Not Random Inspection

The oldest food law now administered by the United States Department of Agriculture is the Meat Inspection Act of 1906. It is a model law. It has served as the blueprint for legislation in a number of states as well as in foreign countries. And it was the model for the Poultry Inspection Act of 1958.

The Act of 1906 has proved to have enduring qualities.

Look at the changes that have taken place in our country since 1906!

Then, more than half of the people of the United States lived in rural areas and a third of them on farms. Almost everyone had first-hand knowledge of the domestic animals that make up our meat supply.

Today, more than 90 per cent of the people of the United States live in cities and towns. Many have not seen a cow, a pig, lambs or chickens outside of a children's zoo.

In 1906, many United States families still bought their meat from farmers who not only raised the animals but also slaughtered and dressed them.

Today, practically all of our meat supply is handled by packers.

One of the interesting changes in recent years has been the decentralization of meat packing. Fifty years ago it was concentrated in a few large cities. Scientific agriculture made it possible for farmers to supply large numbers of animals to plants nearer farms and ranches. It is more economical to ship meat over long distances than to ship animals. And there has been a ten-fold increase in the number of cities where packing plants under federal inspection are located—almost 600 at the end of fiscal 1961.

The same procedures apply to federal inspection of red meat and of poultry. But the Secretary of Agriculture has delegated responsibilities for these acts to different agencies—the Agricultural Research Service for the inspection of red meat—the Agricultural Marketing Service for the inspection of poultry.

The distinctive thing about these two programs is that they put federal inspectors at critical points in the production lines of the

packing plants that are subject to the legislation—specifically the plants that prepare meat and poultry and meat products for distribution in interstate commerce or for export.

The laws give us the groundwork for a program that is enforceable and that is enforced. They provide for complete and continuous inspection starting before slaughter. In fact, the packer must keep federal inspection in mind when he draws up plans for construction. The laws require prior approval of construction of the abbatoir and the processing plant. Further, it requires prior approval of equipment to be installed, of the work flow chart, of formulas used in processing and of informative labels by which the products are identified and sold. No harmful chemicals, no adulteration, no deceptive labeling or packaging is tolerated.

The Meat and Poultry Inspection Acts give the inspector power of seizure all along the inspection route—from the holding pens where each live animal is tagged, if suspect, through post-slaughter where each carcass is examined and through each stage of the meat's preparation for market.

The livestock and poultry of the United States are uniquely free of many of the worst diseases that plague other countries. Nevertheless, some of them are diseased, and last year, federal inspectors condemned almost 300 thousand animals—cattle, hogs, sheep and horses —and millions of pounds of meat and poultry for use as food. The animals that were rejected for slaughter showed symptoms of the whole range of diseases that affect the animal kingdom—tuberculosis, cancer, respiratory and septic and inflammatory diseases.

Every working day, these federal inspectors working throughout the country keep one million pounds of unfit products from reaching food channels.

These totals may seem high. However, they represent only a small per cent of the federal inspection load. Last year, it reached almost 33 billion pounds—more than 26 billion pounds of red meat and six billion pounds of poultry. This huge supply was safe and wholesome because of the department's inspection system.

The Meat Inspection Act of 1906 has given us a durable legal framework for building our federal inspection programs. It has helped these programs gain wide public acceptance. And it has helped to build confidence in the system.

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One measure of the acceptance is the small number of violations of the act. The number is relatively small because enforcement is primarily through control of operations at the processing or slaughtering plant. Last year, we issued 105 letters of warning and prosecuted successfully 26 cases.

These laws are working well. However, the present federal meat and poultry inspection system does not adequately serve the needs of consumers. They assure wholesomeness in the products of plants under federal inspection—plants from which products are shipped in interstate commerce. That represents about 80 per cent of our meat and poultry supplies.

What about the remainder—the 6⅓ billion pounds of meat and poultry sold in this country without federal inspection?

Some of this meat is inspected by state services. More than 30 states have some form of meat inspection services at the slaughter level. Often, this is a voluntary service.

We have always worked in close cooperation with the state departments of agriculture, state veterinarians, departments of health and other interested groups in the states. Recently, we have redoubled our efforts to build a strong liaison with state officials who have responsibilities for meat and poultry inspection. In USDA we have taken the initiative in organizing regional conferences. The lines of communication are being strengthened.

We know that *more* inspection will be required if our citizens are to have the wholesome products they want. It will be required to maintain confidence in our meat industry.

There is rising concern about the dangers of unwholesome meat and meat products from uninspected slaughtering plants . . . more than 2,000 in all. Not quite half of them—about 900—are designated as major plants in the department's marketing reports.

They could be brought under federal meat inspection if the Secretary of Agriculture had authority to require inspection of slaughter and processing at any plant whose business is a part of interstate commerce . . . that is, any firm that buys and sells livestock and supplies in interstate commerce even though the firm does not distribute its products outside the state where they are processed. We are considering proposing legislation to give the Secretary this authority.

One of the toughest jobs in meat inspection—the task of certifying the wholesomeness of processed meats—grows increasingly diffi-

cult as new techniques are used—and as housewives depend more and more on the processor to prepare foods once cooked at home.

However, we can't depend on laboratory analysis of samples to protect consumers against unfit or adulterated meat and poultry products. It's impossible to detect them—even microscopically—when mixtures have been chopped or blended and cooked.

We can't rely on occasional sampling to assure wholesome meat and poultry supplies. Inspection must be continuous. It must be tandem—not random.

Last September, in a joint resolution Congress recognized Samuel Wilson of Troy, New York, as the progenitor of our national "Uncle Sam."

He earned his fame during the War of 1812 when he not only supplied the military with beef from his slaughterhouse but he also served the army as a meat inspector.

None of us wants to go back to the ways of the original "Uncle Sam" when it comes to meat inspection. The task has become far too complicated and the consequences far too risky.

Instead, to quote a recent magazine article on meat inspection, "A dedicated bureaucracy—using the word in its best sense—is needed to do the job." **[The End]**

SECOND SEIZURE UNDER NEW LABELING ACT

Seizure of an extremely flammable lacquer thinner for lack of adequate warnings under the new Federal Hazardous Substances Labeling Act was announced today by the Food and Drug Administration. It was the second seizure of a hazardous substance since the law became fully effective February 1.

United States marshals in Oklahoma City recently seized 95 quart cans and 45 gallon cans of the product described as extremely flammable with a flash point below 20 degrees Fahrenheit.

Label information which should have been conspicuously present on the containers but which was absent, FDA said, includes the common or chemical name of the substances contributing to the hazards; the signal word "Danger"; followed by a statement that it is extremely flammable; precautionary measures to be taken and actions to be avoided; instructions for handling and storage, and the statement "Keep Out of the Reach of Children" or its equivalent.

The first seizure under the Act was made early last month when FDA moved against a soldering compound implicated in the death of a six-year-old child in New York.

Developments With Respect to Product Liability

By WILLIAM J. CONDON

The Author Is a Member of the New York Bar and Is Attorney for Swift & Company.

FOR THE SECOND SUCCESSIVE YEAR the list of cases which we report here is remarkably short. The reasons for this may be many. For example, it may be that claims are not being brought. On the other hand, it may just as well be that cases are not being brought, not being tried, not being appealed, or finally, not being reported. In any event, the list of cases, grouped according to subject matter, follows:

Foreign Substance and Contaminated Food Cases

Greenberg v. Lorenz, CCH Food Drug Cosmetic Law Reports ¶ 22,673 (N. Y.)

Campbell Soup Company v. Dusek, CCH Food Drug Cosmetic Law Reports ¶ 22,694 (Miss.)

Foreign Substance Beverage Cases

Reine v. Baton Rouge Coca-Cola Bottling Company Ltd., CCH Food Drug Cosmetic Law Reports ¶ 22,670 (La. Ct. App.)

Diana v. Canada Dry Corporation, CCH Food Drug Cosmetic Law Reports ¶ 22,677 (U. S. D. C., W. D. Pa.)

Jackson Coca-Cola Bottling Company v. Nails, CCH Food Drug Cosmetic Law Reports ¶ 22,678 (Miss.)

Manzoni v. Detroit Coca-Cola Bottling Company, CCH Food Drug Cosmetic Law Reports ¶ 22,683 (Mich.)

Chiodo v. Otto Milk Company, CCH Food Drug Cosmetic Law Reports ¶ 22,686 (Pa. Common Pleas)

Asher v. Coca-Cola Bottling Company of Scottsbluff, CCH Food Drug Cosmetic Law Reports ¶ 22,693 (Neb.)

Exploding Bottle Cases

Hadley v. Hillcrest Dairy, Inc., CCH Food Drug Cosmetic Law Reports ¶ 22,669 (Mass.)

Bogie v. Royal Crown Bottling Company of Danville, Inc., CCH Food Drug Cosmetic Law Reports ¶ 22,672 (Ky.)

Sanchez-Lopez v. Fedco Food Corporation, CCH Food Drug Cosmetic Law Reports ¶ 22,674 (N. Y. Sup. Ct. Bx. Co.)

Vallis v. Canada Dry Ginger Ale, Inc., CCH Food Drug Cosmetic Law Reports ¶ 22,679 (Calif. Dist. Ct. App.)

Ciociola v. Delaware Coca-Cola Bottling Company, CCH Food Drug Cosmetic Law Reports ¶ 22,681 (Del.)

Revlon, Inc. v. Murdock, CCH Food Drug Cosmetic Law Reports ¶ 22,682 (Ga.)

Employers' Liability Assurance Corporation, Ltd. v. Thomassie, CCH Food Drug Cosmetic Law Reports ¶ 22,685 (CA-5)

Baker v. Coca-Cola Bottling Works of Gary, Indiana, CCH Food Drug Cosmetic Law Reports ¶ 22,689 (App. Ct. Ind.)

Kearns v. The Seven-Up Company, CCH Food Drug Cosmetic Law Reports ¶ 22,690 (U. S. D. C., E. D., Pa.)

Bonura v. Barq's Beverages of Baton Rouge, CCH Food Drug Cosmetic Law Reports ¶ 22,692 (Ct. App. La.)

Drug Cases

Perry v. Thrifty Drug Company, CCH Food Drug Cosmetic Law Reports ¶ 22,668 (Calif. Dist. Ct. App.)

Combrook v. Superior Court, CCH Food Drug Cosmetic Law Reports ¶ 22,676 (Calif. Dist. Ct. App.)

Combrook v. Superior Court, CCH Food Drug Cosmetic Law Reports ¶ 22,684 (Calif.)

Schwartz v. Heyden Newport Chemical Corporation, CCH Food Drug Cosmetic Law Reports ¶ 22,691 (N. Y. Sup. Ct.)

Cosmetic Cases

Caryl Richards Inc. v. Superior Court of Los Angeles, CCH Food Drug Cosmetic Law Reports ¶ 22,671 (Calif. Dist. Ct. App.)

Mealy v. Super Curline Hair Wave Corporation, CCH Food Drug Cosmetic Law Reports ¶ 22,675 (Mass.)

Kohler v. Clairol, Inc., CCH Food Drug Cosmetic Law Reports ¶ 22,680 (U. S. D. C., E. D., Pa.)

Dowd v. Boro Drugs, Inc. and Roux Laboratories, Inc., CCH Food Drug Cosmetic Law Reports ¶ 22,695 (N. J. App. Div.)

Animal Vaccine Case

Canter v. American Cynamid Company, CCH Food Drug Cosmetic Law Reports ¶ 22,667 (N. Y. App. Div. 3rd Dept.)

Detergent Case

Hamon v. Digliani, CCH Food Drug Cosmetic Law Reports ¶ 22,688 (Conn.)

Cigarette Case

Pritchard v. Liggett and Myers Tobacco Company, CCH Food Drug Cosmetic Law Reports ¶ 22,687 (CA-3)

While the cases were few in number, they were productive of some interesting situations and provided light on some areas which have been troublesome in recent years. For some time now, there has been a conflict developing with respect to the extension of implied warranties of quality to containers in which food, drugs, beverages and cosmetic products were sold. A large part of the discussion has centered around those products which are sold in returnable containers, for example, milk and beverage bottles. Some courts have gone to great lengths to determine in cases of this type whether there was in fact a sale of the container. This has led to esoteric distinctions between "sale or return" arrangements, bailments and outright sales. Two courts considered this issue during 1961 and both arrived at the same result. In *Hadley v. Hillcrest Dairy, Inc.,* the Supreme Judicial Court of Massachusetts came to the conclusion that whether or not there was a sale of a milk bottle was of no consequence in determining the result to be reached. The court held that the implied war-

ranties of fitness and merchantability attached to the milk bottle even though there was no sale, so long as that milk bottle was supplied to the consumer as a container for the milk which the consumer purchased from the dairy. The California District Court of Appeals reached the identical result with respect to a carbonated beverage bottle in the case of *Vallis v. Canada Dry Ginger Ale, Inc.* Both courts reached the result which they did, apparently on the basis of that language in Section 15 of the Uniform Sales Act which provides that the implied warranties of quality apply to "goods supplied under a contract to sell or a sale." The courts reasoned that, even though the milk bottle or the beverage bottle were not sold, both were clearly supplied under a contract of sale for the use of the plaintiff, and if they were not fit for the purpose for which they were intended, to wit, containing in a safe fashion the product therein, there was a breach of warranty for which the plaintiff could recover.

Another somewhat similar problem which has developed in recent years evolves out of the method of operation of the modern supermarket. The problem arises when injury occurs to a customer in a supermarket as a result of some defect in a product which has been taken from the shelf by the customer but not yet paid for at the check-out counter. The most common occurrence of this type, of course, is that of the exploding bottle. The question, simply stated, is when do the implied warranties of condition and quality attach? Several courts have confined the attachment of these warranties to the passage of title. From this, they conclude that, since title doesn't pass until the money is paid for the merchandise at the checkout counter, there cannot be any breach of warranty with respect to injuries incurred prior to that time. This approach has caused considerable concern and has seemed to many to be a grossly technical approach to a practical problem. In the case of *Sanchez-Lopez v. Fedco Food Corporation*, the plaintiff had selected a bottle of carbonated beverage, placed it in his shopping cart, wheeled it to the check-out and was removing it to place it upon the cashier's counter when it exploded, causing his injury. The Supreme Court of New York, Bronx County, held that in those circumstances the plaintiff was entitled to the protection of the implied warranties guaranteed under the Personal Property Law. The underlying assumption which the court made seems to be that the seller makes an offer by placing his merchandise on the shelves for the public to take. It said: "It is my belief that by presenting himself to the cashier with his merchandise

plaintiff evinced a definite intention to accept the offer of the seller. A bilateral contract of sale was thereupon effectively entered into at the time when he presented the merchandise to the checker. For the purpose of warranty protection, the sales concept could well be extended to meet the circumstances of the present case." It will be noted that the injury occurred in this case when the plaintiff was placing the merchandise on the check-out counter. It is not clear how much farther back in the line the court would have been willing to extend the warranty protection if the circumstances had been different.

Privity of Contract

Our old friend, the requirement of privity of contract in warranty actions, came in for some discussion in the cases of 1961. In our reports for both 1958 and 1959 we mentioned the case of *Greenberg v. Lorenz,* wherein the courts of New York were struggling with this privity question. You may recall that in that case the trial court allowed the infant plaintiff to recover in warranty for injuries sustained as a result of eating food purchased for her by her father from the defendant retailer. The Appellate Term of the Supreme Court affirmed over a vigorous dissent, but the Appellate Division of the Supreme Court reversed. In 1961, the matter finally received the attention of the Court of Appeals. That body reinstated the trial court's judgment and allowed the infant plaintiff to have her recovery. In reaching this result, the court started out by saying "our difficulty is not in finding the applicable rule but in deciding whether or not to change it." It went on to make the strange observation that "The present rule which we are being asked to modify is itself of judicial making since our statutes say nothing at all about privity and in early times such liabilities were thought to be in tort." The final holding of the court can be summed up in these two sentences: "Today when so much of our food is bought in packages it is not just or sensible to confine the warranty's protection to the individual buyer. At least as to food and household goods, the presumption should be that the purchase was made for all members of the household."

In a concurring opinion, Judge Froessel argued strenuously that the decision in the case should be limited to its peculiar facts. Presumably, he was referring to the fact that the infant plaintiff had requested her father to buy this particular product for her. He said

> This is an action on contract based on a statute . . . not for negligence, and it is basic law that unless privity exists, there can be no warranty, and

where there is no warranty there can be no breach. He went on to say: However much one may think liability should be broadened, that must be left to the legislature.

While this case marks a liberalization of the New York position on privity, it is too early to say how far New York is prepared to go. The case clearly does not stand for the proposition that direct action in warranty may be maintained against a manufacturer or packer of food, and by its terms, it is limited to food and household goods.

A similar fact pattern was presented to the Supreme Court of Delaware in the case of *Ciociola v. Delaware Coca-Cola Bottling Company*. There, a child was injured by the explosion of a soft drink beverage bottle which had been purchased by her father. On behalf of the infant, the court was urged to abolish the privity requirement and permit the recovery by the infant plaintiff in an action for breach of implied warranty. Noting that the rule had been changed in many jurisdictions and criticized by many commentators, the court concluded as follows: "We think, however, that Delaware has been committed by its courts to the common law rule governing actions for breach of implied warranty. A part of that rule is the requirement that there be privity of contract between the plaintiff and the defendant. It may well be desirable as a matter of public policy to impose absolute liability upon a manufacturer for injuries caused by defects in his product but, if such is to be the public policy of this state, it must be made so by the legislative rather than the judicial branch of the government, the function of which is not to change established law but to apply it."

Connecticut Statute

In Connecticut, statutes have been passed which have expanded the coverage of implied warranties of quality so that all members of the buyer's household are covered and to provide an implied warranty of fitness of food and drink for consumption on or off the premises for the benefit of the buyer and all persons for whom the purchase was intended. This year the Connecticut court was presented with a case which fell beyond the reach of any of those statutes. This was the case of *Hamon v. Digliani* and involved an action in warranty against the manufacturer of a detergent which had been purchased by the plaintiff from a retailer. In her complaint, plaintiff alleged that defendant had extensively advertised its detergent product as safe for use in household and other cleaning tasks and that she had purchased the product in reliance upon those advertising claims. She

alleged breaches of both express and implied warranties. The issue before the court was the propriety of the action of the trial level court in sustaining defendant's demurrer to the warranty causes of action. The action of the trial court had been based upon the ground that plaintiff had failed to state a good cause of action in warranty because she was not in privity of contract with the defendant manufacturer. It is clear that the Connecticut court held that the action in warranty will lie against a manufacturer where the purchase of its product has been induced by reliance upon its consumer advertising. It is likely also, however, that the court held that an action in warranty can be sustained against a manufacturer in any case where his product is sold in a sealed package. The pertinent language of the court's holding is as follows:

> The manufacturer or producer who puts a commodity for personal use or consumption on the market in a sealed package or other closed container should he held to have impliedly warranted to the ultimate consumer that the product is reasonably fit for the purpose intended and that it does not contain any harmful and deleterious ingredient of which due and ample warning has not been given . . . . Where the manufacturer or producer makes representations in his advertisements or by the labels on his products as an inducement to the ultimate purchaser, the manufacturer or producer should be held to strict accountability to any person who buys the product in reliance on the representations and later suffers injury because the product fails to conform to them . . . . Lack of privity is not a bar to suit under these circumstances.

The court acquired a right to vie for this year's literary prize with this sentence describing supermarket shopping: "The goods are displayed on shelves and counters lining the aisles, and the customer, as he searches for a product, is bewitched, bewildered and bedeviled by the glittering packaging in riotous color and the alluring enticement of the products qualities as depicted on labels."

Still in the realm of privity, and interesting opinion was rendered by the Georgia Court of Appeals. The case is *Revlon, Inc. v. Murdock* and involved an injury sustained by a beautician in a beauty salon when a service bottle exploded and cut her hand. This bottle was part of a kit sold by the defendant to the operator of the beauty salon for whom plaintiff worked. Georgia enacted in 1957 a statute which reads as follows:

> The manufacturer of any personal property sold as new property, either directly or through wholesale or retail dealers, or any other person, shall warrant the following to the ultimate consumer, who, however, must exercise caution when purchasing to detect defects, and provided there is no express covenant of warranty and no agreement to the contrary:

(1) The article sold is merchantable and reasonably suited to the use intended.

(2) The manufacturer knows of no latent defects undisclosed.

This case marked the first construction of this statute by an appellate court in the State of Georgia. The court pointed out first of all that the statute, being in derogation of the common law, must be strictly construed. Then, reviewing the language of the statute, the court concluded that its provisions are available only to purchasers. While it is clear that the purchaser need not have bought from the defendant, the court concluded that it is equally clear that the consumer must have purchased from someone. Otherwise, the language in the statute "who, however, must exercise caution when purchasing to detect defects," would have no meaning. Accordingly, the court defined the word "ultimate consumer" as used in the statute to be restricted to a consumer who was also a purchaser of the product. Thus, Georgia seems to have expanded its liability for warranty back to the manufacturer before extending it to members of the purchaser's household as has been the case in most other jurisdictions.

Cigarettes and Cancer

The latest in the recent line of cigarette cancer cases, decided last October in the United States Court of Appeals for the Third Circuit, may well mark a turning point in that type of litigation. Otto Pritchard sued Liggett & Meyers Tobacco Company, alleging that cancer of his right lung was caused by smoking Chesterfield cigarettes from 1921 until 1953 when the lung was removed. He brought his action in negligence and warranty. The District Court dismissed the warranty cause of action at the end of plaintiff's case and granted defendant's motion for a directed verdict at the end of all the evidence. Of interest at the trial level is the fact that the trial court required plaintiff to introduce his evidence of causation before he would permit any evidence concerning the other elements of plaintiff's causes of action. Of further interest is that all motions to dismiss were denied at the end of plaintiff's evidence of causation even though defendant subsequently received such relief at the hands of the District Court. On the issue of causation, plaintiff had introduced the testimony of five highly-qualified medical experts, each of whom testified that plaintiff's cancer was caused by long continued smoking. Defendant contended that these opinions should have no validity since there was no proof of the acceptance of this relationship by the medical profession. To this contention, the Court of Appeals said that it was a ques-

tion for the jury since it goes to the weight to be given the several expert opinions.

The evidence on the warranty question was interesting because it relied almost exclusively on defendant's advertising. The court said this:

> The evidence compellingly points to an express warranty, for the defendant, by means of various advertising media, not only repeatedly assured plaintiff that smoking Chesterfields was absolutely harmless, but in addition the jury could very well have concluded that there were express assurances of no harmful effect on the lungs.

In making this statement, the court relied upon various advertising campaigns of defendant over the year immediately prior to 1953, including substantial quotations from television programs of Arthur Godfrey. The court concluded that whether plaintiff's professed reliance upon defendant's assurances that Chesterfields were safe was reasonable was a matter for the jury. One curious note is that most of the advertising cited by the court, and particularly that advertising which seems beamed at safety of use, was published and viewed in 1953, the year when plaintiff discovered his cancer. For all one can tell from reading the opinion, this factor was not considered important by the court.

On the question of negligence, plaintiff's claim was that defendant was negligent in failing to warn him that cancer-producing substances were present in Chesterfield cigarettes although defendant knew or should have known that fact. Defendant contends, of course, that there is no evidence of record to show that at the time plaintiff contracted cancer, defendant had or in the exercise of reasonable care should have had any knowledge or notice that lung cancer probably would have resulted from prolonged excessive smoking. However, plaintiff's five experts all testified to the awareness of a possible link between smoking and cancer going back in some cases at least to 1939 and possibly even farther. In addition, the court pointed out that there was in evidence the fact that defendant had conducted tests through an outside laboratory in 1952 to determine the effects of smoking Chesterfields upon nose, throat and accessory organs. It was a result of these tests that defendant made the claim that Chesterfields had no harmful effect on "nose, throat and accessory organs." Apparently, according to the court, this was the only test conducted by defendant to determine the harmful effects of this product on human beings. The court concluded that under all the circumstances,

whether it was reasonable for defendant not to have conducted different or additional tests was clearly a matter that should have been submitted to the jury. Accordingly, the court ordered a new trial on both the issue of warranty and the issue of negligence.

Of particular interest in this case, is the concurring opinion of Judge Goodrich, who was very careful to limit severely the basis upon which he concurred in the reversal and remand of this matter. In his opinion, the liability of defendant, if any, will arise as a result of defendant's advertising and not as a result of any failure to warn. Pointing out that there is language in defendant's advertisements which could be understood to assert a claim that the cigarettes are harmless, Judge Goodrich states the applicable principles to be that if a manufacturer assures his public that his product is harmless and it is proven that it is not harmless, he can be liable for breach of warranty. Further, if the manufacturer makes a statement which he does not know to be true, intending that the public shall rely upon the truth of it, he is liable for negligent misrepresentation. Beyond this, however, he is unwilling to go. He concludes his opinion with some very worthwhile and thoughtful examples:

> If a man buys whiskey and drinks too much of it and gets some liver trouble as a result, I do not think the manufacturer is liable unless (1) the manufacturer tells the customer the whiskey will not hurt him or (2) the whiskey is adulterated whiskey—made with methyl alcohol, for instance. The same surely is true of one who churns and sells butter to a customer who should be on a non-fat diet. The same is true, likewise, as to one who roasts and sells salted peanuts to a customer who should be on a no salt diet. Surely, if the butter and the peanuts are pure there is no liability if the cholestrol count rises dangerously.
>
> In this case, there was no claim that Chesterfields are not made of commercially satisfactory tobacco.

It is significant that in the light of Judge Goodrich's concurring opinion, the court deemed it advisable that upon the retrial the District Court should submit the case to the jury upon interrogatories, so that it would be known on what basis the jury determines liability, if any.

Statute of Limitations

The disposition of *Schwartz v. Hayden Newport Chemical Corporation,* decided by the New York Supreme Court, turned upon an issue which apparently was not raised in the *Pritchard* case. That issue was the applicable statute of limitations. Plaintiff's claim was that, while a member of the armed forces in 1944, a substance manufactured by

defendant was injected into his body to make the sinuses perceptible to X-rays. A portion of the product so inserted was not removed after the X-rays, remained in his head and caused a cancerous condition which was discovered in 1957 and which resulted in the loss in that year of his left eye. Plaintiff claimed that his claim of right to recover for personal injuries arose upon his discovery of the alleged negligence and breach of warranty. However, the court pointed out that the law of New York is settled that the injury occurs when there is a wrongful invasion of personal or property rights and then the cause of action accrues. The injury to the plaintiff was complete and the defendant's breach of duty, if any, occurred when the product of the defendant was injected and permitted to remain in plaintiff's body. At that time, liability for wrong arose even though the plaintiff was ignorant of the existence of the wrong or the injury. The court, therefore, reluctantly granted defendant's motion to dismiss the complaint.

In his concurring opinion in the *Pritchard* case Judge Goodrich cited Section 402A of *Restatement of Torts 2nd* (tentative draft Number 6). In the event that any of you are not aware of this section, let me say that it was adopted by the American Law Institute at a meeting last May. This is a completely new section which marks a revolutionary concept in the *Restatement* approach. It provides as follows:

> One engaged in the business of selling food for human consumption who sells such food in a defective condition unreasonably dangerous to the consumer is subject to liability for bodily harm thereby caused to one who consumes it, even though (a) the seller has exercised all possible care in the preparation and sale of the food, and (b) the consumer has not bought the food from or entered into any contractual relationship with the seller.

You will note that this section defines a strict tort liability for the manufacturer or seller of food. This strict liability runs to the consumer, irrespective of privity of contract and, of course, irrespective of any fault on the part of the seller or manufacturer. What makes this section revolutionary is its dramatic departure from the object of the restatement of the law as originally defined. The object of the *Restatement* as defined by the American Law Institute in the introduction to the original *Restatement* is to present an orderly statement of the general common law of the United States. From this, one has a right to conclude that what one finds codified in the *Restatement* will be an accurate reflection at least of the weight of authority on any given proposition. Not only is 402A not representative of the weight of authority, but I seriously doubt if it represents the law as

it exists in any jurisdiction of the United States. 402A is purely and simply a statement of the law as the reporter and his advisers would like it to be. All of the cases cited in tentative draft Number 6 as support for this statement of the law are cases in which courts of various jurisdictions have abolished or modified the requirement of privity of contract in order to sustain an action in warranty. In none of them is there any statement by the court to the effect that a strict tort liability exists in the circumstances. Indeed, in the reporter's note to the Institute, he points out that tort liability is to be preferred to warranty liability because of the technicalities of warranties which from time to time may permit defendants to avoid strict liability.

There are a number of things about this section which should be of concern to all the members of the food, drug, cosmetic law bar and indeed to all members of the bar who do any defendants work. First of all, while the section originally was confined to food, the comment to the section defined food to include all articles intended for internal human consumption. This, of course, would include drugs for internal human consumption even though no drug cases can be cited in support of the proposition. Indeed no drug cases are cited in support of the abolition of privity of contract in warranty with the exception of the *Cutter* cases in California, which represent a special situation. However, at the meeting in May, the Institute voted to broaden the coverage of the section to include not only all articles intended for internal human consumption, but also all articles intended for intimate external use in or on or upon the human body. This, of course, will include such things as cigarettes, cigars, lotions, cosmetics, hair dyes, soap, vaccines and liniments, to name a few. Presumably, it will also include clothing, eyeglasses, hearing aids and the like. Needless to say, no background or support for the inclusion of these items is to be found in the case law anywhere.

Secondly, the *Restatements of the Law* occupy a position of considerable stature in the eyes of our courts. They are cited regularly. Therefore, it must be expected that if this section is permitted to remain in the *Restatement* as published, it will have a tremendous effect toward bringing about what the drafters of this section apparently want the law to be. This portends a power in a small group of men, not politically responsible to anyone, to shape the law in this country in a manner which was never intended by the founding fathers or any of their successors. Such a result can only bring about either an influence to the American Law Institute which shouldn't reside in

any private group, or the discreditation of the *Restatements* themselves either of which would be most unfortunate.

A third point of significance in this section and in its promulgation is that it is a big step forward in the development and spread of strict liability. There are many people in this country who feel that strict liability should attach to all products sold in the market. Indeed, I'm not at all sure that even that would mark the limit to which these advocates would press the strict liability concept. One may wonder why there is such a concentrated fire on food cases. The reasons appear to be two. First, it is in the area of food wherein courts have relaxed the privity requirement to the greatest extent. Second, food is used by everyone, represents the most intimate contact possible, and permits, therefore, a highly emotional appeal. Actually, there is little justification for attaching strict liability to food products as opposed to others. In the first place, there are rarely any substantial injuries in food cases. Besides, the standards of proof have been so liberalized in this type of litigation that the plaintiff's burden of establishing negligence is slight indeed.

Nevertheless, we are faced with a clamor for strict liability against sellers of food. Why? The answer is that, for the reasons indicated, food represents the most convenient springboard. Once the principle of strict tort liability is established in food cases it will be a far simpler matter to broaden its application to more and more products until the whole market spectrum is included. If any proof is required that this is the goal, I suggest that it can readily be found in the list of articles which have been brought under the food umbrella of Section 402A itself.

Advocates of strict liability have already been heard to suggest that it be applied to operators of motor vehicles. We know that there is a program designed to provide strict liability to all sellers of merchandise. It is impossible at this juncture to speculate with respect to how many other as yet unexplored areas these social engineers of the law will seek to encompass with this concept. I use the term "social engineers" because this is obviously more an area of social philisophy than it is of law. It is no secret that I do not agree with this philosophy. However, irrespective of its merits, it is a philosophy which ought to be considered by the elected representatives of the people who are politically responsible to them. And it should be foisted on the public only after the people have had an opportunity to express their views on such a significant social change. It ought not to be done by the relatively unpublicized route of judicial decision.

I have said that the American Law Institute is not politically responsible, and this is true. This is not to say, however, that the Institute would not be responsive to the views of the members of the Bar whose opinion, *inter alia,* the *Restatements* profess to represent. On this, I have no knowledge. Accordingly, let me issue a call to those who agree with me—to those who think, as I do, that Section 402A does violence to the objects and purposes of the *Restatements*—to write the responsible members of the American Law Institute to call this matter to their attention. Certainly, that distinguished body of leaders at the Bar would not be unresponsive to the views of a substantial, identifiable group of lawyers. Perhaps, together, we can convince them that the promulgation of a *Restatement* section which reflects neither majority opinion, nor weight of authority, nor even a definable trend, would be unwise.

Surely, those of us who wish to preserve the adversary system of settling disputes cannot sit idly by while issue after issue is removed from the province of the jury. There are but few more issues remaining and when these have disappeared, the use of the adversary system will be over. The necessity for court intervention will no longer exist, and the system will inevitably become administrative in nature and in fact.

By way of conclusion, let me suggest to you that the removal of all risks of life is not necessarily in the best interests of the people. The concomitant diminution of the incentive for self protection and self development may in the long run outweigh the benefit to be derived. The principles of law developed for exclusive application in the products liability field may spill over into other areas presently unforeseeable, with disastrous results, just as the liberalization of rules of law in food products liability cases are even now spilling over into products liability cases generally. Our system of law wherein recovery is based upon fault has served us well. Let us not discard it lightly in favor of a system whose course we know not. Everyone should be aware that the lance of strict liability is pointed at both ends. Today's beneficiary may be tomorrow's sufferer. **[The End]**

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Is There a Need to Change the Factory Inspection Law?

By SAMUEL A. McCAIN

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THE PRESIDENT OF THE UNITED STATES said in his State of the Union message to Congress earlier this month:

> To protect our consumers from the careless and the unscrupulous, I shall recommend improvements in the food and drug laws strengthening inspection and standards, halting unsafe and worthless products, preventing misleading labels and cracking down on the illicit sales of habit forming drugs.

The portion of this paragraph with which we are particularly concerned in this paper is "I shall recommend improvements in the food and drug laws strengthening inspection. . . ."

Another statement of the President in the same message made in another connection is of very great importance and should be considered in specific reference to factory inspection:

> This administration has shown as never before how much could be done through full use of the Executive powers—through the enforcement of laws already passed by the Congress—through persuasion, negotiation, litigation to secure the Constitutional rights of all. . . .

I am sure it will be a great satisfaction to the President to know that as to some particular items of factory inspection I agree with him.

On the other hand, specific proposals for so-called "strengthening" the factory inspection provisions have been made. I think I can speak with some authority in saying that they will be practically unanimously opposed by industry. For instance, I have before me a release dated January 17, 1961, signed by Arthur S. Flemming, containing proposals which I understand are largely unchanged in the Food and Drug Administration's recommendations today and are expected to shortly go to Congress, which states:

> Amendments (a) to extend the factory inspection provision of the Act (§ 704) to all records, files, papers, processes, controls, facilities, and things bearing on violations, or potential violations of the Act and (b) to clarify the

factory inspection provisions by expressly including consulting laboratories (the first of these is not limited to inspection relating to drugs, although the immediate occasion for it arises in connection with drug manufacture, because for *obvious reasons* the same authority is needed for other articles subject to the Act.[1] (Italics supplied)

After consultation with food and drug officials, the only *obvious reason* I have been able to dig up is the laziness of the legislative draftsmen. Three separate and eminent officials assure me that they have no complaint as to either the reception or the information given their inspectors, at least by the food industry.

The text of the present Food and Drug Administration's proposed amendment, which is now being reviewed by the Budget Bureau, is even broader and is reported to be as follows:

> . . . and all things therein (including records, files, papers, processes, control and facilities) bearing on whether articles which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported or held in any such place, or otherwise bearing on violations or potential violations of this Act.

I shall deal briefly with four subjects.

Legal and Historical Background

In order to understand the problems involved in an amendment of the Factory Inspection Law, it is necessary to examine, at least briefly, the history of the present Section 704 of the Act.

Two splendid discussions of the Factory Inspection Law, as it was amended effective August 7, 1953, may be found in 8 FOOD DRUG COSMETIC LAW JOURNAL 792, by Charles Wesley Dunn, and in 9 FOOD DRUG COSMETIC LAW JOURNAL 18, by Charles S. Rhyne and Eugene F. Mullin, Jr.

It should be called to the attention of both the legal and lay readers of this paper that the Food and Drug Act is a very unusual law in at least one respect. What we lawyers call *mens rea* is not an element of a crime under the Act. In other words, I may have a perfectly modern factory, my methods of inspection may be as near

[1] The draft law itself attached to the release reads: "and all records, files, papers, processes, controls, facilities, and things therein bearing on whether articles which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place."

perfect as modern processes allow and at the same time if, through an unforeseeable defect in this operation, some adulteration of the food manufactured may take place. I have committed a crime. I have not been negligent, I had no intention to commit a crime, but, nevertheless, I have committed a crime.

By all standards of criminal law, this is a very drastic statute; nevertheless, I think we all agree the statute in this respect is necessary as it is. By the same token, the very fact that the statute is drastic demands that all constitutional safeguards be vigorously observed.

Under the present law, the Food and Drug Administration acting through the United States Attorney's office can obtain a search warrant from the court, which will include obtaining relevant papers and files in any case in which it can show that it has evidence that a crime is probably being committed. The use of the search warrant type of procedure, because of the burden on the government of first showing probable cause, has been used very little and is not a part of the normal investigative procedure of the Food and Drug Administration.

There is also available the Factory Inspection Law, present Section 704 of the Act, which allows the government inspectors to go through a factory and inspect it and take samples of any material in the food being manufactured at any point in the process. This is much more adapted to the needs of the Administration, since the enforcement by the Food and Drug Administration is directed toward seeing that the foods manufactured are not adulterated and are pure and are manufactured under sanitary conditions.

The search warrant procedure, as Mr. Dunn pointed out in his very able article, is not adapted to the Food and Drug Act because a search warrant procedure assumes that the government has and can show to a court that it has evidence pointing to the probability that a crime is being committed. In the case of food and drug inspection, the very opposite is true—it is inspecting to be sure that a crime is not being committed; and in the case of most of the many, many thousands of reputable manufacturers, it has no reason to believe that a crime is being committed.

Legislative History

This is not the first time that the Food and Drug Administration has attempted to cozen Congress into passing this kind of legislation. As Mr. Dunn points out in his article, at page 794, when the 1938 Act

was originally before the House, a minority effort was made to convert the inspection proceeding into a search warrant procedure, but this was overwhelmingly defeated by a 100 to 22 vote.

When it became necessary to revise the Factory Inspection Law in 1953, this matter was again fought out,[2] and Rhyne and Mullin conclude, at page 37:

> Inspection is now pretty well limited to matters of sanitation. The Food and Drug Administration itself is reported to agree, however reluctantly, with this interpretation. (15 FDQ Reports, No. 26, pp. 2-4, August 8, 1953)

A Food and Drug Administration Release dated August 27, 1953, quoted Commissioner Crawford as stating, in part, as follows:

> Modern production and distribution are carried on to a large extent through the medium of written instructions and records. The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files, and personnel files within the scope of required inspections.

It has been the feeling of Congress that the extreme of criminal liability without either intention or negligence, which is a necessary part of the Food and Drug Act, requires a corresponding limitation on the inspection authority beyond the factory to which it is at present limited.

It is unthinkable that the Food and Drug Administration should be permitted to come in with a Congressional sponsorship of very doubtful, if any, validity on a fishing expedition to allow the government to convict a person, by his own testimony or by the fact that he keeps adequate records, of an inadvertent crime at an indefinite time in the past. It seems almost unnecessary to say that in the opinion of many lawyers the unconstitutionality of such an act is stated very clearly, simply by stating the foregoing facts. There is ample authority condemning fishing bills; see particularly *Jones v. Securities and Exchange Commission*, 298 U. S. 1, at pp. 27 and 28.

In summarizing this part of my paper, in case some of my remarks have been missed in passing, I submit that any extension of visitorial powers over papers to the Food and Drug Administration which administers an act where crime may be without fault, would be legally outrageous and I hope would be safeguarded by the members of Congress and all who have occasion to think seriously about just what is involved in these particular visitorial powers.

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[2] For debate in the Senate, see 99 *Congressional Record* 11299, August 3, 1953, and Report No. 712, 83rd Cong., 1st Sess., by Mr. Purtell. For debate in the House see 99 *Congressional Record* 11358-11359, House Report No. 708, 83rd Cong., 1st Sess.

Practical Considerations

The government, as in all similar cases, states that it does not have power sufficient to deal with the situation. But just let us look for a minute at the powers of the Food and Drug Administration.

They have their factory inspection power, which permits them to enter and inspect any food-making establishment at any time during working hours.

They have the ordinary search warrant procedure, which seemed to have been sufficient for the troubled times during prohibition and which perhaps they have not used enough. I personally have not heard of their using a search warrant procedure, but I think it quite likely they have. In order to procure a search warrant, all they have to do is to go to a judge and show that they have reasonable evidence that a crime is probably being committed in a food-making establishment. A search warrant will enable them to obtain all files, records, documents, formulas and everything else that they can think of, relating to the particular crime they have reason to believe is being committed. After the search, they can even padlock the factory if they can convince the judge this is a proper procedure.

Then, there is the section of the law, Section 705, which I have always termed "the blast section," which permits the Secretary in any case in which he believes that there is a danger to the public health, to give information of the facts to the public. I am sure that everybody in the United States is acquainted with this particular section, which was the legal basis for Secretary Flemming's press release in the so-called cranberry incident. In other words, if the Secretary can work himself up into feeling that the public health is involved, he is empowered to take any product at all off the market entirely, simply by press release and under the section, without legal responsibility to anyone.

And last, but certainly not least, in any case where the Secretary feels that there is danger to the public health, multiple seizures of a product may be made in all markets in the country where it is being sold according to Section 304.

To conclude with powers of the Food and Drug Administration, those of us lawyers who deal with that Administration from day to day are not inclined to shed any tears over its lack of powers. Its powers are perhaps unparalleled by those of any other agency in time of peace with the exception of the office of the President himself, and as a part of that executive office it has all those powers too. And

certainly, the Congress, after the full realization of all these powers, should not be willing to extend them without not only good cause, but extra good cause shown.

One other practical consideration—is the Food and Drug Administration really ready to take on a job of a paper inquisition, more or less of the ancient Spanish type, against a food industry whose only weakness so far, aside from good faith, has been that it probably has cooperated too well with the government?

The following items might be pointed out:

(a) The Food and Drug Administration is hopelessly behind schedule in all its standard hearings, and, so far as I have been able to find out, is not proceeding too expeditiously with most of the standards.

(b) The clearance of food additives is already several years behind and will probably not be cleared up for a number of years yet to come, despite the large amount of both staff and money that has been given to the agency.

(c) The Food and Drug Administration has recently been given the task of enforcing the Hazardous Substances Labeling Act. It did not issue any proposed regulations at all until after the Act had become effective, and is still in the midst of what promises to be voluminous proceedings to try to make some sense out of what was hoped to be a simple enforcement of this statute; again, despite large amounts of dollars and personnel that had been given to the agency.

(d) Enforcement—Food and Drug still does not have either the amount of money or men necessary to adequately enforce the Act, despite the fact that it has been given repeatedly more of both.

(e) Out of the hearings by the antimonopoly subcommittee on the subject of the drug industry, it is now reported that the very least that can come is the granting to the Food and Drug Administration the right to pass on the efficacy of all new drugs. Apparently, Food and Drug still think they do not have enough to do. Assuming enough money can be found, how in the world enough men can be found for such a project, which is basically aimed at protecting the public from its own doctors, is hard to tell.

(f) In addition, the Food and Drug Administration has announced that it is going to be more active in connection with the advertising of both foods and drugs.

All in all, to any objective person, it would seem that the Food and Drug Administration already has enough, if not too much, power delegated to it by Congress, and that it could very well devote itself to proper enforcement and regulation of the acts already under its direction without seeking new inquisitorial powers with no constitutional basis.

Food Additives

Food additives that are ingredients of the food, that is, that are "used for components of food," are foods within the definition in Section 201(f) of the Act and factories making such components of food are subject to inspection under Section 704 of the Act.

On the other hand, if the factory inspection section is construed strictly as it should be, incidental additives such as those which migrate from packaging or, say, harmless residues from catalysts, though they may "become components of food" are not ingredients and are not foods and are not designed, intended or used as components of foods; it would seem equally clear that factories making such incidental food additives are not subject to inspection without an amendment of the law.[3]

Legislative Suggestions

First, with a number of more important considerations to be dealt with on the subject of inspection, it would seem wise to leave the subject of inspection of factories in which incidental additives are made, such as packaging materials and catalysts, for a recommendation from the Food and Drug Administration, after more experience, as to what their enforcement needs are.

Certainly, at the present time, all the materials are subject to sampling by the Food and Drug Administration inspectors in the factory of the food manufacturer to whom the materials are sold.

Second, I have one suggestion for strengthening the Factory Inspection Law, in which the Food and Drug Administration does have a legitimate request for the strengthening of its inspection powers. I understand that some manufacturers have been unwilling to send copies of their labels, labeling and consumer advertising to the Food

[3] See John G. Kuniholm, "Are Empty Containers Food," 15 FOOD DRUG COSMETIC LAW JOURNAL 637; Mr. W. W. Goodrich, 16 FOOD DRUG COSMETIC LAW JOURNAL 51 at p. 57; Richard C. Nelson, "Incidental Additives to Food: Have We Made a Prudent Judgment?" 16 FOOD DRUG COSMETIC LAW JOURNAL 597, at page 608 and following.

and Drug Administration. All of these things might constitute part of the labeling, but, of course, might well not be at the factory at which the product is made at the time of inspection. In this case, since all the materials in question are public documents anyway, industry is quibbling and merely putting the Food and Drug Administration to additional trouble and federal taxpayers to unnecessary expense. If the Section is amended at all, it should include a separate provision making the furnishing of labels, labeling and consumer advertising to the Food and Drug Administration compulsory.

Third, there is one more important suggestion for legislation that certainly should be given serious consideration. The facts are these: Food and Drug admits that it has no power to get factory records, formula files, complaint files and other papers, for which authority of doubtful constitutionality is now requested for it to get by legislative fiat.

While FDA recognizes it has no such powers, its instructions to its inspectors are to ask for such documents, which at the very least is poor administration. In the case of an ordinary petty criminal, the instructions of the policeman are at least to warn the person that what he is saying is being taken down in writing and may be used against him in a criminal proceeding. No such constitutional privilege is accorded the reputable food manufacturer. If he gives up his papers without knowledge that he has a right to withhold them, he can be, and so far as I know, often is, convicted of a crime.

In view of this regular but extra-constitutional procedure of the Food and Drug Administration, there should be added to Section 704 a provision that if an inspector asks for any material which he is not authorized to request under the Section, that he be instructed to warn the owner of the factory of his rights. He would also inform him that in the event that he grants the inspector's request, the material he furnishes may be used in a criminal proceeding against him. A receipt stating the foregoing in so many words would be issued by the inspector to any person who grants such a request.

Conclusion

These are my specific suggestions for amendments to strengthen the factory inspection power both from the standpoint of enforcement and from the standpoint of constitutionality; as I pointed out, this has been suggested generally by the President in his State of the Union message.

Though the recommendations outlined above are not exactly the same as those pending by the Food and Drug Administration, I don't believe that fundamentally the Food and Drug Administration would disagree with any of the proposals I have made. It is true they will undoubtedly say they would like more inspection powers, but it seems to me that this is merely the normal routine of an agency requesting powers from Congress—they ask for more than they think they are going to get, just so they will be sure to get what they actually need.

In closing, let me say that no one is more interested than the food industry itself that the Food and Drug Administration have adequate powers for the enforcement of the Act, and it is my sincere belief that the recommendations contained above are the only ones suitable for action at the present time. **[The End]**

GOVERNMENT'S FIRST EXCLUSIVE RECOGNITION TO A UNION

First exclusive representation to a labor union ever given by the federal government has been granted by the United States Department of Agriculture to a unit of the American Federation of Government Employees, AFL-CIO.

USDA announced today that it has accorded exclusive representation to the AFGE's National Joint Council of Meat Inspection Lodges for all the Department's meat inspectors, with the exception of veterinarians and supervisors. The action was approved by Under Secretary of Agriculture Charles S. Murphy in a letter to James A. Campbell, National President, AFGE.

Covered in the recognition given the AFGE unit today are 2,472 meat inspectors in some 1,500 slaughter houses and processing plants across the nation. A substantial majority of these inspectors are members of AFGE, according to USDA.

Criteria for agreements such as USDA's are set forth in White House Executive Order 10988, "Employee-Management Cooperation in the Federal Service," issued by President Kennedy on January 17. It provides for government recognition of employee organizations. Secretary of Agriculture Orville L. Freeman issued a memorandum January 18 in which he gave "my strong personal endorsement" to the order and called for its implementation within USDA.

AFGE's National Joint Council of Meat Inspection Lodges will represent all USDA employees within jurisdiction of the agreement, and will negotiate with USDA management on terms of employment and working conditions. The union must agree not to assert the right to strike and must not discriminate on the basis of race, color or religion in its activities.

Report on Revision of the Uniform State Food, Drug and Cosmetic Bill

By O. J. WIEMANN

The Author Is Chairman of the Committee on the Uniform State Food, Drug and Cosmetic Bill of the Association of Food and Drug Officials. He Is Currently Chief of the Milk, Food and Drug Section of the Colorado State Department of Public Health.

THE HISTORY of the Uniform State Food, Drug and Cosmetic Bill goes back to 1940 when the initial form was adopted and published. In the ensuing years, only one signficant revision has been accomplished until the current revision. This despite the fact that the "parent law" has been amended in almost every session of the Congress since 1954, and that these amendments have been far reaching in their effect upon the basic philosophy of food and drug law enforcement and the administrative procedures involved in the implementation of its provisions.

Conception, gestation, labor and delivery of the current additions and revisions cover the period from June, 1959, at the Annual Conference of the Association of Food and Drug Officials of the United States in Boston, Massachusetts. The catalyst for this activity at that time was an address and proposal for revisions placed before the general session of the Association by one of the members of this section, speaking as an individual and for himself. This paper was published, and can be found in the *Quarterly Bulletin, Association of Food and Drug Officials of the United States,* January 1960, Vol. 24, No. 1, page 10, "Problems of Uniformity in Legislation, Administration and Enforcement of Food, Drug and Cosmetic Laws" by Michael F. Markel. The fuse in this presentation was an appendix which contained suggested revisions for the Uniform Bill, submitted to the Council of State Governments by the Department of Health, Education, and Welfare at the request of the former organization. As a result, the Association appointed a Special Committee to Study the

Proposals for Amendments to the Uniform Food, Drug and Cosmetic Bill, chaired by Evan Wright of Kansas. After deliberation during the Conference, the committee, feeling that considered and detailed study could not be accomplished in so short a period, recommended and obtained extension of the committee charge and appointment. The secretary of the Association also was instructed to contact the Council of State Governments to request its withholding of a final decision of a recommendation for revision of state food and drug laws until the proposals of the committee had been accepted by the Association and forwarded to the Council. This was accomplished and the Revision Committee commenced its activity, which was directed toward revision without a complete dependence upon adoption of regulations and standards by reference.

Committee deliberations were directed by the opinion of the majority of the conferees that adoption by reference of the provisions of federal laws, regulations and standards was not valid under the provisions of their respective state constitutions.

Currently, the 1961 revision of the Uniform Bill has been accepted by the Executive Committee of the Association of Food and Drug Officials of the United States and I have been informed that printing was authorized at its October, 1961 meeting. Although the Council of State Governments did receive the revision prior to the meeting of its Committee on Uniform Legislation in September, 1961, the Committee laid over final action on recommendation to its members until more exhaustive study could be made. I have not seen the 1962 Recommendations for Uniform State Legislation by the Council of State Governments so I have no knowledge on the subject of final action on the revision.

Underlying the purpose of the Uniform State Food, Drug and Cosmetic Bill is the philosophy that there should be provided a high degree of conformity among the state laws and between the state laws and the Federal Food, Drug and Cosmetic Act, while retaining the flexibility to permit implementation by the states without abrogating state constitutional provisions. During the deliberations of the Committee, many state food, drug and cosmetic laws were reviewed. One fact became apparent—that adoption of provisions of the federal act by reference has been rather frequent, despite considerable discussions concerning the legality of such procedure. There are several instances where blanket adoption of all federal regulations and standards has been accomplished—for now and in perpetuity—and so far

apparently without contest. In the final draft, provision has been made for adoption by reference in several instances. This was accomplished by parenthetical insertion of optional methods for adoption of definitions, standards and regulations by reference and by administrative action following hearing. When revision of a state law is contemplated either approach may be used by simply deleting the one not desired.

A short discussion of the significant changes may be in order.

Section 2—Definitions:

1. A definition of "pesticide chemical" has been added. The alternatives in this case are to adopt by reference the definition of "economic poison" within the structure of the Federal Incesticide, Fungicide and Rodenticide Act or the applicable state law, if any. The only other approach is to make a complete definition of a "pesticide" or "economic poison" as is contained in the referenced acts.

2. "Raw Agricultural Commodity," "food additive," and "color additive" have been defined. These definitions are substantially identical with those contained in the federal act, including the exemptions.

Section 10—Food—Adulteration Defined:

Addition of a definition that a food shall be deemed adulterated if it bears or contains a pesticide chemical, food additive or color additive which is unsafe within the meaning of Section 13(a) or the respective sections of the federal act (option). The exemption of processed foods if they do not bear or contain a pesticide chemical in excess of the residue permitted on the raw agricultural commodity has been included.

Section 11—Food—Misbranding Defined:

The Committee added an adoption by reference in referring to the labeling and packaging requirements for color additives prescribed by the federal act.

Section 13—Food—Added Substances:

1. The old "per se" section was completely rewritten to permit coverage of pesticide chemicals, food additives and color additives, eliminating the application of the broad poisonous and deleterious classification to the three specifically named groups of substances, but retaining it for general use.

2. A second subsection has been added. This material sets forth the procedure for establishing tolerances, zero tolerances in the case of pesticide residues in or on raw agricultural commodities, and the conditions under which food additives and color additives may safely be used. The procedure enumerates the data which must be submitted by the proponent of the use of such substance.

Section 14—Drugs and Devices—Adulteration Defined.

Section 17—Cosmetics—Adulteration Defined:

The revision in each of these instances relates to color additives in the two groups and adoption can be by reference to the federal act or related to the safe conditions of use which may be established under the provisions of Section 13(b).

Section 15—Drugs and Devices—Misbranding Defined.

Section 18—Cosmetics—Misbranding Defined:

Packaging and labeling of color additives in these instances is referenced directly to the requirements of the federal act.

Section 15—Drugs—Misbranding Defined:

1. By reference a drug is declared misbranded if it is composed wholly or in part of insulin and it is not from a batch certified under Section 506 of the federal act.

2. Any drug composed wholly or in part of the five enumerated antibiotics is declared misbranded if it is not from a batch certified pursuant to Section 507 of the federal act.

3. Section 15(m), (n), (o) and (p) have been rewritten to provide for addition or removal of a dangerous drug from prescription requirement, by regulation, to require the prescription legend statement on the label of a Rx drug, and assure that no interference with federal or state narcotics laws ensues from the provisions of this section.

As in all human endeavor, the efforts of the Committee undoubtedly reflect human frailties and possibly some evidence of opinion.

It is well beyond the realm of reality to find complete agreement on the subject of how a bill should be worded or even what the exact content should be.

I do not believe that it was the intent of the Committee or the Association that the revision must be adopted verbatim. The intent is to furnish a model law which is the starting point toward uniform interpretation and administration of state food and drug and cosmetic

laws. This is the purpose of the Association of Food and Drug Officials of the United States. The Uniform Bill, I believe, is the cornerstone of any effort to promote uniformity of interpretation administration and enforcement of food and drug law at the state and local level.

Before I leave the subject, I wish to express my appreciation of the efforts expended by the members of the Committee and to identify them: Earnest Constable, North Carolina; James McDoughty Jr., Texas; Eugene H. Holeman, Tennessee; Donald J. Mitchell, South Dakota; Clayton P. Osgood, Maine; and James C. Pearson, United States Food and Drug Administration. **[The End]**

STRONTIUM-90 IN DIET

The strontium-90 content of a typical diet of an average 19 year old boy in the Washington, D. C. area is being measured by the Food and Drug Administration in a series of "market basket" samplings.

FDA said that samplings in May, August and November of 1961 have yielded three important results: (1) a finding that during 1961 the strontium-90 intake from the total diet, including milk, was only six per cent of the average daily intake considered acceptable for a lifetime by the Federal Radiation Council; (2) a finding that about half of the strontium-90 content of a market basket of foods will be discarded with the garbage, when foods are prepared for the table in the usual manner; (3) the obtaining of additional basic data against which to measure any increase in strontium-90 in foods.

Samplings are being made quarterly. Samplings so far analyzed do not reflect fall-out from the recent Soviet nuclear weapons testing. It is probable that results of these tests will not show up until the May, 1962 sampling, FDA said.

In this survey, complete "market baskets" of foods are purchased from four large chain stores in the area and analyzed for strontium-90. Foods selected are those recommended in the Department of Agriculture's "moderate income plan" as nutritionally adequate for this age group. A 19 year old boy consumes on the average about 55 pounds of food and drink per week—more than any other age group, FDA said.

A market basket for one week's food weighs about 60 pounds. Of this, about 10 per cent is garbage. This garbage or waste is made up of bones, fat, coffee grounds, fruit and vegetable skins, etc. It is also analyzed for strontium-90. The waste has been found to contain about half of the total radioactivity in the whole sample. The largest concentration of strontium-90 was in the bones, with smaller but still important amounts accounted for by the fruit and vegetable waste.

The Federal Radiation Council guideline for an acceptable daily intake of strontium-90 when averaged over one year is 200 micro-microcuries. The average daily intake of strontium-90 form the edible portions of the "market basket" diets samples so far is 11.5 micromicrocuries.

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

February Drug and Device Seizures.—Twenty-six actions were instituted in January against misbranded or adulterated drugs and devices.

Included in the products charged with false and misleading claims were medicines for the treatment of ulcers, anemia, liver and kidney disorders and cancer, and nostrums listing numerous ills and disorders.

Other seizures involved substandard vitamins, drugs and medicated feeds; physicians' samples repacked without the labeling which the law requires; cold tablets containing antihistamines without adequate warnings against use in pathological conditions; a counterfeit hormone; a number of drugs and medicated feeds marketed without new-drug safety clearance; noncertified penicillin preparations and prescription drugs without the required prescription labeling.

Food Seizures.—Approximately 459 tons of contaminated food were seized in 38 federal court actions during the month of January. Filthy and spoiled food accounted for more than one-half of this (292 tons), including 222 tons of rodent-contaminated wheat; 18 tons of rice and flour and flour stored under insanitary conditions; 12 tons of insect-infested green coffee; and almost 10 tons of maggot-infested tomatoes. The remaining contaminated or decomposed foods included macaroni, hush puppies, eggs, mixed fruit, gelatine and nuts.

In the "health protection" category, almost 154 tons of soybeans and 7.5 tons of alfalfa meal were seized because of pesticide contamination. Nonpermitted food additives resulted in three seizures totaling almost 3 tons.

A total of 9.5 tons of food was seized in 16 actions charging short weight or short volume, that label information required by law was absent, hard to find or hard to read, or that the products were substandard. Products short of labeled contents included coffee and chicory, chocolate candies, salad dressing, peanut butter, nut nuggets, dietary formula, butter and oleomargarine. Butter, egg noodles and canned cherries were seized because of failure to comply with official standards.

Voluntary Actions by Industry.—One hundred forty-four voluntary compliance actions were reported in January, in categories as follows:

Adulterated food destroyed or converted to feed—115 tons, 69 actions.

Adulterated drugs and cosmetics destroyed—value $984,421, 41 actions.

Plant improvements—actual or estimated costs $967,395, 34 actions.

One of the largest voluntary actions was taken by a California firm which dumped 20 tons of cherries that had become insect-infested and decomposed due to weakening of the brine solution in which they were packed.

A warehouse in South Carolina consolidated three of the firm's branches, at a cost of $500,000, to eliminate objectionable sanitary conditions of the old buildings which were in poor repair.

A Louisiana firm spent $112,000 on new equipment for weighing, packing, sealing, labeling and boxing, and for a new grinder for spices. The firm moved this equipment into a new building, costing $150,000. The total amount of improvement was given at $262,000.

Several major improvements and new installations of warehouses, food plants, and a cotton mill in California were reported. All of the work was done to insure sanitation.

President's Message on Consumer Protection.—In a special message to Congress on consumer protection, President Kennedy has recommended new legislation to strengthen and broaden existing laws in the food and drug field. He would authorize the Department of Health, Education and Welfare to require proof of efficacy for new drugs and therapeutic devices, as well as safety. He advocated assigning generic names to drugs, requiring batch-by-batch testing and certification of all antibiotics, requiring cosmetics to be tested and proved safe before they are marketed, and providing for more effective inspection of food, drug and cosmetic manufacturing plants.

In addition, the President would authorize the FTC to require that prescription drug advertising directed to physicians disclose the ingredients, efficacy and any adverse effects of such drugs. The President proposed a broadening of the Meat Inspection Act's coverage to promote adequate inspection of all meat slaughtered in the country. Other legislative recommendations dealt with antitrust and trade regulation laws administered by the Justice Department and the FTC.

"It is time to give American men, women and children the same protection we have been giving hogs, sheep and cattle since 1913, under an act forbidding the marketing of worthless serums and other drugs for the treatment of these animals," commented Mr. Kennedy in his recommendations for strengthening regulatory authority over food and drugs.

In regard to packaging and labeling abuses, the President stated: "Just as consumers have the right to know what is in their credit contract, so also do they have the right to know what is in the package they buy. Senator Hart and his subcommittee are to be commended for the important investigation they are now conducting into packaging and labeling practices.

"In our modern society good packaging meets many consumer needs, among them convenience, freshness, safety and attractive appearance. But often in recent years, as the hearings have demonstrated, these benefits have been accompanied by practices which frustrate the consumer's efforts to get the best value for his dollar. In many cases the label seems designed to conceal rather than to reveal the true contents of the package. Sometimes the consumer cannot readily ascertain the net amount of the product, or the ratio of solid contents to air. Frequently he cannot readily compute the comparative costs per unit of different brands packed in odd sizes, or of the same brand in large, giant, king size or jumbo packages. And he may not realize that changes in the customary size or shape of the package may account for apparent bargains, or that 'cents-off' promotions are often not real savings.

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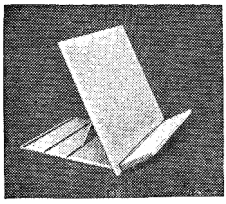

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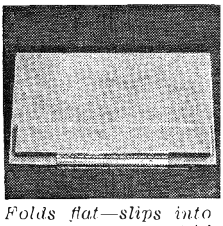

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