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Food Drug Cosmetic Law JOURNAL

Papers Presented at 1962 Meeting, Division of Food, Drug and Cosmetic Law, American Bar Association

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

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

FAO-WHO Conference on Food Standards.—*Franklin M. Depew,* President of the Food Law Institute, has accepted the invitation to attend the FAO-WHO Joint Conference on Food Standards which was extended by the Directors-General of the Food and Agriculture Organization and the World Health Organization of the United Nations. Mr. Depew will attend the Conference in behalf of the Food Law Institute. It will be held at the Palais des Nations, Geneva, Switzerland, during the week of October 1-6, 1962.

This important Conference, the first of its kind sponsored by these organizations, has been called for the purpose of considering plans to further food standards work on an international basis and to make available in unified form all internationally acceptable food standards, with the expectation that this will promote the international trade in food, protect the consumer and assure fair practices in the food trade.

About This Issue.—Although we have good provisions for regulating food additives, pesticide chemicals and color additives, there must be an effective means of assuring compliance. *William W. Goodrich,* Assistant General Counsel for Food and Drugs in the Department of Health, Education and Welfare, in an article which appears at page 516, speaks out in favor of expanding factory inspection authority.

A well-known lawyer in the field, *Vincent A. Kleinfeld,* points out several differences between the Food Additives Amendment and the Color Additive Amendment, in an interesting paper which appears at page 523.

Paul S. Willis, President of the Grocery Manufacturers of America, Inc., of New York City, has extended to the JOURNAL the courtesy of supplying for publication a series of questions and answers on legal and administrative industry problems under the Federal Food, Drug and Cosmetic Act. *Winton B. Rankin,* Assistant Commissioner of Food and Drugs, was prevented by urgent official duties from addressing the GMA Midyear Meeting on June 19, 1962, but he kindly consented to answer a series of questions of interest to that industry. We believe these questions and answers, which appear at page 534, will also be of interest to our readers.

Present enforcement of the Federal Hazardous Labeling Act is discussed in a report which begins on page 539 by *Charles P. Orr,* a food and drug officer in the Division of Federal-State Relations.

The Commissioner of Food and Drugs, *George P. Larrick,* reports on the "Scope and Responsibility of Government in Development and Regulation of Chemical Additives for Food" on page 548.

In an article at page 553, *John L. Harvey,* Deputy Commissioner, Food and Drug Administration, expertly explains this administration's long planned omnibus bill, which is comprised of H. R. 11581 and H. R. 11582.

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Journal

The Case for the Factory Inspection Amendment

By WILLIAM W. GOODRICH

This Paper Was Delivered Before the Division of Food, Drug and Cosmetic Law of the American Bar Association Section of Corporation, Banking and Business Law in San Francisco, California on August 8, 1962. Mr. Goodrich Is Assistant General Counsel for Food and Drugs, Department of Health, Education and Welfare.

OF ALL THE PROPOSALS for strengthening the Federal Food, Drug and Cosmetic Act, the most basic is the one to provide realistic and meaningful factory inspection authority.

We have good provisions to deal with grave problems such as food additives, pesticide chemicals and color additives. We are proposing improvements in the control of new drugs, new therapeutic devices and new cosmetics.

But all this effort is futile, if the laws enacted and the improvements proposed provide no means of assuring compliance. Indeed, such a simple requirement that the label of a food fabricated from two or more ingredients must name the ingredients cannot be fully enforced without factory inspection to determine what is being used in the food.

"Inspection Is Good for Others"

Nonetheless, there are many movements now underway by the food industry, the cosmetic industry, parts of the drug industry, the pharmacy profession—indeed by almost everyone regulated by the

Federal Food, Drug and Cosmetic Act—to make sure that any extension of the factory inspection authority will not apply to them. Only the manufacturers of prescription drugs seem reconciled to some extension of inspection authority, but even they are advancing proposals to circumscribe the inspection in numerous ways.

Recently, I read in a trade paper a report of a speech by an association executive who apparently thought any inspection whatsoever was an unauthorized intrusion of government in strictly private affairs. Others, while not going back quite that far, are conjuring up extreme possibilities to resist any meaningful inspection and are attacking the proposals that have been made on the ground that they are unconstitutional—or worse. Some say that they would agree to any extension of inspection authority if a need could be shown for it, but that thus far no case has been made for the need.

History of Inspection Authority

In showing this need, it is first essential that we review how we got to the present situation.

Authority for compulsory inspection originated with the 1938 Act. Its justification was largely based on the need to visit manufacturing and processing plants to enforce the then new provisions making food, drugs and cosmetics adulterated if prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or may have been rendered injurious to health.

New drug controls became a part of the law in the final hours of its enactment, and no discussion at all occurred to relate these controls to inspection.

And as successive amendments appeared, insulin and antibiotics certification, prohibitions against unauthorized sales of prescription drugs, control of food additives, and a whole new law dealing with the labeling of hazardous household substances, the need for comprehensive inspection authority was not discussed in the new legislative settings. The basic authority in the Act was relied upon, and the Congress assumed that the authority was adequate to enforce the new laws they were writing.

Cardiff (344 U. S. 174) upset any complacency there may have been about factory inspection. The Supreme Court held that an inconsistency in the law made the compulsory inspection authority void for vagueness.

Authority to Define Scope Left to Courts

The Congress then responded with an amendment which did not undertake to define in detail the permissible scope of the inspection authority. Inspection was authorized "at reasonable times, within reasonable limits and in a reasonable manner." But no attempt was made to detail what would be included in "reasonable" inspections of factories, warehouses, establishments, vehicles and all pertinent equipment, finished and unfinished materials, containers and labeling therein. The idea was to leave such questions to the courts to be settled in the factual setting of real cases—not hypothetical possibilities. The only court opinion that hinted at the scope of the authority up to that time was the *Crescent-Kelvan* decision of the Court of Appeals for the Third Circuit (164 F. 2d 582). There Judge Biggs, in a footnote, indicated without deciding that the more reasonable interpretation of the statutory language was that "inspection of a 'factory' include the inspection of everything to be found therein relating to the business of the factory."

That court entertained no doubt as to the constitutionality of a statute providing for the inspection of places of business dealing with food and drugs.

But before the 1953 Amendment was finally enacted, the floor debates in the House of Representatives created the doubts about the authorized scope of inspection on which the present situation rests. The managers of the bill expressed their opinions that it would not be a reasonable inspection to demand access to formula files, complaint files, personnel records, financial records and many other things.

Commissioner Crawford's Comment on Amendment

After enactment, former Commissioner Crawford issued a press release acknowledging that Congress did not want to make inspection of records compulsory. He made it clear that our inspectors would continue to seek all needed information to assure compliance with the law, but that no prosecutions would be attempted in the areas where the Congress had indicated the mandatory inspection should not extend.

Thereupon many companies and some trade associations adopted as their policies the position that the inspectors would be held to the letter of the law.

"Guided Tours"

The result is as former Secretary Ribicoff recently stated it to the House Committee on Interstate and Foreign Commerce:

All too often inspectors are treated to a guided tour through the establishment. They are refused access to formula files, complaint files, shipping records, and a great deal more information that is absolutely essential for them to see in order to determine whether products are being produced in compliance with law.

. . .

Every working day a food, drug, or cosmetic manufacturer refuses to give our inspectors access to information needed to safeguard the public. These refusals are not restricted to the fly-by-night operator but extend to some of the very largest manufacturers in this country.

Number of Refusals Is Long

The list of refusals is indeed a long one. It covers all types of business. It covers all kinds of requested information. And it all arises from the uncertain situation that prevails under existing law.

In addition to asking the Congress to re-examine and to legislate on this problem, we have taken what steps we could by administrative action to improve the situation.

As the reports of refusal of inspection increased in numbers and in variety of questions involved, we centralized them to be sure exactly what was going on. We found that some firms with a fixed policy against inspection were applying for effective new drug applications, certification of antibiotics, insulin, and coal-tar colors, exemptions from certification, food additive regulations and hazardous substance labeling exemptions. They were presenting data to us to support these requests, asking us to rely on it, but at the same time denying our inspectors the right to inspect to determine the accuracy of the data. So long as the refusals of inspection continue, we will—wherever the refusals are germane to the exercise of our statutory responsibilities—use every administrative means to withhold the new drug applications, the exemptions, the regulations and the certificates.

Public Attention Attracted by Thalidomide Episode

The thalidomide episode has sharply focused public attention on the need for closer control over investigational drugs—and a basic part of any such control is the right of access to the records which underlie the investigational use program. Regulations to be announced shortly will impose proper record keeping and inspectional access as conditions on the distribution of investigational drugs.

The same problem as that involved in the use of investigational drugs arises also in protecting the public against hazards from new drugs we have approved for marketing, food additives authorized for use by regulations, and pesticide chemicals for which stringent toler-

ances have been prescribed. Inspection—including the inspection of records—lies at the heart of any enforcement.

Is Desired Inspection Power Unconstitutional?

Two of our leading lawyers have placed important segments of the food industry in very strong opposition to any extension of inspection. They claim the inspection requested is unconstitutional and that there is no need for it.

The constitutional argument was met in 1953 by a most extensive House Committee report. And it is self-defeating, because these very advocates concede that such inspections can be authorized for drug firms and can even be conducted in food plants by local health authorities. So the problem of constitutionality clearly depends on the reasonableness of the inspection. And what is reasonable depends on the facts in each particular case.

We must remember that the type of inspection proposed is not one involving self-help. No authority is sought to use force to make an inspection. No authority is sought for any inspector to "rummage" through private papers. If access to anything in the plant is denied, the burden is on the government to establish in an enforcement case, a suit for an injunction or a criminal prosecution, that its inspection request was reasonable and was within the scope of things relating to actual or potential violations of the Act.

Major Argument Against Extended Authority

The major argument against the need for expanded authority to inspect food establishments is that such inspections are confined to conditions of sanitation; that no possible health hazard exists; and that the inspectors have ample authority to observe the sanitary conditions of the plant under existing law. On this ground, it is said that any extension of inspection rights in drug manufacturing plants is unwarranted for food establishments.

Safe Use of Chemicals Is Major Concern

This argument wholly ignores the paramount problem of the day —the safe use of a multitude of chemicals in our foods.

As former Secretary Ribicoff said to the House Committee:

> [The new] amendments added to an already broad statute which touches significantly upon vital health areas. We are required to establish and police safe

tolerances for known poisons in our food supply . . . Yet we are being denied access to the information in the manufacturing establishment to tell us whether our tolerances are being met . . .

It is no answer to say that we can observe the manufacturing process and the raw materials and that we can analyze the end product. First, we cannot maintain a continuous inspection to station an inspector at the point of manufacture each time a food additive is used. Second, objective analysis is a very expensive and uncertain way to enforcement. Thirdly, many petitioners for food additive regulations —including some lawyers who shall remain nameless—have urged us to establish regulations without adequate methodology, arguing that our "broad factory inspection powers" make the methodology unnecessary.

Merely A "Fishing Expedition" Argument

In final analysis, the argument against inspection is that it would constitute a "fishing expedition." Since the attorney who used that catch phrase so many times quoted so liberally from Supreme Court cases, perhaps I may be excused for borrowing and paraphrasing from the same source a quotation somewhat more directly in point.

The last stand of those opposed to discovery in civil cases was made on the"fishes" ground—those who might be caught are naturally against the entire expedition. Adapting the language to the present situation, it might be said: "no longer can the time-honored cry of 'fishing expedition' serve to preclude [the responsible government agency] from inquiring into the facts underlying [compliance with the law]." *Hickman v. Taylor,* 329 U. S. 495, 507.

In that case, the interest of achieving substantial justice between two private litigants required full and complete disclosure.

Inspections Point Out Danger Areas

We submit that the public interest expressed in the Federal Food, Drug and Cosmetic Act requires an inspection law which permits the regulatory agency an opportunity to observe all things that bear upon compliance with the law. Contrary to what has been said, inspection is not solely concerned with collecting evidence for a criminal charge. We make thousands of inspections annually, and we bring only a few hundred criminal cases. Not all of them are related to the findings of a mandatory factory inspection. Most inspections are helpful in pointing up danger areas, so that violations

can be avoided or corrected before interstate shipments are made. The House Committee stressed this feature in 1953, and it is well to recall it today.

Many members of the two associations so vehemently opposed to the inspection amendments operate parts of their business under the continuous inspection of the Meat Inspection Service. Others voluntarily submit to the inspection service of the United States Department of Agriculture for the processing of agricultural products. They do not object to inspections by the military services, who are their customers. They impose inspection requirements on their suppliers to protect themselves against violations arising from the raw materials, or even the completed goods, which they distribute. And their books and records are open to administrative subpoena under a number of federal and state laws, most of which are concerned with economics and not health.

Why then do they object to inspection rights by the Food and Drug Administration which stands as a representative of the consumer? We have found no satisfactory answer to this question. We think the need is real. And we will continue with all our abilities to urge the Congress to meet the need. **[The End]**

STANDARDS OF IDENTITY FOR TUNA FISH COMPLETED

Canned tuna fish prepared from dark meat must be labeled "dark," and tuna packed in water instead of oil must be labeled to show the words "in water" as a part of the name, according to a food standards ruling published by the Food and Drug Administration.

FDA said the new labeling requirements were made final after a review of objections to a tentative order published March 31, 1961, based on evidence presented at public hearings.

Lighter colored canned tuna is generally considered more desirable and there have been consumer complaints in the past because rather dark tuna was labeled "light." Under the standard, tuna will be required to be labeled "white," "light," or "dark." In the case of blends of light and dark tuna the label will show both color designations. Color designations are determined by measurements made on a special optical instrument.

The new labeling requirements become effective January 5, 1963, and complete the official definitions and standards of identity for tuna fish. These definitions and standards cover composition, fill of container and labeling of canned tuna fish.

Conflicts in Legislation and Regulations

By VINCENT A. KLEINFELD

The Author, a Member of the Washington, D. C. Law Firm of Bernstein, Kleinfeld & Alper, Delivered This Paper at the Annual Meeting of the Institute of Food Technologists in Miami Beach, Florida, June 11, 1962.

NO PARTICULAR ASTUTENESS is required on the part of even a casual observer of national affairs to conclude that during the past several decades the role of the federal government in our daily lives, personal as well as business, has steadily increased. Disagreement can be found to exist among many of us as to the merits or demerits of this increased role of the government, but the fact remains that it has occurred.

A specific area of interest to all of us here, where this paternalistic hand has been frequently felt, relates to regulation of the food, drug and cosmetic industries. From 1906, when federal intervention in this area was first initiated, to the present, the government has continually extended its control over these industries. This extension has been exercised, not only by increasing the scope of the legislation to take in more and more segments of the industries, but also in such a way as to change considerably the type of regulation involved—to adopt an entirely different concept and approach. Initially, the role of the federal government in regulating the industries was that of a watchdog. The government would observe the activities of the industry and, when practices believed to be improper occurred, would seek to curb these apparent evils by the institution of court cases in which the government always carried the burden of sustaining its charges. This type of enforcement activity was the rule up until comparatively recently.

The first real departure took place in 1938 when the present Federal Food, Drug and Cosmetic Act was enacted containing the

"new drug" and "coal tar color certification" provisions. These, in effect, changed the procedures from one of enforcement by policing to one of licensing, even though that nasty word was not employed. The applicable provisions were to the effect that before a new drug or a coal tar color could be placed upon the market, it had to be affirmatively cleared by the Food and Drug Administration. A failure to obtain prior approval could of itself be the basis for a court judgment in favor of the government.

Two New Amendments

More recently, additional licensing provisions have been added to the Federal Food, Drug and Cosmetic Act. These, as you well know, are the Food Additives Amendment and Color Additive Amendments. The former, enacted in 1958, contains an important provision which still adheres (at least in form) to the original philosophy of enforcement, as distinguished from licensing; that is, a manufacturer has the opportunity to decide for himself whether a particular ingredient used in his food products is or is not a food additive. If the manufacturer concludes that a specific substance is generally recognized as safe under the conditions of its intended use, he need not file a food additive petition for it. In this respect, the Flavor Extract Manufacturers Association's decision to stand behind its panel of experts in concluding that certain emulsifiers, quinine compounds and fumaric acid when used in flavors are generally recognized as safe, despite the Food and Drug Administration's apparent view to the contrary, is worthy of note.

Government Must Prove Substance Unsafe

True, if the Food and Drug Administration disagrees with a manufacturer's conclusion it can take him to court. However, even though the manufacturer may have an uphill fight in the courts, the burden of showing that the substance involved is not generally recognized as safe is still one that must be carried by the government. This is in line with the historical concept of the government as a watchdog, more so than as a dispenser of licenses.

Under the Color Additive Amendments, enacted in 1960, only two years after the Food Additives Amendment, even this faint gesture to the affected industries is withdrawn. The manufacturer is not permitted to decide for himself whether a particular substance is or is not a color additive by determining whether it is generally recognized as

safe for its intended purposes. The only leeway given the manufacturer, in the case of color additives, is to decide whether the substance is capable of imparting color to a food, drug or cosmetic. Not only is that a very limited concept, but it is, for all practical purposes, obviously an unreal one. This is because the statutory definition of a color additive does not take into consideration the quantity or manner of use of the substance in a food, drug or cosmetic, and it is almost impossible to imagine any item which, under any or all conceivable circumstances, would not be capable of imparting color, including "black, white, and intermediate grays," to a "food, drug or cosmetic or to the human body or any part thereof." Immediately, therefore, it is apparent that there is a basic and fundamental difference between the concepts involved in the definitions of a food additive and a color additive. The former is dependent upon the conditions of the intended use of a substance; the latter is not dependent upon such conditions.

Notable Differences in Two Amendments

Significant and interesting differences exist in the Color Additive Amendments themselves regarding their applicability to foods, drugs and cosmetics. While the definition of a color additive contained in the law seemingly applies equally to foods, drugs and cosmetics, this definition, as modified by other sections of the amendments, turns out to be far less embracive as applied to drugs. As stated, the basic statutory definition of a color additive is anything capable of imparting color to a food, drug or cosmetic or the human body. The only exception recognized by the definition is one which is left to the discretion of the Secretary of Health, Education and Welfare; that is, the Secretary may by regulation determine that a substance capable of imparting color is not a color additive if he finds that it is used, or is intended to be used, solely for purposes other than coloring.

This exception, as you will note, can be granted only by the Secretary. No manufacturer is free to make the decision for himself without concurrence of the government. However, when the provisions of the Color Additive Amendments which apply specifically to drugs are examined, there is a major modification in the applicability of the definition of color additive. Here, a substance becomes subject to the Color Additive Amendments only if its intended use in drugs is for the sole purpose of coloring. This is a complete turnabout of the basic definition of a color additive. As applied, this modification of the definition places the burden back upon the government to show in a court,

not in an administrative hearing, that the substance, as intended for use in or on drugs, is used solely for coloring purposes. This turnabout in the application of the definition of a color additive was clearly intentional on the part of Congress, and is a carry-over from the coal-tar color provisions made applicable to drugs when the Federal Food, Drug and Cosmetic Act was enacted in 1938.

Excluded Categories

Both the Food Additives Amendment and the Color Additive Amendments provide for the exclusion of certain categories of substances from their coverage. For food additives, these include pesticide chemicals in, on or intended for use on, raw agricultural commodities, and substances used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment under the Federal Food, Drug and Cosmetic Act, the Poultry Products Inspection Act or the Meat Inspection Act. While little difficulty or controversy has been encountered relative to pesticide chemicals, considerable difficulty and misunderstanding exist as to the meaning and import of the "prior sanctions." I wonder whether the government official who declared, in 1958, that the Food Additives Amendment "is a relatively simple law" is still of the same opinion.

Several Inconsistencies Pointed Out

At last year's meeting of this Institute, in a speech delivered by an official of the Food and Drug Administration, it was stated, in connection with the Food Additives Amendment, that "A prior sanction granted one firm for a specific use of a substance applies equally to all others using the same product in the same way." This view seems to me to be a reasonable and valid application of the concept of the prior sanction. However, the Food and Drug Administration has not applied this concept in a manner consistent with its own definition. An example of this inconsistency is displayed by the manner in which the Food and Drug Administration has sought to regulate organic arsenicals used in medicated animal feed. Many such compounds were, prior to 1958, cleared under the new drug provisions of the Federal Food, Drug and Cosmetic Act. In addition to the fact that new drug clearance had been obtained for the drug substance, the Food and Drug Administration had also granted supplemental new drug clearance to feed manufacturers to incorporate the drug in feed. However, commencing in 1960, the Food and Drug Administra-

tion refused to continue clearing supplemental new drug applications on the basis that the product could not be cleared under the Food Additives Amendment because of the alleged applicability of the Delaney Clause.

This position seems wholly inconsistent with the concept of a prior sanction held by the Food and Drug Administration itself. If Feed Manufacturer "A" has a prior sanction for use of Product X, then, under the Food and Drug Administration's own pronouncement that this prior sanction "applies equally to all others using the same product in the same way," it would appear that the sanction is also available to Feed Manufacturer "B." More important, because of "A's" prior sanction, Product X should not be considered a food additive when it is used by "B" in the same manner as it is used by "A." It may still be a new drug, subject to new drug clearance, but it should not be a food additive. Nevertheless, the Food and Drug Administration has insisted that the Food Additives Amendment applies to Product X when used by "B" even though the amendment does not apply to the same product when used by "A" in the same way. This position is insisted upon notwithstanding that "B's" facilities and controls may be as good as, or better than, "A's." The position of the agency has resulted in a most anomalous and inequitable situation—a situation not contemplated by the framers of the Food Additives Amendment, and one which is not justified by logic or law. Certainly it does not appear to be consistent with the statement in the report of the Senate Committee on Labor and Public Welfare that:

> Your committee, which has the responsibility in the Senate of considering all legislation primarily relating to the health of our people, is well aware and thoroughly approving of the vast amount of time and energy which Congressman Delaney, author of that amendment, has devoted to the fight against cancer and to our attempts to find its cause and cure. We have no objections to that amendment whatsoever, but we would point out that in our opinion it is the intent and purpose of this bill, even without that amendment, to assure our people that nothing shall be added to the foods they eat which can reasonably be expected to produce any type of illness in humans or animals. We applaud Congressman Delaney for having taken this, as he has every other opportunity, to focus our attention on the cancer-producing potentialities of various substances, but we want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability. In short, we believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration.

Can anyone who has had a "Delaney Clause" problem believe that this opinion has been adhered to?

Application of "Prior Sanctions"

Another seeming inconsistency involved in the application of the concept of "prior sanctions" was mentioned in a recent speech by an official of the Food and Drug Administration. The official stated that there is a growing tendency for manufacturers to look with favor upon food additives listed in a regulation, and that "this attitude has resulted in requests . . . for the establishment of formal food additive regulations to cover prior sanctioned uses" of substances. It is questionable, however, that a food additive regulation may legitimately issue with respect to a substance which is not a food additive. By definition, of course, prior sanctioned items are not food additives. Consequently, is it not beyond the authority of the Food and Drug Administration to clear a prior sanctioned substance for an identical use as a food additive?

Is There a Real Hazard in Packaging Materials?

One unfortunate, and not generally foreseen, development under the Food Additives Amendment has been the fact that such considerable sums have had to be expended by industry, and so much valuable effort utilized by the government, in dealing with traces and possible traces of chemicals employed in packaging materials. It is doubtful that the results have warranted this tremendous expenditure of time and money which, perhaps, could have been employed to greater advantage in considerably more important food additive areas. It would be interesting to determine whether, before the passage of the Food Additives Amendment, there was any real evidence of hazard to the public health caused by incidental food additives, and whether any evidence of such danger has since been revealed. Can it be fairly stated that a real problem exists? If not, it may be that consideration should be given to excluding food packaging materials from the coverage of the Food Additives Amendment.

Turning to the applicability of the Color Additive Amendments to foods, bearing in mind the potential applicability of the Food Additives Amendment as well, certain other inconsistencies (some intentional, some perhaps not) become apparent. Between 1958, when the Food Additives Amendment became part of the Federal Food, Drug, and Cosmetic Act, and 1960, when the Color Additive Amendments were enacted, but for the existence of the coal-tar color certification provisions of the Act there would have been no problem in applying the provisions of the Food Additives Amendment to all

ingredients used in the preparation and packaging of foods. These, of course, would include all ingredients falling within the Color Additive Amendments' definition of a color additive. However, Congress, in its wisdom, concluded that "an integrated and internally consistent basis for determining the admissibility of any coloring material for use in foods, drugs or cosmetics (other than hair dyes)" should be promulgated.

As a result, there are today in effect two separate portions of the Federal Food, Drug and Cosmetic Act which govern the licensing of many substances for use in food. Each of these portions has its own separate procedure and regulations. While in their essentials these procedures and regulations may not differ significantly (although this is merely a guess since only proposed regulations have thus far issued for color additives), they will nevertheless present a confusing and perplexing situation to a manufacturer who will frequently have to deal with both sets. Even at the present time, a comparison of the Food Additive regulations with the proposed Color Additive regulations discloses several stylistic differences and even some differences of substance. For example, while it is clear that under the Food Additives Amendment permissible tolerances for various substances may eventually become filled, which by implication would prevent those substances from being used in other foods or for different purposes, there is no demand made upon a petitioner to speculate with respect to others who may utilize the substance and as to the quantities that will be consumed in man's diet. Under the proposed Color Additive regulations, however, there is a requirement that a petition contain:

> . . . complete data which will allow the Commissioner to consider . . . the probable consumption of, and/or other relevant exposure from the additive and of any substance formed in or on food, drugs, or cosmetics because of such additives; and the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in the diet, including, but not limited to, food additives and pesticide chemicals for which tolerances or exemption from tolerances have been established. [Part E of proposed petition]

Not only does this potential requirement represent a substantial increase in the mass of data needed for a color additive petition over that which must be presented in a food additive petition, but it seems to me to present an incalculable burden upon a petitioner and one which can never realistically be satisfied. Though this same "total effect" consideration is involved in the Food Additives Amendment, there it is handled as a consideration to be made by the Secretary, and data relating to this is not required to be supplied by the petitioner.

Differences in Clearance Procedure

Other differences exist also in the procedural pattern relating to the clearance, by the petition route, of food additives and color additives. Assume, for example, that a food additive petition has been accepted for filing by the government. This, I realize, is a difficult assumption for many people to make. The statute requires that, within 30 days of the date of filing, notification must be published in the *Federal Register*. Then, within 90 days of the filing of the petition (or 180 days if extended), a regulation must be forwarded for publication in the *Federal Register* specifying the conditions under which the additive may be used. This order is effective upon its publication in the *Federal Register*. But is the order really effective so that a manufacturer can rely upon it? No. Because within 30 days it is possible for an "adversely affected" person to raise objection to the order and these objections, if they state reasonable grounds in the judgment of the Food and Drug Administration and request a hearing, may result in a stay of the already effective order. At least, under these regulations, the petitioner is given an opportunity to reply to the objections.

More Realistic Approach

Under the Color Additive proposed regulations, a more realistic approach is followed, and one which has customarily been employed in Food and Drug Administration proceedings relating to the promulgation of substantive regulations. For color additives, the regulation which must issue within 90 days (or 180 days if extended) after filing of the petition cannot be made effective until at least 30 days have passed after its publication in the *Federal Register*. During this 30-day period, objections may be filed which, of themselves, operate to stay the effectiveness of the regulation. This procedure at least has the benefit of not permitting a manufacturer to rely upon the "immediate effectiveness" of an order which, in reality, is not immediately effective at all. Unfortunately, in the case of color additives, no means is provided by regulation under which the petitioner is required to be informed of the filing of objections.

Time Differences Involved

Another procedural difference between food additive and color additive clearance relates to the time element involved when court review may be sought of the reasonableness of a regulation. Under the Food Additives Amendment, judicial review of an order following

a hearing may be had if applied for within 60 days after the entry of the final Food and Drug Administration order. This review may be sought in either the court of appeals of the circuit where the adversely affected person resides or has his principal place of business, or in the Court of Appeals for the District of Columbia. Review of Color Additive final orders after a hearing may be obtained if sought within 90 days of the date of the order, but this review can be applied for only where the person resides or has his principal place of business. It cannot alternatively be sought, in the first instance, in the District of Columbia. None of the differences between the two Acts are of tremendous import. But is there any reason for creating any distinctions in the procedures for clearing food and color additives? I can see only one reason, presumably of the greatest importance; it is differences such as these which provide the lawyer with greater means for his otherwise skimpy livelihood.

Procedure Used in Evaluating Additives

In addition to the fact that burdens may be cast upon a petitioner seeking clearance for a color additive different from those faced for clearance of a food additive, there are other differences in the statutory pattern relating to the procedure for evaluating the additives. One of these significant differences is the fact that, under the Color Additive Amendments, provision is made for the appointment of an advisory scientific committee whenever a "Delaney Clause" problem is thought to be presented by a particular color additive. This referral can be sought by anyone who will be "adversely affected." In the case of the proposed issuance of a regulation, this might include all consumers. Once a request for referral to the advisory committee is made, under the statutory language the Secretary "shall forthwith appoint an advisory committee" and refer to it all data pertaining to the carcinogenicity of the particular additive.

This reference to an advisory committee can prove of real value to industry in that it provides a basis for sound, objective, scientific judgment. Certainly industry, as a practical matter, cannot lose by this procedure. It is true that theoretically referrals could be requested by "fringe" groups who despise the legitimization of any additives in food. The real danger of such an occurrence is not too great. This is because under the authorization contained in the Color Additive Amendments pertaining to the setting of fees for admitting color additives to listing and certification, the Secretary has proposed that an advance deposit of $2,500 be paid before a problem will be referred

to an advisory committee, and it is contemplated that all other costs of this committee will be borne by the person seeking the referral. The imposition of this sizable fee may be a practical means of controlling requests for referrals. And if it is contended that industry does not know what a committee is doing or what it is relying upon, the short answer is that when the Food and Drug Administration determines to obtain the views of some outside individuals or group, it can do so and has done so regardless of any statutory directive.

Differences in Fees

The statutory authorization relating to fees represents another interesting difference between the Color Additive Amendments and the Food Additives Amendment. Perhaps this is the important reason for specifically withdrawing color additives from coverage under the latter law, for there are no fees assessable on items subject to the Food Additives Amendment. Precedent has existed for a number of years concerning fee payment under the Federal Food, Drug and Cosmetic Act. Coal-tar color certification, insulin and antibiotic certification all were, and are, performed on a fee basis. But, the fees involved in those circumstances are insignificant in comparison to the fees proposed to be charged for color additive proceedings. In addition, the range of the fees proposed under the Color Additive Amendments appears broader than was perhaps contemplated by Congress. For example, a question may very well exist as to the validity of the $2,500 fee proposed to be levied prior to referral to an advisory committee or with respect to the fee of $250 required as a condition precedent to the filing of objections to the issuance, amendment or repeal of regulations.

Another point of comparison between the Food Additives Amendment and the Color Additive Amendments worth considering relates to the question of allocating specific uses for color additives. As mentioned briefly before, the Food Additives Amendment, while it deals somewhat with the question of limiting additives to particular foods or classes of foods, does not specifically enumerate the factors to be considered in allocating additives among the various foods. Under the Color Additive Amendments, several factors are specifically mentioned, including the economic factor of marketability. Interesting legal questions will be presented should the time ever come when allocation of a color additive is sought to be made on the basis of economic need.

Inconsistencies Promise Future Difficulties

It is only in a sketchy fashion that I have sought to point out some differences between the Food Additives Amendment and the Color Additive Amendments. The full impact of these important amendments has not been felt. It is only when these amendments become fully operative and there has been opportunity to live under both that the real and perplexing conflicts and inconsistencies will become apparent. I feel quite certain that even were there only one or the other of these amendments, difficulties of compliance would still be encountered. There being two amendments, these difficulties may very well be compounded. This much is true: as time goes by, and amendments to the Act are enacted and multitudinous regulations are issued, a food company will indeed have to be a Theseus to get through the labyrinth of food regulations. **[The End]**

FDA NAMES NEW ASSISTANT COMMISSIONER FOR SCIENCE

Appointment of Dr. Oral L. Kline as Assistant Commissioner for Science for the Food and Drug Administration was recently announced by Commissioner George P. Larrick. Dr. Kline was formerly Director of the FDA Division of Nutrition.

Commenting on the appointment Mr. Larrick said: "Dr. Kline has a national and international reputation in the fields of nutrition and biochemistry and is the author of many published papers in these fields. He is thoroughly familiar with the scientific problems and needs of the FDA. As Assistant Commissioner for Science, he will participate in the making of FDA policy and will be responsible for maintaining the scientific quality of FDA research in Washington and in field laboratories throughout the country."

In 1956 Dr. Kline received a distinguished service award from the Department of Health, Education and Welfare for "original and notable biological chemistry research and outstanding scientific contributions in the field of nutrition." The award followed his discovery that a deficiency of vitamin B_6 in prepared infant foods was the cause of convulsions in infants receiving these foods.

Research under his direction led to the first successful chemical measurement of vitamin D, a method now adopted as official by the United States Pharmacopoeia. More recently he has directed international studies in the use of radio active tracer compounds in the identification and measurement of vitamin B_{12}.

He was appointed to the Food and Drug Administration as a biochemist in 1936. Dr. Kline became Director of Research in the Division of Nutrition in 1950 and Director of the Division in 1959, after serving one year as Director of the Division of Food.

Federal Food Law Questions and Answers

Questions by PAUL S. WILLIS

Answers by WINTON B. RANKIN

The Following Food Industry Questions, Submitted by Mr. Willis, President, Grocery Manufacturers of America, Inc., Were Answered by Mr. Rankin, Assistant Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health, Education, and Welfare, on June 12, 1962

LABELING OF PACKAGES: Testimony at hearings before the Hart Subcommittee has called attention to various irregularities in the labeling of grocery product packages. The law prescribes what information must appear on the package. As regards the necessary "conspicuousness" of that information what is the FDA policy with respect to location and type-size of such information?

Answer: We believe that the information required by law to appear on food packages should normally appear on the main display panel in readable type; the size of type should bear a reasonable relationship to the other type used on that label. Over the years, we have seen labels where we could conclude that placing the mandatory information on other than the main panel would achieve the requirement of conspicuousness; the cylindrical can labels represent a case in point where many have the mandatory information immediately to the right of the main display panel. On the other hand, there are packages on the market where, in addition to not being on the main panel, the required information is not at all conspicuous because of size of type, being printed with nonessential information, or on parts of the package where the information would be noted only after a careful search.

This question is under consideration now. A possible solution would be to require that certain information such as net weight and ingredient statements be printed on the main display panel in type of specified size and to allow other required information such as the name and address of the manufacturer to appear at some other point on the package.

Enforcement Policy: Granted, that the government can and should aggressively prosecute any food law violation which involves a public health danger or a defiant breach of a significant requirement, does the FDA otherwise recognize a place for more moderate procedure where the violation is inadvertent and technical? If the manufacturer first discovers such a situation, does he necessarily place the FDA in the position of having to prosecute by seizure or suit, by the mere fact that he reports the situation and outlines his plans for voluntary correction of it?

Answer: By no means. The law does not contain a provision which requires prosecution for every violation which is encountered whether or not this be called to our attention by the manufacturer. As many of the members know, the FDA decides to recommend seizure or criminal prosecution only after careful evaluation of the facts and, in the case of the latter, we do give consideration to the views expressed at the informal hearing which we hold. Certainly, we believe that when any situation such as described in the question is encountered, it is good policy to promptly notify the FDA. There have been many instances where this procedure has been followed without involving legal actions.

Factory Inspection: A plant manager calls the management of his company, reports the arrival of an inspector from the FDA, and indicates that the latter, in connection with a plant sanitation inspection, wishes also to examine secret manufacturing formulas and financial records bearing on the validity of promotional offers. Although management sees a legal basis for refusing the formulas and financial information, it is curious to know why the FDA requires it and would willingly confer with higher agency officials to discuss the subject. Under the circumstances would the FDA insist that confidential matters of this nature must be revealed to its field inspectors or would it afford an opportunity for an official conference?

Answer: As a basic policy, we believe that when a Food and Drug Administration inspector makes an official inspection, he should acquire all of the necessary facts to enable a conclusion of whether or not the operation being inspected is in compliance with the terms of the law. We would not favor a procedure that required each inspection to be followed by a conference in Washington before we had the information needed to make a full evaluation of a firm's operations. Keep in mind that the same restrictions on revealing confidential information that apply to the Washington staff are equally applicable to our field personnel.

We should emphasize that the information we request during a factory inspection is solely for the purpose of helping to determine whether the requirements of the law have been met in the production and distribution of products subject to the statute involved. Complete information about what is going on is essential to the proper conduct of the FDA's activities and we have recommended to the Congress that the factory inspection provisions of the statute be changed so that we may get this information firsthand as it is needed.

Food Additives: A manufacturer's food package properly lists various ingredients each of which serves an appropriate purpose of preservation, flavoring, coloring, etc. A customer, about to receive shipment of a large order, tells the manufacturer that his continuing commodity guarantee of compliance with the Act is insufficient, that he must present in addition a statement from the Food and Drug Administration certifying that the chemical ingredients listed have been officially approved. The food and its ingredients are safe in fact and not subject to special food additive regulation. Can the manufacturer answer the customer's demand by a firm explanation that the FDA does not provide a certification procedure in this situation?

Answer: The inquirer is correct in that there is no certification procedure in the instances outlined. Nevertheless, we want to be as helpful as possible and if the manufacturer involved will write us a letter outlining in detail the composition of his product and will supply us with a copy of its label, we will then write to the manufacturer and tell him our views as to the status of that product in the light of the provisions of the law and the applicable regulations. Perhaps such a letter would be acceptable to the customer who is inquiring.

Food Additives Guaranty: A food manufacturer requests and receives from a food additive supplier a guaranty that use of the ingredient supplied will not cause the product to violate the Federal Food, Drug, and Cosmetic Act? Is the manufacturer entitled to rely upon that guaranty for complete exemption from liability under the Food Additives Amendment?

Answer: Only if the particular food additive is re-shipped by the food manufacturer without change. The supplier of the food additive cannot give any valid guaranty which would cover a manufactured food product of which his article is but one ingredient. Nevertheless, we believe that it is highly desirable for any food manufacturer to obtain ample assurance that the ingredients he uses are entirely suitable and legal for use.

Notice of Hearing: Having received a notice of hearing on a violation charging adulteration and misbranding of a shipment of his goods, a food manufacturer resolves to settle the matter promptly and directly. He writes FDA headquarters acknowledging the receipt of the notice from the local station, indicates that the charge is probably and unfortunately true and states in good faith that he is issuing directions for correction of the violation. He concludes with a request that the hearing be canceled as unnecessary under the circumstances. Is this an acceptable response to the notice?

Answer: The letter which the food manufacturer writes would be in this instance referred to the district office which issued the original notice of hearing. Unless some other response were received, the district office would regard the firm's letter as its answer to the hearing notice and make its recommendation on the basis of all of the facts at hand. It should be recognized that when a notice of hearing issues, the recipient is entirely at liberty to answer in writing if he so desires rather than appearing in person.

Sampling: A manufacturer has developed a new and different food product. Before undertaking an extensive marketing and advertising campaign he decides to test consumer acceptance of the item. In order to avoid prejudicing the consumer's reaction with a fancy package, by the impressive name of the manufacturer himself, or even by indicating the particular name or ingredients of the food, he packs it in a blank package, which indicates its weight and identifies the responsible survey operator as distributor. Samples are thereafter sent in interstate commerce to a random selection of consumers, together with a reply envelope for comment. Is this type of survey permissible where limited in time and place, or must the sample package of the product comply with all the requirements of the Act?

Answer: The sample package must comply with all of the requirements of the Act. Certainly, there is no requirement for a fancy package and the proposal to print the name and address of the survey operator as the distributor would be satisfactory. Additionally, however, there should be a statement of net weight, the common or usual name of the food, if any there be, and the list of ingredients.

Salvaged Merchandise: As a result of fire or flood damage several distributors of a manufacturer's packaged food products surrender substantial inventories of damaged merchandise for salvage operations, to mitigate the insurance carrier's loss. The manufacturer has reason to believe that the goods in their present containers have been

contaminated and he seeks to prevent their resale in that condition. May he safely repurchase them for recall and repacking? Should he in any event report the situation to local and federal food officials?

Answer: We believe that the firm should, in every case, report the situation to the food law enforcement officials who have jurisdiction. Where there is opportunity for salvage or whether this should be done on the spot or can be done at some other place, will normally have to be worked out on the basis of the facts in each case.

Bargain Size Package: A producer wishes to pass on to trade and consumers economies earned in the manufacture and sale of a larger size of his product. Accordingly, he distributes the larger size at a relatively lower per ounce price and marks it "bargain size." The trade generally reflects the relatively lower price of the larger package by following the retail price which the manufacturer can only suggest. A local price war involving the smaller size forces its price down so as to produce temporarily a lower per ounce price than that of the "bargain size." What can the manufacturer do to avert enforcement action against the product, which naturally brings harmful product publicity?

Answer: The manufacturer can review his entire labeling operation to be sure that he has not employed legends which could be rendered false or misleading because of the activities of others. Since the manufacturer cannot, in all cases, control the retail price at which his product is marketed, obviously he could not insure that a product labeled "bargain size" would always be a bargain. We can only recommend that he dispense with any such legend in his labeling.

This last question prompts the observation that, as a result of the regulatory action taken by the FDA during the past year against labeling violations, the President's Consumer Message to the Congress, and the hearing held by Senator Hart's committee, there has been very fine reaction on the part of the food industry generally to take a careful look at its labeling and packaging problems. In some instances, it is apparent that top management had not fully appreciated the significance of many of the labeling practices which had developed over the years, especially during the period when the FDA had not been able to be active in this area. We have many instances of marked changes being made as a result of this careful scrutiny. Perhaps each firm should set up a timetable for doing this at periodic intervals just to be sure that something hasn't slipped by to cause difficulty later.

[The End]

The Federal Hazardous Substances Labeling Act

By CHARLES P. ORR

Mr. Orr, a Food and Drug Officer in the Division of Federal-State Relations, Delivered This Paper at the Annual Meeting of the Central Atlantic States Association of Food and Drug Officials in New York on May 24, 1962.

APPROXIMATELY TWO YEARS have elapsed since the Eighty-sixth Congress enacted the Federal Hazardous Substances Labeling Act which the President signed on July 12, 1960. This Act has created another area of common interest among the many states having a similar hazardous substances labeling act and the Food and Drug Administration. In general, we are all interested in the welfare of those who handle and use potentially dangerous substances. Many of the compounds which are of concern to all of us may be found in or around the home. Our laboratory methods and our interest in human experience data are also very similar.

Before discussing the present enforcement of the Federal Hazardous Substances Labeling Act, I would like first to go into the background of this legislation. As is true in the case of the Food, Drug and Cosmetic Act, legislation similar to the Federal Hazardous Substances Labeling Act became law in some states before consideration by the Congress of the United States. Hazardous substances have been recognized for many years as can be attested by the fact that Congress in 1927 enacted the Federal Caustic Poison Act. The precautionary labeling requirements of that law saved many lives.

However, this law soon became obsolete. It did not apply to numerous hazardous household substances that the chemical age placed on the consumer market. New detergents, new types of cleaning agents, various plastics, adhesives, and do-it-yourself kits are only a few that were not subject to the old law were marketed after 1927.

Need for Modernized Version Recognized

There was general agreement by physicians, representatives of poison control centers, manufacturing chemists, consumers and food and drug officials that a modern version of the Caustic Poison Act should be developed to require adequate labeling on hazardous household substances. All thought this would help prevent a great many of the accidents that had been occurring. So, with general support, legislation was enacted by the Eighty-sixth Congress to accomplish this desirable goal.

The Federal Hazardous Substances Labeling Act prohibits the interstate shipment of misbranded packages of hazardous substances. The primary purpose of this law is to protect the public health, particularly that of young children, by establishing adequate labeling for hazardous substances which are packaged, distributed and sold in containers that are suitable or intended for household use.

The purposes of the labeling requirements of this Act are to inform the purchaser and user of the hazards which may be encountered, to prescribe adequate precautionary measures for handling and storage, to provide adequate first aid measures when necessary, and to inform the physician and others of the hazardous ingredients. This, of course, enables the physician to apply proper treatment in cases of accidental or intentional poisoning.

Criteria Set Forth in Act

The criteria which must be employed in determining whether a product is a hazardous substance subject to the provisions of this statute are, (1) is it a container suitable or intended for household use, and (2) is it a substance or mixture of substances which is (a) toxic, (b) corrosive, (c) an irritant, (d) a strong sensitizer, (e) flammable, or (f) capable of generating pressure through decomposition, heat, or other means, or mixtures of substances which may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonable foreseeable handling or use, including the reasonable foreseeable ingestion by children.

Substantial personal injury or illness has been interpreted in the regulations as meaning any illness or injury of a significant nature. It need not be severe or serious. What is excluded by this word is the wholly insignificant or negligible injury or illness.

The reasonable foreseeable handling or use mentioned in the statute includes the potential accidental handling or use, not only by the purchaser or intended user of the product but all others in the household, especially small children.

Containers for Household Use

The criteria which is to be employed in determining whether a container is suitable or intended for household use is whether it may be found in or around a dwelling or any related building. This includes, but is not limited to, the garage, carport, barn and storage shed. Articles intended for professional use but also available in hobby shops and other retail stores for lay use will be considered as being available for household use and must be appropriately labeled. The term "containers intended or suitable for household use" does not include articles labeled as *and marketed* solely for industrial use. Such articles do not become subject to the provisions of this law because of the possibility that an industrial worker may misappropriate a supply for his own use. However, when there is a significant possibility that containers of a hazardous substance, though primarily produced and marketed for industrial use may reach a household, it is suggested that the warning labeling required by the Federal Hazardous Substances Labeling Act be used. It should be emphasized here that the Act states that the proffer or delivery of a hazardous substance in a reused food, drug or cosmetic container identifiable as such is a misbranded substance.

The Act also provides for the Food and Drug Administration to issue, amend, or repeal regulations under the Act for its efficient enforcement.

Regulations Arouse Comments

On April 29, 1961, the Commissioner published in the *Federal Register* proposed definitive and interpretative regulations. We had no illusions that our proposed regulations would receive no comment but we were not prepared for the deluge of comments we did receive. Surprisingly, many quite critical comments were apparently based on the assumption that these regulations were not really proposals but were a prepublication of what would be finally issued as the rules under which everyone must play. Few proposed regulations have elicited so much of this kind of response. Many thoughtful and very helpful suggestions were received. Pleas were made by many that they wished an opportunity to be further heard. Some demanded a

public hearing which was not required by the statute. However, a meeting was held on July 13 and 14 of that year in Washington at which time many firms, associations, and organizations presented their views on the proposed regulations.

All comments were studied, discussed and evaluated. Many of the suggestions made in response to the proposals were accepted. Some others were accepted in part and some were rejected completely. For some of the scientific problems imposed, we impaneled two committees of outstanding scientists to assist us. One of these was composed of outstanding experts in the field of dermo-toxicity. The other consisted of outstanding national and international experts in the fields of pharmacology and clinical toxicology. The final regulations were published in the *Federal Register* on August 12, 1961.

Objection to "Over-Labeling"

There was a general cry that "over-labeling" would defeat the protective purposes of this statute when the proposed regulations were first issued. However, our panel of scientists did not agree with this view and they advised us to retain some of the proposed regulations, for to do otherwise would eliminate from coverage many products that were actually hazardous. One and perhaps the most controversial of all regulations, the requirement of front panel placement, is certainly not completely without judicial support. We firmly believe that the front panel placement regulation fulfills the purpose of this law, and it is a reasonable interpretation of what is required for compliance and that it can be enforced.

Information Required on Labels

Articles subject to the provisions of the Federal Hazardous Substances Labeling Act are required to bear a label which states conspicuously (a) the name and place of business of the manufacturer, packer, distributor or seller, (b) the common or usual name, or if none exists, the chemical name of the hazardous substance, (c) the signal word "danger" on substances which are extremely flammable, corrosive, or highly toxic, (d) the signal word "warning" or "caution" on all other hazardous substances, (e) an affirmative statement of the principal hazard or hazards, such as "flammable," "vapor harmful," "causes burns," "absorbed through skin," or similar wording descriptive of the hazard, (f) precautionary measures describing the action to be followed or avoided, (g) instructions when necessary or appro-

priate for first aid treatment, (h) the word "poison" for any hazardous substance which is highly toxic, (i) instructions for handling or storage of packages which require special care and handling or storage, and (j) the statement "keep out of the reach of children" or its practical equivalent. A highly toxic substance is also required by regulation to exhibit the skull and crossbones symbol.

Special Labeling

This new law provides authority to prescribe special labeling for special hazards, to name strong sensitizers and to prescribe tests for flammable solids and the contents of self pressurized containers. One legal point that needs to be brought to your attention is that but one class of these important regulations requires special hearing procedures and judicial review. Whenever the Secretary, to avoid or resolve uncertainty, proposes to make a specific substance subject to the labeling requirements of this Act, he must proceed by formal rule-making procedures comparable to the food additive procedures but in requiring special hazard labeling, in granting exemptions for small packages and minor hazards and indeed in all other important respects, the Department is not subject to the procedures for formal rule-making.

The law extends its protection to hazardous substances which are repacked from bulk containers into smaller containers for sale to the householder. In this sense, it is important to the local retailer as well as to the manufacturer and interstate distributor. The kerosene we buy for fire lighters and the gasoline for power motors will be in misbranded packages if the appropriate warnings are not provided by either printed matter on the can or a stick-on or other suitable labeling.

There are certain scientific considerations that the Food and Drug Administration must take into account in enforcing the Act. It enumerates seven different categories of hazardous substances. These I have pointed out but would like to state again as, (1) articles which are toxic through ingestion, inhalation or absorption through any body surface, (2) corrosive, (3) irritants, (4) strong sensitizers, (5) articles which are flammable, (6) substances which generate pressure and (7) radio-active substances. Since these terms are not scientifically precise, it is necessary to define them concretely on the basis of empirical data. For instance, what is the exact meaning of "toxic?" Any substance may be toxic under some conditions, even

oxygen or water or salt. The law itself describes tests with laboratory animals to determine what substances should be considered highly toxic. But when is a substance "nontoxic" and therefore exempt from the requirements of the law?

"Toxic" Definition

In order to evolve a clear definition for "toxic" which is discriminating enough to serve as a meaningful basis for law enforcement, we must accumulate a mass of indicative pharmacological and clinical data. For administrative reasons, the term "toxic substances" is defined in the federal regulations as any substance which has an LD 50 toxicity test value in rats of between 50 milligrams per kilogram and 5 grams per kilogram of body weight, when orally administered. However, a product having an LD 50 value greater than 5 grams in rats may also be subject to labeling under the federal law if it is shown by human experience to be a hazardous substance.

Animal testing and study of the incidence of adverse reaction in human beings are similarly the test zones for determining when a substance is corrosive, an irritant or a strong sensitizer. Consequently, our scientific division has been assigned the responsibility for developing and coordinating our research efforts in this area. Definitions for the three categories of hazardous substances, flammable, pressure generating and radioactive depend upon physical and chemical data rather than biological data to provide a uniform and practical basis for classifying a substance as hazardous.

Many States Have Their Own Laws

Many states have enacted their own hazardous substances labeling laws. Some of these, as previously stated, were enacted prior to the federal Act, while others have been enacted since the federal Act. However, we are unaware of any state which has on its own, promulgated administrative and procedural regulations under the Act which they administer. One state is adopting regulations which are similar to those the federal government has promulgated. We have been corresponding with many of the states in regard to enforcement of the federal and respective state laws. The need for uniform interpretation of federal and state hazardous substances labeling laws is illustrated by the fact that industry frequently comes to either state personnel or to the federal Food and Drug Administration with a claim that the other agency does not require certain precautionary statements

on the label or that these statements are not required to be located in a particular place on the label. We have tried to resolve these differences with the states and have done so very successfully. It is anticipated that further meetings to resolve some of the differences in interpretation will be most useful to us, to the individual states, and to the affected industries.

Urge States to Enact Uniform Law

In addition, we would encourage all states to enact a uniform hazardous substances labeling act. It is our understanding that the Association of Food and Drug Officials of the United States has a committee considering a uniform hazardous substances labeling bill. When action is taken on this bill by the Association it will probably be published in a similar manner to that of the revised Uniform Food, Drug and Cosmetic Bill which has recently been published. It is also hoped that the Association will publish proposed regulations which may be adopted by the individual states and which will not be in conflict with those published under the federal Act which we feel have not only legal backing but were also based on scientific considerations and human experience before they were promulgated.

Two other points should be made before I conclude. These are the exemptions which are permitted under the Act and the effective date for front panel labeling. Economic poisons subject to the Federal Insecticide, Fungicide and Rodenticide Act, articles subject to the Federal Food, Drug and Cosmetic Act and substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigerating system of a house, and radioactive substances which are regulated by the Atomic Energy Commission are exempt from the provisions of the Hazardous Substances Labeling Act.

Exemptions Permitted

Provision is made within the statute and regulations for exempting specific containers of hazardous substances from all or part of the labeling provisions of the law. We have received 95 requests for exemptions. We have granted 22, denied 23 (because there was no basis for the request, except not wanting to label their product) and are in the process of acting on the others. The following are among the articles that have been exempted from the various portions of the labeling requirements of the Act since publication of the final regulations: (1) laboratory chemicals intended solely for investigational or

laboratory use have been exempted from front panel labeling requirements with the proviso that the required information be placed on a panel adjacent to the main panel, (2) certain types of ball point ink cartridges, (3) dry ink concentrate capsules meeting certain criteria, (4) small arms ammunition have been exempt from some of the labeling requirements but must bear the signal word "warning" and the statement "keep out of the reach of children" as well as the types of ammunition and name and place of manufacturer, packer, seller or distributor, (5) paste wax preparations containing 10 percent or more of turpentine and/or petroleum distillates have been exempt from the special labeling requirements by regulations for these substances, (6) felt tip marking devices have been exempt from the labeling requirements pertaining to toxic substances and petroleum distillates, (7) extremely flammable substances and substances capable of generating pressure through heat, decomposition or other means are exempt from the requirements of stating the component which contributes to the hazard, provided flammability or pressure generation is the only hazardous quality of the substance.

Requirements Now Effective

The labeling requirements found in the regulations under 191.101 regarding placement, conspicuousness, and contrast of required information on the main label panel will become effective on August 1, 1962. In the meantime, all the information must appear on the container.

The first legal action under the Federal Hazardous Substances Labeling Act was the seizure of a zinc chloride soldering compound implicated in the death of a 6-year-old child. The Administration in its second action seized an extremely flammable lacquer thinner which lacked adequate warning regarding the flammability of the article. The third action under this law and the second involving the accidental death of a child was a seizure of a large quantity of household turpentine lacking all required warnings and other information. Investigation of this case began the day after the Administration learned that a year-old infant had drunk some and died.

Consumer Must Be Educated

The Food and Drug Administration, as well as state and local food and drug officials, realize the great need to educate the consumer in the area of accidental poisoning. The educational activities of the

Administration includes a publication of a pamphlet "Protect Your Family Against Poisoning," the booklet "Read the Label on Food, Drugs, Devices, Cosmetics and Household Chemicals," and the comic book, "Dennis the Menace Takes a Poke at Poisons." In addition, we have prepared a set of slides which are available on a loan basis. Interested groups can obtain limited quantities of the educational publications mentioned above directly from the Administration. With voluntary compliance by purveyors of articles containing hazardous substances, protection of the health of the public will be provided with the full cooperation of professional health workers and the consumer and great strides will be made in the protection of the public in an area which is controlled for the first time. **[The End]**

VANILLA BEAN STANDARDS SET

Federal standards of identity setting the amount of vanilla beans in vanilla extract and certain other vanilla products were announced recently by the Food and Drug Administration. The new standards become effective on October 31, 1962, unless objections are received which require a public hearing.

FDA said the purpose of the standards is to assure the consumer a better product, put all manufacturers on an equitable basis, and provide a sound basis on which to proceed against products in which spurious ingredients have been substituted for the vanilla beans which the consumer expects.

Standarized products include: (1) vanilla extract and concentrated vanilla extract; (2) vanilla flavoring and concentrated vanilla flavoring ("extracts" differ from "flavorings" in that extracts contain 35 per cent or more of alcohol, and flavorings contain less than that amount, under the standards); (3) vanilla powder (in some cases called vanilla sugar); (4) counterparts of these products containing, in addition to vanilla bean extractives, limited amounts of vanillin, an artificial flavor. The amount of flavor contributed by the vanillin must be not more than half of the over-all vanilla flavor in the counterpart products.

The new standards prescribe the required content of vanilla beans in terms of "unit of vanilla constituent." This unit is specified to mean the flavoring equivalent of 13.35 ounces of beans containing not more than 25 per cent moisture. If beans containing more than 25 per cent moisture are used, the amount used must be increased accordingly. Vanilla extract is required by the standard to have not less than one unit of vanilla constituent per gallon.

Labels of products containing vanillin will be required to declare the presence of the artificial flavoring and to give the flavoring strength by a number which equals the number of units of vanilla constituent contributed by vanilla beans, plus the number of ounces of added vanillin per gallon, or, in the case of vanilla-vanillin powder, per eight pounds.

Scope and Responsibility of Government in Development and Regulation of Chemical Additives for Food

By GEORGE P. LARRICK

This Address Was Presented at the American Chemical Society Symposium on "The Role of Chemicals in Modern Food and Fiber Production," in Washington, D. C. on March 22, 1962. The Author Is Commissioner of Food and Drugs, Department of Health, Education and Welfare.

THAT THE ROLE OF CHEMICALS in modern food and fibre production is an important one is evident from the titles of the papers delivered at this symposium. In fact, the inclusion of a symposium of this kind on the program of a national meeting of the American Chemical Society with the distinguished speakers who have appeared attests to the importance of the subject. But this is not a new discovery. Many scientists, scientific organizations and legislative bodies have observed the rapid scientific developments of recent decades and have recognized the profound implications to present day society and civilization.

Recognizing the hazards accompanying the technological developments and the unprecedented growth of scientific knowledge in this atomic age and being concerned with a responsible role for scientists in modern society, the Council of the American Association for Advancement of Science in 1955 established a "Committee on the Social Aspects of Science." Many interesting and cogent observations appear in the reports of that committee. One of the reports begins with the statement:

For nearly two decades scientists have viewed with growing concern the troublesome events that have been evoked by the interaction between scientific

progress and public affairs. With each advance in our knowledge of nature, science adds to the already immense power that the social order exerts over human welfare. With each increment of power, the problem of directing its use toward beneficial ends becomes more complex, the consequences of failure more disastrous, and the time for decision more brief.

Under the heading "Social Consequences of Technological Progress," the report lists five examples of important problems with which scientists must deal. The third example is stated in these words: "The effects of new organic insecticides, food additives, and food colors on animals and man."

New Chemicals Create Problems

This symposium today amply confirms the judgment of that committee as to the importance of the scientific and social problems created by the host of new chemicals made available by present day research.

In dealing with the topic assigned to me—Scope and Responsibility of Government in Development and Regulation of Chemical Additives for Food, I shall direct my remarks toward the problems of regulation. The government organization which I represent—the Food and Drug Administration—has no responsibility in the development of chemical additives. It does have primary responsibility for regulating the use of chemical additives in food, as well as pesticide chemicals and color additives under the terms of amendments to the Federal Food, Drug and Cosmetic Act. The government through other agencies such as the Department of Agriculture, the Fish and Wildlife Service and the military establishments, has responsibilities for development of products and processes important to the country generally. Dr. Clarkson and others on this program have discussed some of this developmental research of the Department of Agriculture which illustrates the scope and responsibility of the government in this area. The government has a broad responsibility for the promulgation and enforcement of regulations defining safe use of chemical additives.

1906 Act Considered an Important Step

The first federal law regulating foods and drugs generally was enacted in 1906. This culminated about 25 years of agitation and debate. Much of the opposition in Congress had stemmed from the view that a federal regulatory law would be unconstitutional. The enactment of the law marked an important forward step. In its day it seemed daring and bold, and to many of doubtful propriety, to interpret the Commerce Clause of the constitution as authorizing such

regulatory meddling by the federal government. Today, I think that none would question the authority, and few the necessity and desirability of federal regulation of interstate commerce in foods. The scientific and technological developments during the century preceding 1906 underlaid the "industrial revolution" of that period. The change from an agricultural to a predominantly industrial society brought new processes in food production and storage and wider distribution of and dependence on commercial foods. In enacting the Food and Drugs Act of 1906, the Congress in effect repealed the doctrine of *caveat emptor* —"let the buyer beware"—as applied to foods and drugs. The "play of the market place" was not considered sufficient to ensure the purity and integrity of the food supply. Moreover, in that enactment, the Congress asserted the responsibility of the government to require the wholesomeness and integrity of foods and drugs within its jurisdiction.

Many deficiencies in the Act of 1906 later became apparent. In 1938 substantial improvement was accomplished. The Food, Drug and Cosmetic Act of that year improved and modernized consumer protection in many ways. This new statute declared a food adulterated if it contained any added poisonous or deleterious ingredient unless such was necessary in its production or could not be avoided under good manufacturing practices. In such cases, but only in such cases, the law authorized establishment of safe tolerances.

This provision was inadequate and unscientific. It was not capable of effective enforcement. It assumed that a substance could be classed as poisonous or nonpoisonous in the abstract without respect to quantities, dosage and time. Furthermore, the burden of proof was borne by the government to show that a substance was toxic or deleterious before its use in food could be stopped or prevented. Little was known about the toxicity of the many new chemicals that were being used or advocated for uses that might place residues in food.

New Amendments

In 1950, the House of Representatives of the Congress established the "Select Committee to Investigate the Use of Chemicals in Food Products." This committee held extensive hearings over a period of two years and made recommendations for legislation to deal with the problem. In response Congress enacted the Pesticide Chemicals Amendment of 1954, the Food Additives Amendment of 1958, and the Color Additive Amendments of 1960.

The purpose of all of these amendments to the Food, Drug and Cosmetic Act as stated in their enacting clauses is to ensure the

adequate safety testing of chemicals employed in or on foods. Safety to consumers is the prime consideration. These amendments replace the "per se" rule with authority to establish regulations governing the safe use of these substances, including where necessary safe tolerances. They shift the burden of proof. The proponents of the use of chemicals must establish their safety before use, whereas, formerly the government had to establish their toxicity before use could be prevented.

Scientists' Judgment of Prime Importance

The problems involved in administering these amendments are complex. Evaluation of the safety of chemicals and proposed uses which may place residues in food is primarily a scientific problem. This means that the judgment of the scientists who review the petitions and proposals for food additive regulations is of prime importance. It is scientists who must determine whether petitioners have established the chemistry of their additives, adequate residue data, evidence of validity of analytical methods and sufficient safety tests. But the government scientists do not perform their functions in isolation. The scientific community as a whole has an important responsibility to contribute to the development of knowledge of the facts about food additives and the means for ensuring protection of the public health.

When food additive legislation was under consideration, we hesitantly suggested that there might be as many as seven or eight hundred different chemicals that would be subject to such regulation. We grossly underestimated the volume. It now appears that there are perhaps several thousand chemicals that fall in the category of direct food additives; substances intentionally added such as preservatives, anti-oxidants, emulsifiers and flavoring substances of all kinds. There are additional hundreds of "indirect" or "unintentional" additives; chemicals employed in manufacture of food handling equipment, containers, packaging materials, paper, and the like, that may migrate to food.

Under the Food Additives Amendment, we have published orders which currently extend the effective date for direct additives with respect to 822 substances (658 are flavors). We have established regulations covering use of 253 direct additives. Hundreds of chemicals have been involved in regulations which have been issued with respect to packaging materials, cellophane, can-liners, resins and so forth.

Numerous Petitions Filed

We have before us a large number of petitions for regulations and are dealing with these as promptly as we can with the limited scientific staff which is available for this work. It is of interest that while our regulations have spelled out in substantial detail just what must be submitted in any petition for a food additive regulation, we have received all sorts of petitions which could not be filed on receipt.

Perhaps the easiest to deal with was the type of petition which involved a substance generally recognized as safe, thus calling for no regulation at all. Others were deficient in one or more ways, such as describing substances by trade names which were not known to us, failure to give use data, failure to supply sufficient pharmacological information, and, where tolerances were necessary, failure to supply a good analytical method which could be used for the enforcement of that tolerance.

We are committed to the policy whereby we will not issue a regulation without clear evidence of (1) just what we are regulating, (2) adequate safety data, (3) adequate use information, so that we authorize no more than is necessary to achieve the necessary physical or technical effect. Finally, we will not issue a regulation which we conclude is one which cannot be reasonably enforced.

We noted initially that the term "food additive" was one which apparently had an unpleasant connotation and there was a great deal of effort to try to get the Food and Drug Administration to agree that this and that item was not covered by the amendment. It is gratifying to us to note a marked change in attitude now. Uses which are prior-sanctioned under the statute do not need regulations; in fact, they are not even subject to the Food Additives Amendment by definition. Nevertheless, we are beginning to receive requests that we formalize by regulations published for all to see, some of the sanctions which we issued prior to the enactment of the statute based on information supplied to us by those who had pre-tested their additives even though at that time the law did not require that they do so.

The scope of this amendment is broad. Our responsibility in the development and administration of regulations for food additives is heavy. We intend to do the best job possible to see that no unsafe foods are permitted to be marketed in this country and all of the help we can get from scientific groups such as this one will be appreciated.

[The End]

The Omnibus Bill

By JOHN L. HARVEY

The Deputy Commissioner of the Food and Drug Administration Delivered This Talk Before the Food, Drug and Cosmetic Law Division of the American Bar Association Section of Corporation, Banking and Business Law in San Francisco, California on August 8, 1962.

THE ADMINISTRATION BILLS, H. R. 11581 and H. R. 11582, were introduced into the House of Representatives on May 3, 1962 by Chairman Oren Harris of the Interstate and Foreign Commerce Committee. Together they comprise the omnibus bill, if you will. I use the term singly although it is introduced in two separate bills for reasons which have no interest for what I have to say.

These bills are not duplicates of the Kefauver bill, or of the Celler bill, or of the Kefauver bill as amended or modified by the Judiciary Committee. These bills are those that were long planned as the administration's omnibus bill, and are designed to fulfill the requests made by President Kennedy in his message to the Congress, issued March 15, 1962.

H. R. 11581, DRUG AND FACTORY INSPECTION AMENDMENTS OF 1962

PART A. AMENDMENTS TO ASSURE SAFETY, EFFICACY, AND RELIABILITY

Section 101. Requirements of Adequate Controls in Manufacture

Present law does not require a drug manufacturer to produce his products under adequate manufacturing controls. These are controls that will insure that a drug contains the proper ingredients in the proper dosage, and bears the proper label. If it does not, it can kill you.

Many firms do have extensive and effective manufacturing control systems, but others endanger the public health by short-cut practices.

Until the law requires all manufacturers to maintain adequate facilities and controls, we may expect continuing drug mixups such as the following:

In September, 1961 FDA learned that a dicalcium phosphate product used as a dietary supplement was contaminated with diethylstilbestrol, a synthetic sex hormone. Some male patients taking the product were developing enlarged breasts. Some female patients who were using it had abnormal uterine bleeding. The manufacturer recalled outstanding shipments of the contaminated product. In April, 1962 FDA learned that another drug, isonicotinic acid hydrazide, manufactured by the same firm, was contaminated with a potent synthetic sex hormone. It was causing excessive breast development in the male babies and growth of pubic hair in female babies in San Francisco City Hospital. This product was also recalled. Subsequent investigation of the firm revealed two more of their products, soda mint tablets and a nasal decongestant, contaminated with synthetic sex hormones. This manufacturer was not exercising sufficient controls to prevent cross-contamination of his products.

In January, 1962 the manufacturer of a penicillin powder had to recall the product because it was contaminated with sulfonamides. After thorough investigation of this plant, the Food and Drug Administration concluded that a breakdown in controls, plus human error, was responsible for the adulteration.

Earlier, federal, state and local food and drug inspectors, police and others had to make a nationwide search to recover all tablets of a bad batch of sulfathiazole. The tablets were contaminated with a chemical that made them hazardous to life.

In the calendar year 1961, 47 drugs were recalled from the market because of significant failure to comply with the Food, Drug and Cosmetic Act. Forty-five of these drugs were for human use and two were veterinary drugs. Thirty-seven different firms were involved. Most of these recalls were made necessary by faulty manufacturing practices.

The bill would require adequate controls by deeming adulterated any drug manufactured with inadequate methods, controls, facilities or personnel. It allows the Secretary of Health, Education and Welfare to establish by regulation what constitutes good manufacturing practices so that the safety, identity, strength, purity, and quality of drugs produced are as represented.

Section 102. Premarketing Showing of New Drug Efficacy

Present law requires proof only of safety before a new drug may be cleared for the market. Except in those instances in which the question of the drug's efficacy is involved in determining its safety, the Food and Drug Administration must approve the new drug application once the requirements of safety have been met even if there is reason to believe that the drug is not effective for the purposes claimed. Then the manufacturer is at liberty to promote his products. If claims for effectiveness are made which the government believes are groundless, a proceeding must then be brought to take the drug off the market as a misbranded product. At that point the burden of proof is on the government to establish that the drug is not effective. And throughout the period of time it takes for the government to prepare its case and secure relief in the courts, the manufacturer will have foisted his product upon an unsuspecting public.

Where public health is involved, it is intolerable to permit the marketing of worthless products under the rules of a cat-and-mouse game where a manufacturer can fool the public until the government finally catches up with him.

The situation should be reversed. The manufacturer should prove that his product is effective for the purposes claimed before it is marketed.

The only issue is whether the claims of effectiveness are going to be reviewed before a worthless product is put on the market or sometime later, after the public's funds have been wasted and its hopes for relief or cure have been cruelly disappointed.

The leading drug manufacturers have in many cases recognized their responsibilities to the public and have assembled substantial evidence of effectiveness before marketing their products. Yet abuses have occurred. In several instances the FDA has had to clear drugs for general distribution because they were shown to be safe under the conditions of use proposed in their labelings, despite the fact that its medical officers knew of no evidence to support some of the therapeutic claims made by the manufacturer.

The proposed amendments would require a showing that the drug described in a new drug application is safe for use and is effective in use, under conditions prescribed, recommended, or suggested in the labeling thereof. This would not require a showing of relatively greater

efficacy than that of other drugs. It would merely require that a drug claimed to be effective for a particular purpose has been demonstrated by sound scientific procedures to be effective for that purpose. In short, it must live up to the claims made for it.

It must be recognized that some drugs which prove out safely on a reasonable amount of pretesting will show due effects in massive use which cannot be forecast. When these side effects are such as to change the original evaluation of the drug, changes must be made or the drug may be found to require removal from the market. The Food and Drug Administration must be informed of adverse reports on new drugs.

Section 103. Records and Reports as to Experience on New Drugs

Present law does not require drug manufacturers to notify the government of reports they receive which attribute injuries to the use of their drugs. Many manufacturers voluntarily advise the FDA promptly when they receive such reports, but other drug firms have reports of side reactions to their product long before they pass this information on to the government.

To be able to safeguard consumers, FDA must learn of adverse side effects when they are first recognized. The present system is faulty because it does not require this.

In July, 1961 the Food and Drug Administration was notified by a drug firm that one of its products was implicated in 54 cases of hepatitis and jaundice, including 15 deaths, about which the FDA did not have adequate prior knowledge. This drug, a skeletal muscle relaxant, had been on the market since early 1956. It was later learned the firm had accumulated reports of jaundice and deaths associated with the drug's use for a period of over five years before submitting the case reports to the government. After studying the reports and consulting a number of medical authorities outside the government, it was decided the product should be removed from the market. The firm was asked to recall the drug, which it did, and the product's new drug application was suspended.

Last October the FDA learned of blood disorders associated with the use of a mild tranquilizer which had been on the market since April, 1960. Upon investigation they found that the firm had information about 11 cases of injury attributed to the drug, including three deaths, that had not been reported to the government. After evalua-

tion of the evidence, this drug was recalled from the market and the new drug application was suspended.

In January, 1962 the FDA first learned of serious blood disorders associated with the use of a psychic energizer which had been on the market since April, 1961. They requested more complete data regarding all such cases known to the manufacturer. These case reports showed (1) that the first injury occurred in August, 1961, (2) the firm had received in October, 1961 reports of the blood disorders in some patients who had received the drug, and (3) four of the seven cases ended in death. Study of the case reports submitted indicated that this drug should be taken off the market. This view was confirmed in contacts with outside experts and the drug was recalled from the market and the new drug application suspended.

These examples point out the serious consequences resulting from delays in advising the government about adverse drug reactions. Had full reports of the experience with these drugs been submitted as soon as the manufacturers received them, undoubtedly it would have saved lives. We believe the public has the right to the protection that would be given by requiring the distributor of a new drug to advise the government of reports of adverse reactions to a drug as soon as they are received. Then corrective action could be taken promptly when it is needed.

The bill requires new drug applicants to keep records and make reports to the Secretary of Health, Education and Welfare of clinical experience and other information bearing on a new drug's safety or efficacy. It also provides that these records shall be made available to designated employees of the Secretary. Failure to establish or maintain such records, to make any required report, or to permit copying of such records would constitute grounds for withdrawing approval of the new drug application to which the records applied.

Section 104. Procedural Changes as to New Drugs, and Additional Grounds for Withdrawal or Suspension of Approval of New Drug Applications

1. Under existing law a new drug application is automatically cleared without affirmative action on the part of the Secretary by the mere lapse of a specified time (60 days, which may be extended by the Secretary up to 180 days), unless within the time limit, after

opportunity for hearing, the Secretary has issued an order "refusing to permit the application to become effective."

It is not good public health protection to have a provision in the law that would allow a new therapeutic agent to be marketed commercially because the Secretary failed to act to block such marketing within an arbitrary time limit. A new drug should never be allowed to be on the market until the Secretary has made an affirmative determination that it will be safe and effective in the diseases and under the conditions of use for which it is offered.

The bill would close the gap in public health protection by requiring that affirmative action by the Secretary of Health, Education and Welfare be taken before a new drug can go on the market. The Secretary would be required to approve the application, give the applicant opportunity for a hearing, or if necessary, deny the application within 90 days after filing (or 180 days in case of extension).

2. Present law does not allow the suspension of a new drug application on the basis of substantial doubt as to its safety. If it can be proven that the applicant made false statements when filing his original application, it can then be suspended and thus stop distribution of the drug; or if new tests show that the drug is unsafe the application may be suspended, but while these tests are being run the product may remain on the market.

This situation leaves a serious gap in consumer protection. This is illustrated by the following example:

The new drug application for MER/29 became effective on the basis that the drug was safe for the conditions and dosage recommended by the manufacturer in the drug's labeling. In evaluating the pharmacological data submitted in connection with this new drug application, FDA pharmacologists said that if the drug was safe, its safety would have to be based on clinical evidence. However, the new drug officer who reviewed the application believed that the considerable body of clinical evidence available established the safety of the drug, and he allowed the drug to go on the market.

However, by mid-November, 1961, FDA knew of four cases in which patients receiving MER/29 had developed cataracts. These cases, plus the animal evidence in file, raised substantial doubt as to the safety of the drug and the government scientists recommended that the application be suspended and the drug removed from the market.

When this recommendation was presented to the Commissioner's Office of FDA and the General Counsel's Office of the department, it became apparent that while there was substantial doubt as to the safety of the drug and reason to believe that upon further investigation it would be found that the drug was causing harm when administered in recommended dosage, at that time FDA did not have sufficient evidence to satisfy the requirements set forth in the law for suspension of the application. That is, the government could not yet prove that the drug was unsafe in the dosage recommended in the labeling. In three of the four cases where cataracts developed, the drug was administered in higher dosage than was recommended. Thus these cases in and of themselves did not prove the drug unsafe in the dosage recommended by the manufacturer. In the fourth case the recommended dosage apparently was followed, but the development of the cataracts was quite atypical and raised real doubts as to whether the drug had caused the cataracts. Against this evidence there was the firm's strong assurance that they had ample evidence of safety with which to refute the government's position if an attempt were made to suspend the application for MER/29. Despite the fact that the administrators and lawyers agreed with the scientific view that the drug should be removed from the market, the FDA had to content itself with requiring the firm to issue a warning letter to physicians calling attention to the new findings and cautioning them not to use more than the recommended dosage. This letter issued on December 1, 1961.

By mid-April, 1962 the drug caused sufficient injuries, some at the recommended dosage, to permit FDA to require the manufacturer to withdraw the product from the market. The firm's withdrawal letter issued on April 17, 1962, and upon its request the new drug application was suspended.

In retrospect, it is apparent that the drug should not have gone on the market in the first place. However, when this conclusion was reached in mid-November, 1961, FDA was unable, in the absence of new data and in the absence at that time of proof that the application contained untrue statements, to correct the situation. The product was used for another four and one-half months before clear evidence of lack of safety made it possible to get it out of the hands of physicians.

This bill authorizes the Secretary, when he finds that there is a substantial doubt as to a new drug's effectiveness or safety, to give the applicant due notice and opportunity for a hearing on the question

of withdrawing approval of the application by order. Further, if the Secretary finds that there is an imminent public health hazard, he may suspend the approval of a new drug application immediately upon notice pending the opportunity for a hearing.

3. The bill also changes the first appeal from the Secretary's decision relating to the denying or withdrawing approval of a new drug application to the court of appeals rather than the district court, as is provided in the present law. The change makes this type of appeal consistent with comparable appeals under other sections of the law.

Section 105. Certification of All Antibiotics

Present law requires certification before marketing of only five basic antibiotic drugs and their derivatives. Thirty antibiotics which do not have to be certified are handled as new drugs. Each must be shown to be safe before marketing, but individual batches are not tested by the government nor do they have to be proved effective.

Batch-by-batch certification of all antibiotic drugs is needed because:

(a) More than any other drug, antibiotics are the first choice in treating life-threatening infectious conditions.

(b) Most antibiotics are produced by complex processes in which both the desirable antibiotics and quantities of undesirable byproducts are manufactured.

(c) The potency of antibiotics must be determined by biological assay procedures, the interpretation of which requires unusual competence.

Despite the manufacturers' check of each batch of antibiotics before submitting it for certification, in fiscal year 1961 samples from over 100 batches of antibiotics offered for certification failed to meet the standards set forth in the regulations.

Countless organisms can produce antibiotic substances. Hundreds of thousands of cultures have already been tested in preliminary screening operations in the laboratories of industry, educational institutions and government, and thousands of antibiotic substances have been discovered. Most of them are either not effective enough or not safe enough to warrant marketing. Domestic and foreign laboratories continue to screen thousands of new organisms in the hope that more desirable, safer antibiotic substances will be discovered. It is reasonable to expect that presently unknown antibiotics will be discovered

and marketed. The reasons for establishing the certification system in the first place were sound and are still valid reasons for applying an extra degree of control to antibiotic substances now on the market and those to be developed in the future. The pharmaceutical manufacturers should not be the sole judges before marketing of the safety and efficacy of individual batches of antibiotics that are produced.

The bill would require batch-by-batch certification of all antibiotics, except those exempted by the Secretary because he finds that certification is not necessary to insure their safety and efficacy.

Withdrawal of Antibiotic Certification Service

Within the past three years we have had to withhold for varying periods of time, certification services with respect to all certifiable antibiotics manufactured by seven firms until their manufacturing operations were brought into compliance with the regulations which are designed to insure safety and efficacy of certified lots.

In addition there have been a number of suspensions of certification for individual products of antibiotic firms because of unsatisfactory conditions with respect to their production.

Clearly, certification of all antibiotic drugs as proposed in H. R. 11581 would be in the public interest, and the cost is quite reasonable. Last calendar year certification of the antibiotics now subject to this control cost, on the average, about one-twentieth of a cent per dose. (Total fees received in that year, $912,000.)

Section 106. Records and Reports as to Experience on Antibiotics

Present law does not require manufacturers of antibiotics to report adverse side effects attributable to their drugs. As explained in connection with Section 103, it is imperative that the government learn of adverse reactions to drugs as soon as they occur.

This bill requires manufacturers of antibiotics to keep records and make reports of clinical and other data they obtain bearing on the safety or efficacy of the antibiotics. It also provides that these records shall be made available to designated employees of the Secretary. (These requirements parallel the requirements added to the new drug section of the act by Section 103 of this bill.)

PART B. STANDARDIZATION OF DRUG NAMES

Section 111. Authority to Standardize Names

Present law does not provide for any system to establish a single standard name for a given drug.

Today, when a drug is being developed, it may be known only by a complex chemical name or by the manufacturer's code number. As it reaches the market, the manufacturer frequently gives it two names—first, a short, catchy brand name that he hopes doctors will remember, and second, to protect his brand name, a so-called common, or generic name. In many cases, the common name is far more difficult to use and remember than the brand name. Moreover, there are often a number of common names for the same product with resulting confusion among medical practitioners and consumers alike.

The common name does not have to be complicated and hard to use. It should be as simple as many of the brand names in use today. It is understandable that doctors do not often use the chemical or common name of a drug called "desoxycorticosterone acetate" when they can prescribe it by the brand name "Cortate."

It would be in the interest of good medical practice and good consumer protection to have only one common name for each drug.

The bill would give the Secretary of Health, Education and Welfare authority to standardize drug names. These standard names would have to appear on drug labels.

The authority which the bill provides, to establish a single standard name for a drug, is a standby authority that could be exercised by the Secretary of HEW whenever in his judgment such action is necessary to achieve usefulness and simplicity of drug nomenclature. This would permit voluntary procedures to be established and used to improve the system of drug nomenclature. But voluntary procedures would, in the final analysis, depend on the cooperation of drug manufacturers. To insure that they are effective, the Department of Health, Education and Welfare should have the proposed standby authority to be used in the event the voluntary procedure breaks down or fails to provide common names meeting the objectives we seek.

Section 112. Name to Be Used on Drug Label

Present law requires that the label of a drug bear the common or usual name of the drug unless it is designated solely by a name

recognized in an official compendium. It also requires that the common or usual name of each active ingredient be stated on the label if the drug is composed of two or more active ingredients.

These requirements result in certain drug labeling which tends to overemphasize the brand name of a drug and to underemphasize the common or usual name. This is done by giving the brand name of the drug precedence in placement on the label, and size of type, over the common or usual name. This practice encourages the identification of drugs by brand name and reinforces the brand name in the minds of those who prescribe and dispense drugs.

The bill requires a drug label to bear the standard name (as defined in Sec. 111 of the bill) of the drug in a position of precedence over, and in type at least as large and prominent as used for, the brand name.

It also requires the quantity and established name of each active ingredient to be declared if the drug is composed of two or more active ingredients.

PART C. SPECIAL CONTROL FOR BARBITURATE AND STIMULANT DRUGS

Under the present Food, Drug and Cosmetic Act, barbiturates and amphetamines shipped in interstate commerce must meet certain standards as to strength, purity, quality, and must, prior to being dispensed on prescription, bear the statement, "Caution: Federal law prohibits dispensing without prescription." These controls have proved inadequate to prevent the unsupervised, unwise use of these drugs which can and frequently does lead to serious physical and social changes in the user.

Large quantities of these drugs have been diverted into illicit channels as the result of shipments from manufacturers and wholesalers to unauthorized individuals. Places of distribution include roadside taverns, service stations, houses of ill-repute, bars, hotels and restaurants. Acute barbiturate poisoning is now the most common cause of death from any solid poison, or any other poison except carbon monoxide gas. The abuse of these drugs by taking them without proper medical supervision presents serious public health problems, leading to abnormal and antisocial behavior and to the commission of crimes. The illicit traffic in these drugs, unlike the traffic in narcotics, attacks small as well as large communities.

A problem of growing proportions has been created by chronic users of barbiturates and amphetamines who are a menace to the public when driving on our streets and highways. Medical and driving-safety experts agree that drivers who use amphetamines to continue to stay awake and continue to drive beyond the limits of physical and mental endurance constitute a serious hazard to themselves and innocent travelers. Amphetamines have been found in vehicles or on drivers involved in serious accidents. A letter found on a driver killed in a crash told how he had been using amphetamine pills to keep going. His cattle-loaded truck, traveling on a modern highway with a wide center divider, veered across the divider into oncoming traffic, crashed head-on into a passenger bus outside of Tucson, Arizona, killing 9 persons and injuring 31 others. According to the Interstate Commerce Commission's accident investigation report, the truck driver was under the influence of amphetamine drugs and had gone 49 hours without rest.

The Food and Drug Administration estimates that the volume of amphetamines being sold illegally through truck stops and other outlets apparently exceeds the volume sold legally through drugstores. The cases in which the government has brought legal actions show that the drugs are being handled illegally in transactions involving tens of thousands of tablets at a time. They also show that the drugs are being peddled by operators whose activities cover many states. One investigation revealed illicit distribution of these drugs in four states and led ultimately, while the principal peddler was being held in jail by the New York State Police, to the source of supply—a man who furnished government agents, who represented themselves as peddlers, with 70,000 amphetamine tablets and 1,000 barbiturate capsules.

More recently, the operators and supplier of a syndicate making wholesale distribution of amphetamine drugs to truck stops throughout the southeastern United States were convicted and received two- and three-year jail sentences. Millions of tablets were involved in this operation. Over 600,000 amphetamines and barbiturates the supplier had in his possession were seized when an undercover buy was made from him.

The Federal Food, Drug and Cosmetic Act neither contains appropriate means for detecting illegal diversions from legitimate channels nor makes traffic in these drugs by such outlets per se a federal offense. It applies (outside the District of Columbia) only when it can be shown that the drugs are or have been in the stream of interstate

commerce. In order to make regulation and protection of interstate commerce in barbiturates and habit-forming stimulant drugs effective, regulation of intrastate commerce is necessary because such drugs, when held for illicit sale, often do not bear labeling showing their places of origin and because, in the form in which they are so held or in which they are consumed, a determination of their place of origin is sometimes extremely difficult or impossible. Moreover, to subject interstate commerce to the needed controls without applying them to intrastate commerce would have the effect of discriminating against and depressing interstate commerce.

The bill would require manufacturers, compounders and processors of barbiturates, amphetamines, and other habit-forming central-nervous-system stimulant drugs to register with the Department of Health, Education and Welfare. It would require them and all other firms or individuals dealing in such drugs to prepare and preserve for three years records of all stocks of such drugs on hand, produced, received, delivered or otherwise disposed of. These requirements, however, would not apply to licensed practitioners who dispense such drugs in the course of their professional practice.

The bill would restrict manufacture, compounding or processing of these drugs to regularly established manufacturers, compounders, and processors who have registered with the Department of Health, Education and Welfare; and other authorized firms and individuals such as bona fide wholesale druggists; pharmacies; hospitals; licensed practitioners; persons using such drugs in research; public officers handling such drugs in the course of their official duties; and an employee of any of the foregoing who lawfully handles such drugs in the course of his duties.

It would restrict the possession of such drugs to the above-mentioned categories of persons, individuals to whom such drugs are dispensed or for whom they have been prescribed, and carriers and wholesalers handling them in the usual course of their business.

The bill would give the Secretary of Health, Education and Welfare the authority to bring newly discovered habit-forming stimulant drugs under the same controls as proposed for amphetamines.

Finally, the bill would apply to barbiturates and habit-forming stimulant drugs whether or not they enter or are destined for interstate commerce.

Convictions under the Food, Drug, and Cosmetic Act for illegal sales of prescription drugs from July 1, 1949, through April, 1962

Total cases terminated	1,123
Total defendants convicted	1,881

Of the above, 988 cases involved druggists or their employees with 1,655 defendants being convicted in these cases.

Included in the total are 17 cases against 20 medical practitioners.

Now, bear with me and I will take up H. R. 11582, a bill on cosmetics, therapeutic, and diagnostic devices, and one or two other things.

H. R. 11582, COSMETICS AND THERAPEUTIC DEVICES AMENDMENTS OF 1962

TITLE I. PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY

1. New Cosmetics

Present law does not require cosmetics to be tested for safety before they are marketed. As a result untested or inadequately tested cosmetics have been placed on the market and thousands of women have been injured.

This situation has been continuing for many years and may be expected to continue until the law requires all manufacturers to conduct adequate safety tests on their products before they are made available to consumers.

A review of the notices of judgment reporting legal actions taken against dangerous cosmetics under authority of the Food, Drug and Cosmetic Act gives some idea of the hazards to which American women have been exposed for about two decades. In 1941 the Food and Drug Administration had to remove the Willat Method of Heatless Permanent Waving from the market because it contained the poison ammonium hydrogen sulfide. The wave killed a woman in Atlanta and 207 lots were seized. Other actions against cosmetics that contained poisonous or deleterious substances included bleach creams containing dangerous quantities of ammoniated mercury, mole removers containing nitric and acetic acid, lotions containing dangerous amounts of bichloride of mercury, hair straighteners containing enough lye to burn users, hair lacquer pads and hair lacquer containing an ingredient injurious to users, cleansing cream colored with a known cancer-producing chemical, "butter yellow," coconut oil shampoo containing alkali in dangerous amount, a deodorant which was a primary

irritant, perma-nail base coat containing synthetic rubber and phenol formaldehyde resin in methyl ethyl ketone which injured many women, ammoniated dental cream which contained a hard material with sharp edges that injured users, shampoo containing polyethylene oxide alkyl phenol in dangerous amount, and hair dryer containing enough carbon tetrachloride, a potent liver poison, to be hazardous.

Events such as this led to a study in 1951 and 1952 by the Select Committee of the House to Investigate the Use of Chemicals in Food and Cosmetics. This committee under the able chairmanship of Congressman James J. Delaney reported, among other things, "The evidence has convinced this committee that a number of cosmetic companies are not adequately testing their preparations; that the public is entitled to greater protection with respect to products as widely used as cosmetics; and that such protection is not afforded by existing legislation, under which a manufacturer may be punished, and his product seized, after injury has occurred. Your committee recommends, therefore, that the Federal Food, Drug and Cosmetic Act be amended to require that cosmetics be subjected to essentially the same safety requirements as now apply to new drugs" (p. 11, H. Rept. No. 2182, 82d Cong., 2d sess.).

Certain other improvements in the law which were suggested by the Delaney committee with respect to chemicals in food have been enacted as the Pesticide Chemicals Amendment of 1954 (Public Law 518, 83d Cong.), and the Food Additives Amendment of 1958 (Public Law 85-929). These require pesticide chemical residues and food additive residues to be proved safe before they may be tolerated in our food. But cosmetics still are marketed without proper safety testing and women continue to be injured.

The following examples relate to three recent episodes:

In late 1959 a home permanent contained a neutralizing solution which had to be called off the market because of serious injuries which resulted when the neutralizer ran into the eyes of users. Over one million units of this product were on the market before these injuries came to our attention and the recall was started.

The following are examples of the injuries caused by the neutralizer. An employee of the Colorado Health Department was hospitalized for a week after using the product. The day after its use she had acute edema of the eyelids and of the forehead. Her eyes were severely inflamed, including inflammation of the iris. She was in pain with

her eyes swollen completely shut. Over a week after her release from the hospital she was still unable to read newsprint and unable to return to work.

After using this product a Colorado housewife was temporarily blinded with what her doctor diagnosed as "rather intense ulceration" of the cornea of both eyes.

The wife of a wholesale druggist in North Carolina received a sample of the product prior to its national distribution. Her use of the product resulted in hospitalization for ten days during five of which she was blind. After her release from the hospital she said she had difficulty in having her glasses readjusted with four changes of glasses occurring in three months.

A babysitter in Oklahoma City was treated by her eye doctor for almost three weeks for painful corneal abrasions of both eyes after using this product.

A housewife in Florida was treated by her doctor the day after using the product and examinations showed that the entire membrane-like tissue covering the cornea of one eye had been eaten away and there were extreme chemical burns on the inner surface of her eyelid.

The manufacturer subsequently developed a nonirritating neutralizer which was used to replace thousands of units of the harmful product which were destroyed during the recall. Our files contain some 250 reports of injuries resulting from the use of this home permanent. In most cases the injured women suffered intense pain, required professional medical treatment and many required hospitalization ranging from emergency treatment to confinement of over a week.

In 1959 during an inspection of a cosmetic plant on Long Island, one of our inspectors discovered that the records in possession of the firm showed a batch of special eye lotion that was not sterile. Although the firm occasionally sent a sample of the lotion to an outside consulting laboratory for sterility testing, it had overlooked notification from this analytical laboratory almost eight months before inspection that a sample of the eye lotion contained slime bacteria and molds. The firm was continuing to market the lotion, to "cleanse and refresh the eye" by twice daily applications.

When the serious nature of the situation was pointed out to the firm it undertook a complete recall of the product and instituted manufacturing procedures to assure the product's sterility.

In 1958, a 10-day Press-On Nail Polish was recalled by the manufacturer because of the severe nail damage suffered by hundreds of users of the product. Almost 32 million units of the nail covering had been distributed throughout the entire country before the dangerous nature of this product came to the attention of the Food and Drug Administration. When we first heard of the injuries, the firm already had over 200 complaints on file. It maintained that most of these were of a very minor nature and were really insignificant considering that millions of women had used the product without injury. However, our investigation revealed that continuing use of the adhesive-backed coverings greatly increased the possibility of eventual nail damage. It further revealed that many of the injuries could not properly be classified as minor.

For example, a Kansas City businesswoman used the product three times over a period of one month. Her nails became brittle and progressively deteriorated. They became sore and discolored. Four nails had black spots on them and four were loose. Three weeks after removing the last application of nail covering her nails were heavily ridged and discolored, with five separated from the nail bed back past the quick.

After several applications of this product a nurse in Brooklyn developed an infection near the base of one fingernail which took approximately two months to heal.

A New Orleans housewife used the product for about one month then discontinued its use when her nails began chipping off at the ends unnaturally and small flakes of her nails sloughed off. The ends of the nails began curving upward and away from the skin underneath. She sought medical treatment because of the pain associated with this condition. This irritation continued for at least four months after she discontinued using the product and at that time her nails still appeared abnormally thin and ridged.

These are just a few examples of hundreds of injury complaints which were received by both the manufacturer of this product and the Food and Drug Administration. The pattern of the complaints was that after the second or third application, the surface of the nails began to fleck off as the product was removed or occasionally to peel off in layers; and that for a period of weeks or months thereafter the nails presented an uneven ridged appearance and tore or broke very readily. This was accompanied upon occasion by severe pain and in some cases there were secondary infections involving the cuticles or nail beds.

Ultimately almost 1,000 injury complaints implicating this product were received. We do not know, of course, how many injuries were never reported.

As a result of the recall, over two million units of the product were returned to the manufacturer and destroyed.

H. R. 11582 would correct this situation by requiring a cosmetic that is not already recognized as safe by appropriate experts to be tested for safety before it is marketed for general distribution. The safety evidence would have to be submitted to our department for evaluation by the Food and Drug Administration. And only after such evaluation and approval of the application would a manufacturer be authorized to distribute his product in interstate commerce.

The testing requirement would apply to cosmetics already on the market which are not recognized as safe by experts, as well as to new cosmetics yet to be developed. It would not be in the public interest to exempt all products now being sold because of the vast evidence that some of them have caused and are causing harm.

The bill also contains an anticancer clause that would ban the use of a chemical in cosmetics if it had been found to induce cancer in man or animal when tested by an appropriate method. Certainly this is a worthwhile provision. We are unable to visualize a situation that would justify the use of a cancer producer in cosmetics.

2. Repeal of Exemptions for Hair Dyes

Present law deems a cosmetic to be adulterated and thus illegal in interstate commerce if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. However, this provision does not apply to a coal-tar hair dye if it bears a prescribed caution warning that a preliminary test for sensitization, a so-called patch test, must be made, and provided the labeling also warns "This product must not be used for dyeing the eyelashes or eyebrows—to do so may cause blindness." In other words, hair dyes are not required to be safe if they bear the prescribed precautionary labeling.

When this provision was written into the cosmetic chapter of the law in 1938, coal-tar-containing hair dyes were recognized as substances that caused a significant number of individuals to become sensitized upon using the products. Upon repeated use, the sensitized

person develops an allergic reaction which may manifest itself in mild skin irritation in the area of the scalp or in many cases manifests itself as violent irritation accompanied by rash, fever, pustules in the scalp area which may become infected. The person who suffers a severe reaction is seriously ill and may require hospitalization followed by medical treatment for months.

However, the Congress concluded in 1938 that the patch test would enable individuals who became sensitized to the coal-tar hair dyes to safeguard themselves against that type of injury and it decided that the widespread desire for a permanent-type hair dye was great enough to warrant the exemption provision which made it unnecessary for coal-tar hair dyes to be free from deleterious or poisonous substances.

The situation with respect to these hair dyes has materially changed in the last 24 years according to information that we have received from scientists who are in a position to know. We are advised by industry representatives that the incidence of injuries from coal-tar hair dyes has declined steadily and that the number of damage claims has correspondingly declined. In other words, industry representatives assure us that the coal-tar hair dyes, as manufactured today are in fact safe under the directions for use that appear in their labeling. Whether this is due to improved manufacturing methods that remove sensitizing impurities from the dyes, or to greater use of the patch test, or to some other factor, no one seems to know.

Frankly, we do not know whether the hair dyes are now safe and we are not in a position to secure this information at this time. This is true because under the present factory section of the law, we do not have the authority to determine the formulas used for the coal-tar hair dyes, nor do we have the authority to review the complaint files of the manufacturers. Most hairdye manufacturers do not allow us to review their formula or complaint files. So we have no way of confirming statements made to us by industry representatives about safety of coal-tar hair dyes. On the other hand, we have no reason to doubt the accuracy of these statements.

If the coal-tar hair dyes are in fact safe under directions of use that appear in their labeling, industry has no reason to fear the closing of this gap that was left in the law in 1938, as proposed in H. R. 11582. If the coal-tar hair dyes in fact are not safe, the time has come to give cosmetic users protection all the way across the board and not leave a loophole that allows poisonous materials to be used without control.

With the loophole in the law as at present, our department is not privileged to take action against a coal-tar hair dye that has the prescribed warning, even though it is a hazard to health for some reason other than its ability to sensitize users. For example, we could not remove such a product from the market if it had a known cancer producer in it, or if it contained a chemical that caused high blood pressure, or diabetes or any other serious ailment. We are not convinced that the industry should be the sole judge as to the safety of the products that go into hair dyes that are now used by so many women and for that matter so many men in the United States. No matter how careful most representatives of industry might be, there still should be a provision and law to enable the government representing all the people to guard against the actions of the ignorant, the careless, or the indifferent manufacturer.

3. Effective Date and Transitional Provisions

The new cosmetic title of the bill would become effective for newly developed cosmetics six months after enactment. Cosmetics commercially used or sold immediately prior to enactment would be allowed 12 months for the conduct of necessary safety tests; this 12-month period could be postponed for up to 30 months after enactment upon a showing that the additional time would not involve an undue risk to the public health.

TITLE II. SAFETY, EFFICACY, AND RELIABILITY OF DEVICES

Present law does not require therapeutic, prosthetic or diagnostic devices to be tested for safety or efficacy before they are marketed. As a result, a manufacturer can produce and market dangerous or worthless devices until the government is able to accumulate sufficient evidence to prove the device is unsafe or ineffective.

Injuries have resulted from the use of unfit prescription devices which are important tools in the hands of our medical practitioners as well as from the quasi-medical or out-and-out quack devices which are used or promoted by charlatans. For example, artificial hip joints made from the wrong plastic have broken after being inserted; plates and screws used in mending broken bones have broken, corroded, and produced adverse reactions necessitating repeating operations; plastics used in humans have produced malignant cancers when implanted in test animals; stem pessaries have caused female genital tract injuries and infections, some of which were fatal; electronic,

ultrasonic, and radioactive devices have burned patients because of excessive amounts of energy emitted from the devices.

A wide variety of quack devices have required legal action to protect the consumer because the devices were either unsafe or worthless. Many of these involved irrational combinations of wires, tubes, dials and gadgets, housed in imposing looking cabinets making the machines appear to be legitimate diagnostic or therapeutic devices to the unsuspecting patient. The advent of the atomic era has provided the quack device producer with many lucrative possibilities. For example, uranium ore in pads or pillows of mattress ticking was offered for treatment of sinus pains, arthritis and bursitis.

Deaths and injuries plus substantial economic waste may be expected to continue until the law requires all device manufacturers to conduct adequate tests for safety and efficacy on their products before they are made available to consumers.

The bill requires that new devices be proved safe and effective before they can be marketed. This would be accomplished by requiring new device applications (similar to those required under the new drug section of the act) to be submitted for determination by the Secretary of the safety and efficacy of the device. Further, the bill would require quality manufacturing controls and reporting of adverse reactions and would allow withdrawal of approval of a new device application if substantial doubt as to the safety or efficacy of the device arises. (These provisions are consistent with similar proposals in H. R. 11581 relating to drugs.)

TITLE III. MISCELLANEOUS

Section 301. Cautionary Labeling of Hazardous Substances on Containers Under the Food, Drug, and Cosmetic Act

Basically, the Food, Drug and Cosmetic Act does not attempt to reach household problems arising from flammability of contents, hazards inherent in pressurized containers, and hazards resulting from the exposure of infants and young children to contact with substances that may seriously injure them or endanger their lives if incorrectly employed (drinking a hair wave solution, for example). No warnings are required to appear on pressurized containers of food, although such warnings are voluntarily applied by responsible manufacturers today. Likewise no warnings are required on cosmetics (save for the warning on certain permanent hair dyes that is not germane). While the Food, Drug and Cosmetic Act requires certain warnings to appear

on drugs to guard against unwise therapeutic use, even this requirement does not appear to reach satisfactorily a number of household problems which the proposed federal hazardous substance bill would deal with.

A number of examples will illustrate the problem:

1. Pressurized containers such as those now employed in the packaging of hair sprays, whipping cream, and preparations for application to burns should warn against handling or storage that may result in injury (exposure of the container to excessive heat which may result in explosion, for example).

2. Aspirin is a major cause of accidental poisoning of children today. Many parents are not aware of the dangers and are prone to leave this medicine within reach of youngsters. Similarly, methyl salicylate (oil of wintergreen) is quite toxic when taken in quantities of a teaspoonful or more. Because minute amounts are frequently used as a flavoring, it is mistakenly regarded by many as harmless. Oil of wintergreen and preparations containing it have caused a number of deaths through accidental misuse by both adults and children.

The Food and Drug Administration has attempted to deal with these problems by issuing policy statements suggesting that labels of aspirin (and other salicylates) should warn that the products be kept out of the reach of children, and that oil of wintergreen and preparations containing it should bear such a warning plus a warning that use otherwise than as directed may be injurious. There may be some question as to whether the Food, Drug and Cosmetic Act can, in fact, require such warnings. No manufacturer has yet challenged the policy statements. However, there should be no question as to the government's authority to require warnings to reduce poisonings from aspirin, oil of wintergreen or other products that require such warnings.

3. Cosmetics also cause numerous injuries when misused. Records of the Division of Accident Prevention of the Public Health Service show that in 1961 over 1,700 children were poisoned by the ingestion of cosmetics. There have recently been two deaths—one from inhalation of talcum powder and one from ingestion of a hair color rinse.

H. R. 11582 would make it clear that appropriate warnings may be required under the Food, Drug and Cosmetic Act against possible household injuries arising from the use of foods, drugs and cosmetics. This would be accomplished by:

1. Amending the food chapter of the Food, Drug and Cosmetic Act to deem misbranded a food, contained in a dispenser pressurized by a gaseous propellant unless it bears necessary cautionary labeling with respect to handling, storage, and use.

2. By amending the warning provisions of the drug chapter of the act to make it clear that drug labeling is required to warn among other things against any substantial and reasonably foreseeable risk of accidental injury and that cautionary labeling must include instructions for first aid treatment where necessary or appropriate.

3. By amending the cosmetic chapter of the act to deem misbranded a cosmetic that involves a substantial risk of causing injury during reasonably foreseeable handling, storage, or use unless it bears such cautionary labeling as is necessary to protect individuals and instructions for first aid treatment where appropriate.

That portion of Federal Caustic Poison Act which is still in effect with respect to foods, drugs, and cosmetics would be repealed since the inadequate protection which it now affords would be expanded by these amendments to the Food, Drug, and Cosmetic Act.

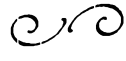
Section 302. Feed Additives Leaving No Residue in Food for Humans

The anticancer clause of the Food Additives Amendment deprives some feed manufacturers of the opportunity of using at least one additive that is widely employed by their competitors. For several years the synthetic hormone-like chemical, stilbestrol, has been used in cattle feed as an aid in meat production. Use of the material has been sanctioned through effective new drug applications. Under the conditions of use prescribed by these applications, no residues of the chemical remain in edible parts of the treated animals after slaughter. Since enactment of the Food Additives Amendment, we have had to turn down further new drug applications requesting permission for this use of diethylstilbestrol. However, since there is no health hazard involved in such use of the product, the applications that became effective before enactment of the amendment are still in force and firms holding them are still marketing cattle feed containing the chemical. We believe that this situation has no effect on the total quantity of diethylstilbestrol used in animal feeds. It simply deprives newcomers of the opportunity of competing in this particular area with established manufacturers.

Accordingly, we would favor a change in the food additives amendment to correct this situation as proposed in Section 302 of H. R. 11582. This would exempt from the anticancer clause chemicals for use in feed for animals raised for food production provided the use of the chemical (1) left no residue in any edible portion of the animals after slaughter, and (2) did not adversely affect the animals.

As an added element of consumer protection we endorse the proposal to authorize our department to prescribe or approve by regulations the methods of examination to be used to determine whether residues of the chemicals in question remain in man's food. Such a precaution would forestall any debate as to the sensitivity of the analytical procedures to be employed in determining whether a feed ingredient may be excused from the application of the anticancer clause.

This change would fully protect the public health, provided we have authority to rescind the effectiveness of a new drug application when substantial doubt arises as to its safety. This authority would be granted by Section 104 of H. R. 11581. In case H. R. 11582, which contains the feed additives amendment, should become separated from the former bill, we recommend that the necessary authority to rescind a decision on the basis of substantial doubt be incorporated in H. R. 11582, as proposed in Section 303 of that bill. **[The End]**



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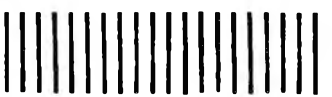

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