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Food·Drug·Cosmetic Law JOURNAL

Papers Presented at the Stanford Law School Symposium on Food and Drug Law on April 27, 1962: The Food Additives Amendment of 1958 . . . Kenneth E. Mulford; Uniformity in Federal-State Food Regulations . . . William W. Goodrich; Regulatory Control in Canada Under the Food and Drugs Act . . . Robert E. Curran.

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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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Table of Contents . . . . . May, 1962

VOLUME 17 NUMBER 5

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FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Charles Wesley Dunn Lectures.—On April 17, 1962 at the University of Southern California an interested audience made up of government and industry members, former FLI Fellows, university representatives and students listened as *Dean Robert Kingsley* described the Food Law Institute program. He spoke glowingly of Mr. Dunn's foresight in having the vision to take such effective means of increasing knowledge of our food, drug and cosmetic laws. *Franklin M. Depew*, President of the Food Law Institute, introduced the speaker, *William T. Brady,* whose paper is presented in this month's JOURNAL. Mr. Depew described the purpose of the Charles Wesley Dunn lectures and paid tribute to the Pharmaceutical Manufacturing Association for making the lectures possible at the university.

Kenneth E. Mulford gave a separate Charles Wesley Dunn lecture at the Stanford University Law School on April 27, 1962. The lecture was part of a symposium on current developments in the food law, particularly in relation to food standards. The panelists who discussed these problems were *Robert E. Curran,* Legal Advisor to the Canadian Department of National Health and Welfare; *Wayne D. Hudson,* Secretary and General Counsel of Foremost Dairies, Inc.; *William W. Goodrich,* Assistant General Counsel for Food and Drugs, Department of Health, Education and Welfare; and *Milton P. Duffy,* Chief of the Bureau of Food and Drug Inspection, California Department of Public Health. They discussed food standards and related problems from their four differing viewpoints. Their remarks stimulated an interesting round of questions and answers.

In addition to Mr. Hudson, a former FLI Fellow, other Fellows in the San Francisco area, *Gary Lovell* and *Richard Nelson* attended the lecture and symposium. Industry counsel and technical people as well as members of the staff of the Food and Drug Administration and the California Board of Health were in attendance.

Broader Inspection Powers.—The President of the Food Law Institute, *Franklin M. Depew* discusses on page 331 the proposal which seeks increased factory inspection authority. Although this would make administration easier, one must consider the rights of reputable and responsible business men to be secure in their privacy with respect to highly confidential and essential production knowledge, Mr. Depew contends. He proposes a solution which he feels will satisfy both industry and the Food and Drug Administration.

New Members.—The Hoffman Beverage Company and the Glidden Company have recently become members of the Food Law Institute, according to *Franklin M. Depew,* President of the Institute.

Vol. 17, No. 5 May, 1962

Food·Drug·Cosmetic Law
Journal

The Food Additives Amendment of 1958

By KENNETH E. MULFORD

On April 27, 1962 Mr. Mulford Presented This Charles Wesley Dunn Lecture at Stanford University. This Lecture Was Part of a Symposium on Current Developments in the Food Law. Mr. Mulford Is Assistant to the Executive Vice President, Atlas Chemical Industries, Inc.

IT IS WITH BOTH PRIDE AND HUMILITY that I appear today to present the Stanford Law School Charles Wesley Dunn lecture . . . proud to have been so honored . . . and humble with thoughts and remembrances of that distinguished lawyer and scholar. It was my great privilege to have known and worked with Mr. Dunn, particularly on the troublesome problems which arose when the framework of the Food Additives Amendment of 1958, my subject today, was being developed.

This complicated amendment, weaving its way in and out of the various provisions of the Federal Food, Drug and Cosmetic Act of 1938 and other amendments thereto may best be understood if two salient concepts are first established. These, in my opinion, are the cornerstones of the amendment.

Licensing Type Law

The first involves the concept of the change of a policing type law to a licensing type law. In a policing type law certain acts or products are specified to be illegal and the governmental agency involved enforces the law against violators by traditional police powers. A licensing type law, by contrast, says that one cannot perform the act or deal in the product unless he first obtains permission from the government to do so.

A prohibition against reckless driving relies upon compliance by most members of the public and the policing of violators. A prohibition against driving without a driver's license makes the act a violation of a licensing type law, regardless of the driving abilities of the violator.

Licensing type provisions are not strangers in food and drug laws of this country. Ever since 1906 the Meat Inspection Act has made it illegal to ship meat food products in interstate commerce unless inspected and passed by the Meat Inspection Division of the Department of Agriculture, and this irrespective of how sound and wholesome the meat food product might be. The new drug and coal tar color provisions of the 1938 Food, Drug and Cosmetic Act are other examples.

However, with respect to most food ingredients, whether intentionally added or resulting unintentionally from food processing, the burden of proving unsuitability, as for example harmfulness, was on the government. The food could be sold to the public while the government developed evidence to sustain this burden and while most food or food ingredient manufacturers extensively tested their products for safety before introducing them, the possibility existed that some unscrupulous person might not do so.

The Food Additives Amendment changed this. Under the new law it is illegal, with the exception of certain products known to be safe for use and others subject to transitional extension provisions, to use substances in or on food unless a regulation is issued by the Food and Drug Administration permitting such use. This in broad terms is the first cornerstone.

The second cornerstone involves a scientific law as well as the subject law of human conduct. Sections 402 and 406 of the 1938 Act provided that a food shall be deemed to be adulterated if it contains any added poisonous or deleterious substance unless the added substance was required, could not be avoided by good manufacturing practice and was permitted by regulation under Section 406 limiting the quantity used to a safe amount. Because it was practically impossible to establish new added substance to be "required" or "unavoidable" and further by reason of the fact that Section 406 involved cumbersome hearing procedures, few, if any, regulations were issued under Section 406.

Delaney Committee

On the other hand during the first ten or 12 years of the 1938 Act many new ingredients were added to food which were perfectly safe for their intended use. However, in about 1950 the House of Representatives formed what was known as the Delaney Committee to investigate chemicals in foods. The conflicting and highly technical nature of the testimony at these,[1] as well as other hearings,[2] left even the more experienced food technologists in a state of confusion as to what was safe for use in foods.

As a result, the Food and Drug Administration in the 1950's began to develop a very strict interpretation of the "added poisonous or added deleterious" substances provisions of Section 402. Substances which produced harmful effects in any species of animal when fed in any amounts were considered to be poisonous or deleterious substances, an interpretation, which, if enforced to the hilt, would have excluded such materials as common table salt. This became known as the "absolute safety" or "poisonous per se doctrine" and began effectively to prevent the addition of new technologically valuable products to foods even though they were perfectly safe for the intended use. Unfortunately, Sections 402 and 406 as they existed at that time, as well as their legislative history, gave considerable support to this construction of the statute. It was interesting to note later that the United States Supreme Court in *Fleming v. Florida Fruit Exchange,* 358 U. S. 153, upheld a similar interpretation of the word "harmless" in the coal tar color provisions of the Act.

In any event industry, government and others realized the need for a change in this unscientific concept. This change is the second cornerstone of the Food Additives Amendment. With the exception of the controversial cancer clause which I shall discuss later, the criteria of safety of an ingredient is that it be safe under the conditions of the intended use and not under the old criteria of absolute safety regardless of the conditions of use.

In summary then, the two basic cornerstones are, first, that before food additives as defined in the Act be introduced into foods, the Food and Drug Administration must reach a conclusion and by order

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[1] Hearings before the House Select Committee to Investigate Chemicals in Food Products, 81st Cong., 2d Sess. and 82d Cong., 1st and 2d Sess.

[2] Hearings on Definitions and Standards of Identity for Bakery Products, 1948-1949.

establish a regulation that the ingredient may be safely used, and, secondly, that the criteria of safety, with the cancer clause exception, be safety under the conditions of use.

With these concepts in mind, let us consider the Food Additives Amendment and for this purpose apply the amendment to a situation that took place about the time Congress amended the food law last year to allow the Secretary of Health, Education and Welfare to extend its effective date under certain conditions.

An Interesting Situation

A producer of textile size used on binder thread for filter cloth became concerned because he had just learned that a use for his size might be subject to the regulatory provisions of the law. It seems that a food producer, in checking his ingredients for compliance, turned to the task of examining his production operations to see whether there were any incidental food additive problems as, for example, minute amounts of material that might get into his food products from equipment, packaging materials and the like.

Since this food manufacturer used filters in his production, he contacted the filter cloth producer to find out whether the filter had clearance under the Food Additives Amendment. The principal concern of the filter cloth manufacturer involved clearance of the fibers used in the main section of the filter. However, he finally got around to consideration of a thread which he purchased to bind the edges of the filter. When the intricacies of the Food Additives Amendment were explained to the binder thread manufacturer, he in turn learned that he should ascertain the status of his thread sizing material and contacted the size manufacturer. As a result, some two and one-half years after the passage of that amendment, the size manufacturer learned that this use for his size might be subject to the law.

I chose this example because the application of the amendment to indirect or incidental additives such as the size is frequently more complex than in the case of ingredients intentionally added for functional purposes in the food.

In determining the status of the size material, naturally the first thing to do is to examine the law and regulations to ascertain why the size is involved.

In the amendment we find that the term "food additive" has a specific legal definition in Section 301(s), and that not all products

getting into food are additives under this definition. Ingredients that are not food additives are as follows:

(1) A substance "generally recognized, among experts qualified by scientific training and experience to evaluate *its* safety, as having been adequately shown through scientific procedures (or, in the case of substances used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use." These substances are generally referred to as GRAS.

(2) Pesticide chemicals in or on a raw agricultural commodity.

(3) Food colors.

(4) Any substance used in accordance with a sanction or approval granted prior to September 6, 1958 pursuant to the Food, Drug and Cosmetic Act or the Poultry or Meat Inspection Act.

Food colors and pesticides are covered by other sections of the law, and, in examining these exclusions from the food additive definition, let us assume that the size is neither a pesticide nor a color. With these exemptions disposed of, the next question is: "Does this use for the size have a governmental prior sanction or approval granted prior to September 6, 1958, the fourth exclusion mentioned above?"

If so, and the prior sanction or approval included consideration of the safety of the use, this sizing use is permissible without further consideration. However, let us assume that neither FDA nor any of the industry people involved knew of any such prior sanction and that none existed.

Determining GRAS Exemption

Consideration should then be given as to whether this use is exempt as being generally recognized as safe. If, for example, the size consisted solely of a well-recognized food ingredient such as glycerine, it quite likely would qualify for GRAS status and hence be exempt.

In this connection, it is to be noted that industry may reach its own conclusion as to whether or not a use for a material is GRAS. The Flavor Extract Manufacturers' Association established a scientific panel for this purpose and many food additive problems might be eliminated if this procedure was pursued more frequently.

However, an independent GRAS determination has its problems. If FDA disagrees with the conclusion reached, it may prosecute to obtain a judicial determination. Secondly, interpretations of the meaning of the clause differ. FDA views the clause as requiring a general knowledge and concensus by competent scientific opinion

of the safety of the use. Others emphasize the word "its" in the GRAS definition and contend that of all experts, only those who have studied the particular ingredient are in the group who must recognize its safety in order to qualify the material for the exemption.[3]

Lastly, there is probably no way to force the Secretary to either agree or disagree with such an independent finding. In one unreported decision[4] on a declaratory judgment action brought against the government, the court refused to make a GRAS finding and indicated that the proper procedure was to file a food additive petition calling upon the Department to make a decision when it acted on the petition, a rather unsatisfactory result for one trying to establish exemption from the petition procedure.

Resuming our example, if we assume that the size was not GRAS, this disposes of the last possibility of exemption and we then consider the positive definition of a food additive, which reads in part as follows: "The term food additive means any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly in its becoming a component or otherwise affecting the characteristics of any food."

Consequently, it is necessary to determine whether the use of the filter results or may reasonably be expected to result in the size becoming a component or otherwise affecting the characteristics of the food passing through the filter. Obviously, in making this determination the size manufacturer needs the cooperation of the food manufacturer because the latter controls the operation.

In the event that the use of the filter is such that the food never contacts the binder thread, it would appear to be fairly obvious that the size is not a food additive because it would never get into the food or affect its characteristics.

On the other hand, if the binder thread does contact the food, it will be necessary to determine whether or not any of the size is leached out into the food. In my opinion, if the use does not result in the size becoming a component of the food and the size does not affect the characteristics of the food, it is not a food additive and the investigation may end.

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[3] Compare "Safe Food Additives and Additives Generally Recognized as Safe—There is a Difference", William W. Goodrich, 15 Food Drug Cosmetic Law Journal 624, with "The GRAS Clause of the Food Additives Amendment," Joseph D. Becker, 15 Food Drug Cosmetic Law Journal 444.

[4] Goodrich, cited at footnote 3, at p. 629.

Again, for practical purposes, it may be that the manufacturer desires FDA concurrence in the conclusion that the material is not a food additive. FDA will probably not give such concurrence on the ground that if there was enough reason to run extraction studies, it may be concluded that it would be "reasonable to expect" that the substance involved would become a part of the food. FDA suggests instead that a petition for a regulation be filed.

Actually, this policy was developed after FDA had given letters of concurrence and firms receiving them had used the letters for sales purposes to the disadvantage of competing companies without letters.[5]

In my opinion, however, anyone is entitled to make tests in order to have positive proof in his own hands that the material does not leach out, and, if it neither becomes a component nor affects the characteristics of the food, to conclude that it is not a food additive.

However, let us assume that the use of the filter is such that some of the size migrates into the food. Since, in accordance with our previous assumptions, it is not subject to the GRAS provision or any of the other exemptions, it then must be classified as a food additive, the use of which is illegal unless it conforms with a regulation issued by the Food and Drug Administration prescribing the conditions under which it may be safely used or unless it is subject to an FDA extension of time for obtaining such a regulation.

Basic Information for Petition

Any person may file a petition proposing the issuance of such a regulation. Under Section 409(b) these petitions are required to include five types of basic information.

The first is a full description of the chemical identity and composition of the additive. This may be a very substantial portion of the petition involving such matters as specifications, uniformity, reproducibility, stability, degradation residues, and so forth.

The second is a description of the conditions of the proposed use, including recommendations for the use and specimens of proposed labeling.

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[5] "Food Additives and Regulations," presented by John L. Harvey, Deputy Commissioner, Food and Drug Administration, at the Food Industry Science School, Rutgers University, January 18, 1962.

Third, data must be supplied on the technological usefulness of the material and the quantity of the material required to produce the effect.

Fourth, a practicable method must be offered for determining the quantity of the additive in or on food including any substance formed in the food because of its use. Generally FDA requires validation data establishing the operability and accuracy of the method.

Last, but not least, full reports of investigations made to determine the safety of this use for the additive must be included.

It can be seen that the development of information for a petition is quite a formidable task. However, with respect to many additives in use at the time the amendment was enacted, a great deal of the data required in the petitions was available in some form with the exception of the analytical methods. Consequently, the development of these analytical methods for old additives has been one of the more difficult problems under the new law.

If the additive is a direct food additive, as distinguished from the incidental size additive referred to above, the analytical method must be applicable to the food in the presence of all ingredients that might be in the food. Generally, it is desirable that its accuracy be within plus or minus 10 per cent. Frequently a quantitative method meeting these requirements for an additive in one food will not be satisfactory for the same additive in another food with the result that a second method must be developed.

In the case of incidental additives, such as the size, it is customary to determine extractability in solvents simulating the food, as, for example, water for aqueous foods and ethyl alcohol for alcoholic beverages. However, in the case of solvents such as heptane which may be employed to simulate fatty foods, some correlation is desired by FDA between the actual extractability in fats and oils and the extractability in the simulating solvent.

Conditions for Issuing Regulation

After the Secretary receives the foregoing types of information in the form of a petition, Section 409 specifies that the Secretary may not issue a regulation if a fair evaluation of the data in the petition either fails to establish or establishes certain things.

In the first place, he may not issue the regulation if the safety data fails to establish that the proposed use will be safe.

Second, no food additive shall be permitted under any circumstances if it induces cancer when ingested by man or animal.

Third, no regulation may be issued if the proposed use would promote deception of the consumer.

Fourth, the regulation shall not permit the use of the additive at a higher level than that found to be reasonably required to accomplish the technological effect for which the additive is intended.

Fifth, the Secretary shall not issue a regulation if he finds that the additive does not accomplish the technological effect claimed for it.

Lastly, the Secretary must take into consideration the cumulative effect of the additive in all food uses for which it may be approved. Thus, it is possible that the permissible safe tolerance for a food additive would have already been used up by prior permitted uses so that a new additional use could not be permitted.

Controversial Cancer Clause

No discussion of the Food Additives Amendment would be complete without reference to the cancer clause proviso of Section 409(c)(3). While the 1958 food law sought to replace the concept of absolute safety, the cancer clause has been interpreted by FDA as prohibiting the use of any substance if it induces cancer when ingested in any quantity and in any manner. Thus, in this area, the old concept of absolute safety was retained.

It is probably in part because of certain complexities spelled out later that Congress retained the cancer clause in the Food Additives Amendment as well as in the subsequent Color Additive Amendments. It did so even though such responsible scientific groups as the Food Protection Committee of the National Research Council, and the Scientific Advisory Committee to President Eisenhower headed by Dr. Kistiakowsky, have cited and discussed substances which can be used safely but are banned by the amendment under FDA interpretation. Also, the Food and Nutrition Council of the American Medical Association has recommended that the cancer clause be repealed or revised.

The basic scientific problems created are these. In the first place, whenever the amendment is discussed, it is generally referred to as a ban on carcinogens, yet the cancer clause makes no mention of carcinogens.

Second, there is a highly vocal and eloquent minority of scientific opinion to the effect that there is no same tolerance for a carcinogen.

Some of the other complexities are best illustrated by materials used in animal feeds or drugs which may be suspected of having cancer inducing properties when consumed in large amounts over long periods of time. The law governs animal feed as well as human food. Thus a material incorporated in animal feed may be banned under the food law.

But now we may find ourselves involved not only in complexities but inconsistencies as well. Take the case of stilbestrol, which can be made to cause cancer in some animals under very special conditions involving a high spontaneous susceptibility of the animal to cancer. The current situation is this:

(1) Stilbestrol is being used for cattle feed under new drug applications which became effective before enactment of the Food Additives Amendment. Since the amendment exempts any substance used in accordance with a prior approval or sanction from the definition of an additive, stilbestrol is not technically an additive in this use. Any revocation of a new drug application would require the government to prove the substance was unsafe. This the government has not attempted in the case of cattle, since it is satisfied there is no residue in cattle under the analytical methods currently used, which go down to two parts per billion.

(2) In the case of new drug applications filed after the amendment, however, stilbestrol in feed would also be a food additive—since there would be no prior sanction—and FDA has not permitted additional new drug applications to become effective. Thus a substance permissible for use by some under prior sanction is barred to others.

Modification for Feed Additives Considered

For the past several years, FDA has indicated that it would support modification of the cancer clause to allow additions to feed, even if they are believed capable of producing cancer, if they leave no residue either in the animal after slaughter or in any food product obtained from a living animal. As a condition for modification, it is believed that FDA would want to substantially broaden the existing grounds for suspending an effective New Drug Application thus indirectly affecting the Food Additives Amendment by making it easier to revoke certain prior sanctions.

Even if the cancer clause is so modified, this would offer only a partial solution. There is, for instance, the interesting question of what is zero. In other words, if by yesterday's best analytical procedures, no residues were found in the animal tissues, the use is permissible as an animal drug. On the other hand, if new improved analytical methods are developed tomorrow and these detect trace residues, the meat food product which was legal yesterday becomes illegal tomorrow.

In view of the board coverage of the Food Addtives Amendment —FDA estimates there are nearly 4,000 direct and indirect additives— and of the time-consuming research required to either support petitions or determine if the law really applies, it is not surprising that industry and government supported legislation to extend the effective date.

Extensions Granted

In the original food law—and this was not changed—the effective date for all uses for products commencing after January 1, 1958 was March 5, 1959. In the case of products used before 1958, however, the Secretary was given the right to grant extensions until March 5, 1961, if he found no undue risk to public health was involved. As this date approached, it became apparent that only a comparatively few regulations could be completed.

As a result, Congress passed an amendment providing that if an extension had been granted or requested before March 5, 1961, the Secretary could grant a further extension until June 30, 1964. In granting a further extension, the Secretary must not only find that there is no undue risk to health but that bona fide action to determine the applicability of the law or to develop the required scientific data had been undertaken before March 6, 1960, and that efforts were being pursued with diligence. The general practice has been to require filing of progress reports every six months to keep extensions alive.

There are two further rather interesting legal questions on which I should like to comment briefly.

If we return for a moment to the definition of food additive in Section 201(s) we find that it includes items such as sources of radiation for the treatment of food, food packages, and the like, that in themselves are clearly not subject to the basic definition of "food" in section 201(f) which reads:

> The term "food" means: (1) Articles used for food or drink for man or other animals, (2) Chewing gum, and (3) Articles used for components of any such article.

Since the prohibited acts of Section 301 and the injunction, criminal and seizure provisions of Sections 302 to 304 all have to do with the introduction into or receipt in interstate commerce of "food" and the factory inspection provisions of Section 704 have to do with establishments in which "food" is manufactured, it would appear that there are no prohibited acts regarding food additives per se so long as they are not "food" within the definition of Section 201(f). Further, the inspection powers would not appear to apply to factories which are only producing such nonfood additives. John Kuniholm in his interesting article "Are Empty Containers Food?", 15 FOOD DRUG COSMETIC LAW JOURNAL, 637, raises the interesting possibility of enforcement action against a container manufacturer, for example, on the ground that he was "causing" the food to be adulterated. He notes in this connection that the first statement of the prohibited acts Section 301 is that "The following acts and the causing thereof are hereby prohibited:"

Even on this theory, however, some element of intent would appear to be necessary, which is not the case where the food itself is in violation.

Appeals From Food Additive Orders

The second comment has to do with appeals from food additive orders. The procedures under Section 409 of the Food Additives Amendment are similar to the procedures of Section 701 for other food and drug regulations. After a preliminary publication of the proposal, the Secretary reaches a conclusion and publishes the regulation in the *Federal Register*. Persons adversely affected have 30 days to file objections stating reasonable grounds therefor and to request a public hearing. If the objections and reasons are pertinent, a hearing is held after which the Secretary issues a final order and persons adversely affected can obtain judicial review in the United States Court of Appeals in which the person resides. In the case of the Food Additives Amendment the Court of Appeals for the District of Columbia also has jurisdiction.

However, under Section 701 the findings of fact by the Secretary following the hearing need only be supported by "substantial evidence" and, if so supported, are conclusive on appeal. Section 701(f)(3).

In the case of the Food Additives Amendment, the findings of the Secretary following the hearing shall be based on "a fair evaluation of the entire record" at the hearing and the court is to sustain

the findings "if based upon a fair evaluation of the entire record." Section 409(f)(2) and 409(g)(2).

The view has been expressed that this change in language is not substantive. I disagree.

As stated by the Senate Committee on Labor and Public Welfare in reporting this bill to the Senate:

> Your committee agrees with the House (of Representatives) that the Secretary's findings should not be based on isolated evidence in the record, which evidence in itself may be considered substantial without taking account of contradictory evidence of possibly equal or even greater substance.

Even so, there will be few appeals in which the court fails to sustain the Secretary's findings on matters of public health.

Conclusion

In concluding, I should like to suggest that the food and associated industries are being overregulated in fields where not even a remote possibility of hazard to public health has existed in fact. On the other hand the details of the composition and production of packaging, can lining and other like materials are now known to FDA and their approval by this governmental agency should alleviate public fears about the unknown.

Unfortunately, politically profitable innuendos remain, as for example, the alleged need for retention of the cancer clause. If scientists in government, industry and elsewhere diligently pursue a course of development and distribution of facts regarding such matters, the latter will become unattractive political issues and we can all concentrate on the development of the nation's food supply under sound administration and enforcement of the Food Additives Amendment of 1958. **[The End]**

Uniformity in Federal-State Food Regulations

By WILLIAM W. GOODRICH

The Author Is Assistant General Counsel for Food and Drugs, United States Department of Health, Education and Welfare. He Presented This Talk at a Symposium on Food and Drug Law at Stanford University Law School on April 27, 1962.

IT IS A GREAT PRIVILEGE to be here in California on this important program. Thank you for inviting me.

My invitation called for a discusion of federal preemption in the field of food standards. With such a subject, a Washington visitor to California might well be greeted with something less than enthusiasm.

We thought that it would be much more constructive to explore the ways and means of achieving uniformity in federal-state regulations, so that the perplexing problem of pre-emption need not arise. Professor Baxter was good enough to accept this modification.

28 States Have Modern Laws

Every step toward uniform regulations must, of course, start with the laws under which federal and state authorities function. It is a distressing fact that in regulating national commerce in so basic a commodity as the food we eat, only 28 of the 50 states have modernized their food and drug laws to catch up with the 1938 Federal Food, Drug and Cosmetic Act. Twenty-two states are still using the regulatory scheme of the 1906 Federal Act, drawn for the problems of Dr. Wiley's times, but now hopelessly outdated. And as near as we can tell from our records, only five states have new laws to deal with the great problems of the 1960's—food additives, pesticide chemicals, and color additives.

It is in this legal setting that we must move to avoid Balkanization of our food controls.

Food standards became a part of the federal act in 1930, with the enactment of the McNary-Mapes Amendment. Standards of quality, condition, and fill of container for canned foods were authorized.

The extension of this authority was one of the main features of the 1938 revision. Standards of identity, quality, and fill of container for substantially all foods were authorized, if in the judgment of the Secretary such action would promote honesty and fair dealing in the interest of consumers.

The five year legislative record of this basic revision in the nation's food and drug laws abounds with discussion—and controversy—over this regulatory authority.

Legislation Necessary

The need was not disputed; indeed, it was made quite clear that many consumer abuses could not be controlled without the authority.

"Bred-Spred", a fruit preserve deficient in fruit, could not be regarded as adulterated jam, unless there were first a standard for comparison. It was not a product of concealed inferiority unless it could lawfully be compared with standard jam. The real effectiveness of the economic adulteration provisions of the new law depended largely on adequate administrative authority to establish standards.

And the Congress responded to the need.

The principal controversy over this phase of the legislation centered on its procedural aspects. Standards had to be promulgated through the most formal of procedures. Notice and public hearing, findings on the record, and judicial review in the courts of appeals were provided.

Quaker Oats Controversy

Shortly after enactment of this law, a controversy arose which was to shape the course of the future. The Quaker Oats Company challenged the Department's right to specify what ingredients should be allowed in a standardized food, what ingredients might be prohibited, whether the levels of use of ingredients could be prescribed, and how the optional ingredients could be controlled and declared.

The Department ruled that enriched flour should consist of flour with four required nutrient additives and two optional nutrients. No added nutrients at all were permitted in plain flour. The same pattern was followed for farina and enriched farina.

Quaker had long been marketing farina with added Vitamin D, but without the newly required nutrients. It argued that the law did not authorize the exclusion of any wholesome ingredient, so long as it was plainly declared on the label.

The Supreme Court rejected the argument and sustained the standard. The Department's right to make meaningful standards of identity was thus firmly established.

Consumer Protection Guaranteed

Since the very purpose of standards of identity is to protect the consumer by guaranteeing the integrity of the standardized food, deviations were limited to the permitted optional ingredients. The Court recognized that with modern food fabrication—particularly foods fabricated to contribute important nutrients to the American dietary—the consumer was not equipped to evaluate the merits of the food on the basis of labeling information alone. The Department's expertise could properly be called into play to assure the public of a rational selection, among a variety of vitamin-mineral enriched foods superficially simulating one another.

Later cases, following this lead, sustained the authority to exclude ingredients when their safety for use had not been adequately established. Honesty and fair dealing could not be served by permitting any ingredient of uncertain safety.

But all these cases make it clear that the regulatory scheme has the needed flexibility. When specific and detailed standards are appropriate for consumer benefit, they may be adopted. When flexibility is the key to consumer interest, the standard may be flexible.

The excess formalism which attended the early standard making led to protracted proceedings and voluminous records. This was supplanted in 1954 by simplified procedures. Rule-making now begins with notice of proposed rule-making and invitation of written comments; procedures which are quite informal. The order which emerges is subject to objections by persons adversely affected, and if reasonable grounds can be stated, the formal proceeding is begun. It is reversed for the areas of controversy that cannot be resolved by informal means.

This simplifying amendment had one upsetting feature, in terms of uniformity in federal and state standards, when it authorized any interested person to initiate the rule-making process. Previously, only the Department on its own initiative, or on the request of a substantial

segment of the affected industry, could bring the administrative process into action. The result is that the Department now is required to act on proposed standards or proposed amendments that do not have broad impact on the regulated industries, and consequently may not be of great concern to the states.

Various State Laws

State laws—even the ones patterned upon the 1938 federal act—vary considerably in their acceptance of the federal standards and in the binding effect given to those standards.

California's pure foods act is quite similar to the federal act in authorizing the Board of Public Health to promulgate standards of identity, quality, and fill of container. And your law provides that such standards "shall not in any instance require a higher standard" than the standards required by the FDA and the Meat Inspection Service.

Indiana's Food, Drug and Cosmetic Act requires the state board promptly to promulgate as its own any standards adopted under federal law. And it may adopt additional standards under the same statutory guide as apply in the federal act.

Kentucky, with a 1960 law, simply requires that its standards conform so far as practicable to the standards adopted under federal laws.

Arkansas follows the same pattern, but provides in addition, that any food which fails to meet an applicable federal standard of identity is misbranded, without the standard having been adopted by the State Board.

These laws are typical of the new breed spawned by the 1938 federal law.

But the 22 states which follow the 1906 Food and Drugs Act have no general provisions for standards at all. Standard making in these states is limited to advisory standards and to special standards adopted under special food laws, such as the state's dairy laws. It is here that conflicts in standards are most likely to occur. The test of promoting honesty and fair dealing in the interest of consumers is not always the touchstone of these special standards.

The modernized state laws, on the other hand, plainly attempt to aviod conflicts with federal standards. In actual practice, the states take advantage of the work that goes into the promulgation of such standards, and do not find it necessary to engage in the protracted public proceedings that sometimes bind our actions.

Yet, despite the legal differences that control us, only occasionally do conflicts arise that may bring forth a question of federal pre-emption.

Leading Cases

The leading cases, at the federal level, are *McDermott v. Wisconsin,* U. S. Sup. Ct. 1913, 228 U. S. 115, 33 S. Ct. 431; and *Savage v. Jones,* U. S. Sup. Ct., 1912, 225 U. S. 501, 32 S. Ct. 715.

The first holds that the state has no power to require the removal of a label which complies with federal law and its replacement by a new label regarded as more informative by the state. Wisconsin could not require "Karo Corn Syrup with Cane Flavor" to be relabeled while held for sale after interstate commerce had ended as "Glucose flavored with refiners syrup".

Savage v. Jones, however, held that the Indiana authorities could require a tag to be placed on animal feed giving full chemical analysis data for crude protein, fat, and fibre. They could also require registration of the label and inspections of the feed stuffs to assure compliance. The Supreme Court held that these additional state requirements could be upheld without impairing in any way the operation and effect of the federal law. In short, the state could legally require a statement of ingredients, when Congress had not seen fit to do so.

Within these rules, the New York Court of Appeals has held that New York cannot require a lower moisture content for corned beef than is permitted by federal standards.

Pennsylvania has held that a drug labeled for over-the-counter sale in compliance with federal law, can be limited to prescription only sale by state law. Currently in contest in the Eighth Circuit is Borden's challenge to Iowa's right to require that ice cream have a minimum of 12 per cent fat, when the federal standard requires only 10 per cent.

There are few satisfying rules that can be drawn from these cases to tell us explicitly when the state requirements are additional to federal rules or when they involve a necessary conflict. Fortunately, the need for such rules is infrequent.

Consistency Needed

But the need for uniformity is a real one of every day concern to federal and state officials alike, as well as to any producer who does a national or multi-state business. Consistency of governmental ac-

tion can be and is being attained in the practical operation of our laws, despite the difficulties which inhere in somewhat inconsistent legislative patterns.

The greatest present day needs for uniform food requirements arise, not in the economic area of food standardizing action, but rather in the sensitive area of food protection—of safe use of pesticide chemicals, food additives and color additives. There is little room for variable restrictions here, because the problem is health protection. Foods must be safe, and federal and state requirements should certainly be consistent in achieving this goal. Inconsistency indicates at once a different judgment on what is safe and what is not. And if there is any real basis at all for the difference in judgment, it should be resolved on the side of caution. If there is no basis for the difference, it cannot be justified by appeals to food faddism.

Most of the states have not yet modernized their laws to meet the challenge of adequate food protection. California, fortunately, was one of the first to do so.

Should States Accept Federal Evaluations?

The policy problem that must be met is how we can best handle the emerging issues in the public interest. Can and should the states undertake the development of scientific resources—essentially duplicating those of the federal government—to review the investigational data on which the safety decision must depend? Or should the states rather accept the evaluation made at the federal level and devote their energies to enforcement of the established tolerances and restrictions on these chemicals in our foods?

Certainly, the scientific resources are in short supply. Only a handful of properly qualified chemists, pharmacologists and related scientists are available. Fewer still at the salaries most governments can offer. Duplicating scientific decisions already reached at the federal level in 50 states would be a monumental undertaking. Reaching such decisions without adequate scientific resources could be catastrophic. It would be far better for the states to participate in the safety decision when first reached under the federal act, and to seek revision of any such safety decision if doubt arose about it. Reserving the decision to themselves should be confined to the rare instances where the states can identify a reason, applicable to their own special circumstances, to impose a stricter requirement.

The states have accepted federal listing and certification of coal-tar colors for years. They also have accepted certification of antibiotics and insulin. So far as we know, no disputes have arisen from these scientific decisions.

A special Committee on Chemicals and Health Hazards in Wisconsin reported in April, 1960, that the pattern of food protection legislation in the federal act was as advanced and effective as that found in any part of the world. Wisconsin adopted all the food additive and pesticide chemical regulations promulgated under the federal act by declaring adulterated any food that bears or contains any such additive, unsafe within the meaning of the federal law. This enabled that state to lead the way to increased consumer protection.

One critical fact is clear. Earlier and more extensive consumer protection can be achieved by putting the state resources to work at once helping control the safe use of food additives, pesticide chemicals, and color additives. There is too much to be done to dilute our efforts by unnecessary duplication of work in readopting detailed regulations already officially promulgated at the federal level on the basis of extensive scientific review. **[The End]**

"GIANT ECONOMY SIZE" JARS SEIZED

Seizure of a quantity of "giant economy size" jars of a well known instant coffee has been announced by the Food and Drug Administration. The agency said the coffee costs more per ounce in the "economy size" than in smaller size containers.

United States marshals seized over 8,000 "economy size" jars at the National Tea Company warehouse, Chicago, and 22 jars at a National Tea Company retail store in Westchester, Illinois. The product is distributed throughout the United States.

FDA said an investigation showed the product is being sold in retail stores of the National Tea Company at $1.44 per jar, or 14.4 cents per ounce, while the six ounce jars of the same product are being sold in the same stores at 75 cents per jar, or 12½ cents per ounce. The difference is 1.9 cents per ounce.

Court papers said that the product, when shipped to Chicago was misbranded under the Federal Food, Drug, and Cosmetic Act "when introduced into, while in, and while held for sale after shipment in interstate commerce."

The papers charged the label statement "Giant Economy Size" is false and misleading since it implies that it is cheaper for the consumer to buy the 10 ounce jar than the six ounce size, when the reverse is actually true.

FDA Commissioner George P. Larrick said recent hearings by the Senate Antitrust and Monopoly Subcommittee, headed by Senator Hart of Michigan, have made it clear that consumers are interested in food packaging and labels. Mr. Larrick said that the present action resulted from complaints.

Regulatory Control in Canada Under the Food and Drugs Act

By ROBERT E. CURRAN

This Address Was Given at the Stanford University Law School Symposium on Food and Drug Law on April 27, 1962. Mr. Curran Is Legal Advisor to the Canadian Department of National Health and Welfare.

IN SPEAKING IN EACH OTHER'S COUNTRY it is customary to pay tribute to our common ancestry, our neighbourly associations, the friendship that binds our peoples, and last but not least, the 4,000 miles of common undefended border. While such tribute may be traditional, it does not follow that the sentiments expressed are trite. They are realities and their importance is not lessened by repetition. On the contrary, the importance to all of us of our happy situation is one that cannot be emphasized too frequently.

Because this hemisphere, and perhaps this continent, may become the single repository of freedom in the world, it is even more important that we should continue to remind ourselves of our heritage and our privileges.

As a Canadian I am not unaware that there are many persons in this country who look askance at some of our habits, policies and views as not being in conformity with theirs. These differences include some of our trade relationships, foreign investment capital, the quality and independence of entertainment through our broadcasting system and the kind and content of advertising in publications to mention only some.

I suggest that in any normal family there are bound to be many differences of view and the matters to which I have made reference involve substantially the same type of differences as would occur in a family.

I hope that Americans who come to Canada feel, as I do when I come to the United States, that they are in a happy family atmosphere. It is one that is possible in very few countries in the world.

It is perhaps unique to find in two countries the possibility of independence of thought and action but always keeping intact the strongest ties of friendship and mutual respect.

I felt that on an occasion such as this the sentiments that I have tried to express warrant special mention and cannot too often be stressed.

Now as I am not here as an ambassador I should perhaps get on with the purpose of my visit which is to explain the Canadian approach to the subject of the discussion.

For reasons that will, I hope, become clear I will not confine my remarks only to standards of identity as a technique of control because in Canada the use of our regulations goes far beyond standards and encompasses wide areas of control.

Canadian Law Is Oldest of Its Kind

Our first food and drug act was passed in 1874. It is therefore the oldest national law of its kind in the Western Hemisphere. It was of humble origin. When it came into the world few expected that it would develop into legislation of the social and economic importance that it today occupies. It saw the light of day as an amendment to the Inland Revenue Act and one essentially concerned with the imposition of license fees or duties on compounders of spirits with the protection of the public obviously of secondary importance.

From the emphasis given to the tax aspect it would not be unreasonable to conclude that the protection of the public purse was at least as important as the protection of the public health.

From this humble beginning it has gone through many stages of growth and development. We consider our present act to be the best of them all and, with becoming Canadian modesty, perhaps the best in the world.

Speaking of Canadian modesty, this reminds me of something that took place in connection with the commemoration of your national law in 1956. The late Charles Wesley Dunn who had arranged a very impressive program for this occasion, kindly invited the Honourable Paul Martin, who was then our Minister of Health and Welfare, to be an evening guest speaker. Mr. Dunn, who had been exposed to Mr. Martin's eloquence on at least one previous occasion, took me aside and told me to remind Mr. Martin that he had been invited to participate in the commemoration of the Fiftieth Anniversary of the United States legislation, not the Eightieth Anniversary of its Canadian counterpart.

Differences in Canadian Law

Our act is criminal law on the basis that injury to the public health and fraud were crimes at common law. In Canada, criminal law is a federal responsibility. It therefore has general application and does not depend on interprovincial commerce to have effect.

Although we also have a commerce clause in our constitution, it was the criminal law that was utilized. We have not found any disadvantage in this basis but, on the contrary, there are possibly many advantages, chief of which is its universality.

If there is any disadvantage, it would lie in the fact that our legislation and its regulations must be related to prevention of injury to health and fraud and not to the pure regulatory control of a trade or industry.

Delegated Legislation

In addition to the constitutional differences in our legislation and that in force in this country, there is a further difference in the Canadian administrative and legal approach which perhaps brings me more directly into the subject of this discussion. This is our use of regulations which is more technically described as delegated legislation. I think we probably do a great deal more through our regulation-making authority in Canada than may be the case in this country.

Under our act the Governor in Council, which for practical purposes is the Cabinet, is given authority to make regulations covering all phases of the manufacture, distribution and sale of foods, drugs, cosmetics and therapeutic devices. My remarks will be confined to those applicable to food.

The Governor in Council is authorized to make regulations for carrying the purposes and the provisions of the Act into effect. Without limiting the generality of this, there is set out a long list of particular subject areas in which regulations can be made.

Coming more closely to the discussion subject, specific authority is given to prescribe standards of composition, strength, potency, purity, quality or other property of any article of food. You will notice that the word "identity" is not contained in this impressive grouping but for practical purposes there is possibly little difference between a standard of composition and a standard of identity. Actually we do not attempt to differentiate between kinds of standards. Hence, some can be regarded as a form of legal definition or recipe, others can involve definition as well as composition, others

can well bring in strength, purity or quality and some perhaps combine all of these. Recognizing this practice, we have provided by way of general regulation that where applicable, the regulations prescribe the standards of composition, strength, potency, purity, quality or other property of the food to which they refer.

Areas Covered by Regulations

I should now like to discuss the areas in which our food regulations generally fall and illustrate the procedure which we employ in making regulations which incidentally will include food standards.

Dealing with the subject in more or less chronological order, the first wide area involves labeling, the second food standards, the third what are now known as food additives, and the last the use of vitamins in foods.

We have no provision in our law requiring a public inquiry or any other form of inquiry before a regulation is made. As a matter of practical policy we have, however, developed a procedure which involves discussion with the trade, either in general or in particular, before a regulation is made. This, of course, is not a formal or rigid procedure but is one which is based on practical considerations.

The need for a regulation or an amendment can be initiated, and often is, by a segment of industry. It can also initiate in the Food and Drug Directorate, as that particular division of our administration is called. This Directorate corresponds to the Food and Drug Administration in this country.

Making a New Regulation

After careful consideration as to the need or desirability of a regulation or an amendment, irrespective of whether this involves a standard or some other aspect of the production, distribution or sale of food, a decision is reached and the form and extent of the proposed regulation is then reviewed. This as a rule, will then be discussed with the affected part of the food industry and their comments sought. The usual means of communication by the Directorate is through the use of what is called a "Trade Information Letter." This is used to inform the trade of proposals and the nature and extent of whatever change may be under consideration.

Unless there is some urgency or the matter is one affecting only our administrative responsibility and not involving the trade in any

particular area, an opportunity is given to consider the matter and to provide comments. The comments are then reviewed and it may be that in the light of such comments further consideration of the proposed regulation is required. If so, an additional "Trade Information Letter" will be sent out or it may be that a meeting will be convened of the industry itself or a special committee of industry, whichever is most appropriate.

Following this, the regulation is then put into appropriate legal form and on the recommendation of the Minister of National Health and Welfare is submitted to His Excellency in Council for enactment. Our regulations when made are published in the *Canada Gazette* which in this context corresponds to the *Federal Security Register*. There is no provision for any period of delay in the coming into force of our regulations nor in the absence of executive directive will a regulation so made be delayed. We usually do provide in the case of regulations that involve extensive changes in manufacturing, packaging or labeling practices, that they will come into force at a future date. This is fixed to give industry ample opportunity to conform.

There is one further point which is relevant and this involves the legal force of the regulations. Under our Act, a violation of the regulations carries exactly the same penalty as a violation of the Act.

We who deal with the regulations in Canada are quick to point out that their use gives a flexibility and life to a statute which would otherwise be difficult if the Act required amendment before changes could be made.

Canadian Labeling Regulations

I should now like to illustrate by one or two practical examples how our procedure works. I mentioned the area involving labeling and this perhaps provides a good illustration. We have always had regulations requiring certain information to be contained on a package. A review of our regulations indicated that wide diversity existed in a number of areas where we felt certain mandatory information should be readily available to a purchaser. In particular, the disclosure of the net weight of contents was the area in which perhaps the widest variation of practice occurred.

In a great many labels, the content was clearly set out. In others the manufacturer, either through inadvertence or choice, seemed surprisingly shy in letting the customer know how much she was getting. A review of several thousand labels strikingly illustrated

the need for some uniformity. At the appropriate time a meeting was convened with the packaging association at which were also represented a large number of food manufacturers. There was general agreement as to the need for some revision of this portion of our regulations. Manufacturers quickly recognized the desirability of uniformity because if good rules are established, then the threat of the unethical operator is avoided.

Various suggestions were made by industry and, as can be imagined, these were not in all respects uniform. It was eventually decided to enact a rather simple form of regulation which would clearly set out basic requirements to be contained on the main label and suitable provision for other mandatorv information.

It was felt that a customer should have readily available and clearly discernible information as to the brand or trade name, if any, the common name of the food, and a correct declaration of net content. The new regulations, require this information to be on the main panel clearly and prominently displayed thereon without distracting intervening subject matter and readily discernible under the usual conditions of purchase and use. Other mandatory information such as list of ingredients, presence of preservatives, colour, and so forth, could also be on the main label or any other panel except the bottom of the package. In order to provide a convenient yardstick to manufacturers as regards the size of type to be used in connection with the declaration of net content, certain sizes are set out in the regulations bearing a ratio to the dimensions of the label.

The regulations in draft form were circulated to the trade. Some of you undoubtedly received this information. Recognizing that in many instances new labels would be required, the Directorate set a date some two years hence for the regulations to come into force. Incidentally, they came into force on the first of January, 1962. In that intervening period ample opportunity had been given to all concerned to make such label changes as might be required.

Despite some isolated protests of bureaucracy, regimentation, and so forth, the manufacturers have cooperated fully and we think without any loss of the merchandising effectiveness of their labels. No longer in Canada will a declaration of net content be found in infinitesimal print hidden away in some obscure corner of a label and in a colour which blends with the background. These were amongst the most objectionable features of labels that the new regulations were intended to overcome.

Meat Standards Defined

I should now like to give another illustration of a regulation which was not discussed before its enactment. Last summer, information had reached the department concerning an illicit traffic in meat from dead or fallen animals. Evidence indicated that certain unscrupulous persons were selling such meat for human consumption. An investigation was made by the Royal Canadian Mounted Police and because this was a brand new situation which the regulations had not contemplated, they were examined as to complete adequacy. I was of the opinion that they possibly fell short of meeting precisely the situation involved. We therefore enacted regulations under the authority of the Act expressly prohibiting the sale of meat from diseased animals or animals that had died other than by proper slaughter, with, of course, slaughter being defined.

Obviously little purpose would be served in discussing the form of the regulation with the persons that it was intended to catch and it goes without saying that it was passed without prior discussion.

Just to follow through on this illustration, the investigation resulted in a large number of prosecutions being instituted and probably served to arouse the Canadian public to the need for adequate meat inspection. I should mention that the Meat Inspection Act is a commerce act, and, therefore, deals only with interprovincial trade. Approximately 80 per cent of Canadian meat is federally inspected under this legislation. The traffic, however, existed in a small part of the remaining 20 per cent and we are confident that the investigation and publicity has done a great deal to bring it to a halt.

Coming now to standards, the same general procedure respecting consultation with the trade is followed. Contrary to what some of our industry representatives may think, the department does not make standards for the sake of making regulations. A standard is made only where it is felt that the public good will be served. We also take into account the industry benefit through the establishment of uniform rules.

As we are not required to hold hearings or otherwise to engage in any form of proceedings, a standard can be quickly or expeditiously made or stretched out over a period of time, depending upon its nature and the urgency of the problem to be met. I can only say that

every effort is made to reflect to the extent possible the views of industry in the making of a standard. This brings me to another illustration with which many of you will be familiar.

Bread Standard Inquiries

I refer to the bread standard inquiries in this country and to the consequent action taken in Canada. Incidentally, this illustration is one that Mr. Dunn liked to use in discussing the flexibility or as he described it the authoritarian effect of the Canadian approach. We had standards for flour. These standards did not permit the use of vitamin fortified flour. We were, however, subjected to considerable pressure by the milling and baking industries to bring our standards in line with those that had been developed in this country following your bread hearings. The pressure, was to some extent accentuated by the fact that the public had become conscious of excess weight and many staple commodities felt the pinch of dietary fads. The baking industry was one. Nutritional claims for bread through enrichment, as it was euphemistically described, seemed desirable to the industry.

After a careful review of the action taken in this country, we formulated a tentative standard and this was discussed. A few meetings were held following which we felt the issue had narrowed down to some half-dozen points. Two at least of these points involved what we regarded as inter-nicene disputes in industry. They related to rival claims for certain types of softeners.

A meeting was convened by the department at which industry representatives were present, including a number of representatives from this country. The meeting, as I recall lasted a little better than half a day. Certain of the points were settled around the table. The department undertook to reach a decision on the remaining points in the light of its best consideration. This was done, the regulation passed and the trade was notified. The department did not receive any critical comments as to the seemingly arbitrary action taken but, on the contrary, received commendation from industry in Canada as well as this country.

I mention this to suggest that while our procedure may appear as bureaucracy gone rampant, in practice this is not so. Our Minister as an elected Member of Parliament is responsible not only to the electorate that supported him but also to Parliament. While he must heed the advice of his officials, he nevertheless is open to direct access by industry in respect of any matter affecting it. I can say that we

have not noticed any reluctance by any group in industry to approach him if they felt there was a point that might escape the consideration that in their opinion it deserved.

Proposed Additives Regulations

I now come to what many of you will regard as, if not the most important, the most timely development in our regulations. I refer to our proposed food additive regulations.

I might say that I have attended a great many meetings in this country at which the subject of food additives loomed large. Rather smugly I sat back thinking naively that it could not happen to us—I hoped that our simple and straightforward approach would be maintained and we would not be subjected to additive fallout from this country. We were. We now have before the trade a very comprehensive set of regulations which will follow to some extent the food additive pattern of this country. There is this difference, however, that our pattern is entirely by regulation and not by special legislation. While it appears different from our former approach, it basically is only an extension or elaboration of it. We always have had a list of certain permitted food additives. These were in the area of preservatives. The proposals which are now before industry represent rather a substantial extension of the list which has been in force for some 25 years or more than the introduction of a new principle.

We propose to define a food additive in rather broad terms but technically to exclude a number of substances that might otherwise come within this term. Vitamins, food colors, spices and nutritives are therefore excluded. Incidentally, at least for the time being food packaging materials are also being excluded.

We deal with the subject by some dozen regulations but then set out 40 odd pages in the form of tables which list the additives by name, the foods in or upon which particular additives can be used, and the maximum levels of use.

To illustrate, in the case of a standardized food, the only additives that can be used are those set forth in the tables in relation to that food. In the case of unstandardized foods, the level of use, also in relation to specified additives, is limited to good manufacturing practice.

It remains to be seen what further changes, if any, will be required before these regulations can be considered to function as easily and as effectively as we normally expect of our regulations. With the cooperation that has been received, we have no grounds for being fearful.

Some of you may be interested in the procedure to obtain the recognition of a food additive or some alteration in its level or extension of use. Here we have built in a procedure which resembles in some respects our New Drug Regulations. This involves the submission of certain specified data to the department with appropriate information respecting its purpose, use, safety and other factors.

Unique Vitamin Regulations

The last area, as I mentioned, involves vitamins.

Our regulations are perhaps unique in setting out a complete code governing the use of vitamins in foods. I refer here particularly to added vitamins and not so much to those naturally present although here our regulations do apply. In general, the regulations specify the claims that can be made with respect to vitamins generally and to particular vitamins. We like to think that our regulations have helped to stabilize, or moderate if you like, the claims that might otherwise have been made with respect to the necessity of vitamin enrichment.

The subject is one that has been controversial. Many manufacturers feel that some bona fide or perhaps pseudo-nutritional claim related to the addition of a vitamin helps to sell a product. This may be true. We feel that our regulations are not primarily designed to support merchandising techniques but rather to ensure that the public is not provided with misinformation and thus is given some assurance of protection against extravagance in claims.

From a health point of view, there is little evidence to support injury or danger from the majority of generally used vitamins. Vitamin D is an exception and here there is clear evidence of hazard from excessive intake. Our main purpose is to reduce vitamin claims to reasonable limits. Even though the public did not suffer from excessive intake, there is the question of value or need to be considered.

We have little evidence of any vitamin deficiency in Canada. Vitamins are actually a form of daily insurance but if there is no risk, then the question of why pay a premium becomes relevant. The public is perhaps gullible and taken in by the type of claim that suggests that in case there is a risk of deficiency you should pay the premium anyway. This undoubtedly supports the volume of sale. Whether the department feels that this is in all respects justified, it is not our function or responsibility to attempt to prevent the legitimate use and advertisement of vitamins.

Additions of Unnecessary Vitamins

There is one area, however, that is giving growing concern. This involves the addition of vitamins to certain foods where it is not one naturally associated with the food and there is no evidence of either a vitamin deficiency or that it is a suitable vehicle through which the vitamin reaches the public. I would not say what action, if any, may be contemplated except that this is a problem which has given rise to concern not only by the Food and Drug Directorate of our department but also by the Canadian Council on Nutrition. I assume that similar concern has been expressed in this country.

This concludes my description of our regulatory approach. If I have strayed down a number of side alleys from the main thoroughfare of the discussion, I hope you will accept my apologies. I felt that in preference to confining my remarks strictly to standards of identity, which is hard to find in our regulatory approach, it would make for better understanding of our legislation and its administration if I brought in the other areas in which our use of regulations is so important.

In conclusion, I hope that what I have said will do two things; first, it will show that our legislation and yours has a common purpose, and, second, that what we are doing, while differing in some respects, is generally comparable and always directed to a common end.

[The End]

ELECTRIC TOOTHBRUSHES SEIZED

The Food and Drug Administration today announced seizure of electric toothbrushes and warned purchasers that the motor and cord units are not sealed and are capable of transmitting severe or fatal shock to the user after immersion in water. FDA particularly warned that the devices should be kept out of the hands of small children who might dip or drop them into the wash bowl.

United States marshals seized 224 of the nationally advertised devices May 8 in New Orleans. FDA said some 50,000 electric toothbrushes and gum massagers, distributed since last February, are in commercial channels.

Papers filed in the federal court at New Orleans charged the toothbrush is misbranded under the Federal Food, Drug, and Cosmetic Act because the labeling fails to bear adequate warnings against the potential electric shock hazard. The papers also charged that printed material accompanying the toothbrush contains statements falsely representing that the motor unit and cord unit are sealed, that the device helps the user to reach every tooth surface to remove food and debris that often cause tooth decay and that it offers "the best in a complete home dental treatment."

Responsibility, Freedom and the Law

By WILLIAM T. BRADY

Mr. Brady, Chairman of the Board of Trustees of the Food Law Institute, Delivered the Charles Wesley Dunn Lecture at the University of Southern California on April 17, 1962.

THERE IS SOMETHING ABOUT THE LAW that both fascinates and confuses the layman.

Most of us are able to pick our way carefully and honorably through the bewildering collection of laws, regulations, ordinances and codes which surround us. Most of us have a great respect for the law, something approaching affection for the remote blindfolded lady who holds the scales. Few of us question that there should be laws, and still fewer of us have either the knowledge or the inclination to question the laws which are written into our books and documents.

The thoughts I will express here today are not particularly original. As I think out loud with you, I'm sure you will recognize the familiar thought patterns of all men who would justify their deep faith in the concept of law with the laws which are on the books.

Law Makes People Responsible

It seems to me that the ultimate purpose of the law—and I speak here only about regulatory law—is to make people responsible. It seems to me that the very heart of the law is a basic and positive assumption that men can be responsible, and that laws serve as a minimum standard of integrity. But when laws multiply to the extent that they hem in every action, they tend to become more nearly a maximum standard. People become so occupied with legality that they have no time for morality. Once it has been decided that there are so few responsible people around willing and able to shoulder responsibility and accountability for their own actions, there is no

recourse but to keep piling on the police power until there's practically no freedom left. I won't say that in certain times, in certain countries, in certain circumstances this may not be necessary . . . temporarily. But it is a terrible indictment against the people at which it is aimed, and judicious men do not take such a decision lightly. Not only are they denying people the right to prove themselves worthy, but they are claiming for themselves rather extraordinary powers.

The particular context of these remarks is, of course, our nation's food laws. And if I seem to be over-playing the threat to the food industry, and therefore to the consumers who are its benefactors, let me tell you I am deeply concerned. There may be yet no clear and present danger, but I am alarmed by the gradual chipping away at our right to exercise responsible judgment. And I am dismayed by the implied reason for it, which I believe to be greatly in error—that our industry cannot be trusted to properly serve the public interest.

Let me say so there can be no misunderstanding, that my company has no intention of ignoring any law, good, bad, or indifferent, that is now on the books. Let me say further that we are convinced of the necessity of a food law and of the integrity and good intentions of the people in Washington and the 50 states who are enforcing the ones we have. Further we are convinced that these enforcement agencies need adequate budgets to carry out their duties. There is no question in my mind that both the public and responsible business need protection from the lawless and irresponsible few who infect any society. It is not my intention to belittle the law when I point out that its contribution is essentially a negative one, a concession that, after all, this isn't Utopia.

No. My concern is founded on a projection of the trend of both the legislation and the underlying philosophies behind it. Perhaps a brief review would be in order, then.

Cooperation Responsible for Legislation

Food legislation and administration is a long story of cooperation between Congress, the executive and judicial branches of government and the food industry. It has had as its prime object, and has most certainly helped to give the American public the safest, most varied, nutritious, flavorful, and least expensive food supply in the history of the world.

In 1883, when he was named Chief Chemist of the Department of Agriculture, Doctor Harvey W. Wiley, started a crusade for the

passage of a food and drug law. As a result, the first Federal Pure Food and Drug Law was enacted in 1906 and its enforcement was assigned to the Bureau of Chemistry in the Department of Agriculture.

The Food and Drugs Act of 1906 was entitled "An Act for preventing the manufacture, sale or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes." The most important amendments of this law were the Gould Amendment in 1913, which required that specific information about the quantity of food in the package appear on the label, and the McNary-Mapes Amendment of 1930, also known as the Canner's Bill. The latter authorized the setting of standards for canned food, except meat and meat products and canned milk, and the prescribing of a statement on the label to differentiate substandard items from those that met the standards.

1938 Act and Its Amendments

With the passing years, it became apparent that a new law was needed. The Federal Food, Drug and Cosmetic Act in 1938, enacted after five years of legislative efforts, was the result. It retained the worthy features of the original Food and Drug Act, but greatly expanded its scope and provided more effective enforcement.

There were several important amendments of the 1938 Act applicable to food. The Miller Amendment of 1938 affirmed the government's jurisdiction over products that became adulterated or misbranded after interstate products "all the way to the moment of their ultimate delivery to the consumer."

The next important amendment was the Oleomargarine Act in 1950, which regulated the labeling and sale of margarine.

Two further significant amendments of the Act were the Amended Factory Inspection Act of 1953 and the Food Standards Simplification of Procedure Act of 1954, also known as the Hale Amendment.

The Amended Factory Inspection Act passed Congress with the combined support of the food industry and the Food and Drug Administration following a Supreme Court decision that in effect nullified the factory inspection provision of the 1938 Act. The Hale Amendment was passed because it was found that hearings on food standards were unnecessarily long and expensive, both for the industry and the government. The Hale Act provided that hearings would be

held only if some interested party objected. Then the hearings would be confined to the particular provision to which objection was made.

The next amendment of the 1938 Act was the Pesticidal Chemicals Amendment of 1954. Under this amendment, the Food and Drug Administration was authorized to establish tolerances for pesticide chemicals in or on raw agricultural commodities. Again, the amendment was passed with the joint support of the food industry and the Food and Drug Administration.

Food Additive Amendment

Without question the most important amendment of the 1938 Act was the Food Additives Amendment of 1958. This Act too was passed with the cooperation and support of the food industry. It provided for a legal requirement of pre-testing food additives, similar to that which had been previously followed by responsible industry itself.

The Act was passed in the closing days of Congress in the summer of 1958 and, because of the time factor, required the unanimous consent of the Senate. My company had filed an objection before the Senate Committee stating that the Bill should not be reported without hearings. This was mainly because of the Delaney Amendment, which prohibited substances found to induce cancer in man or animal. After a talk with Commissioner Larrick, in which he assured us that the Delaney Amendment was regarded by the FDA as adding no new material and that the rule of reason would be applied to all materials, cancer producing and otherwise (the Commissioner was also on record with the Senate to this effect), my company withdrew its objection. The Bill was passed unanimously by the Senate, which would not have been possible except with industry's support. We have been much disappointed that the Commissioner has apparently since been overruled by the Secretary in the interpretation of the Delaney Amendment.

Color Additive Amendment

The last important amendment of the 1938 Act is the Color Additives Amendment, which, again, was passed with the combined efforts of the food industry, the Food and Drug Administration and Congress.

You will note I have placed particular stress on the cooperation between my company—and for that matter most of the food industry—and government. There has always been a high respect in our industry for the distinguished and dedicated men who served as Commissioners of the Food and Drug Administration. Doctor Paul B.

Dunbar was the Commissioner when the Food Law Institute was first organized. He initiated the policy of cooperating with the Institute. When, in 1951, Commissioner Dunbar retired, Commissioner Charles W. Crawford continued in his enlightened policies.

Commissioner Crawford retired at about the same time that the Department of Health, Education and Welfare was created by Congress. The Food and Drug Administration, which had been a part of the Federal Security Agency, was made a part of the Department of Health, Education and Welfare.

The present Commissioner, George P. Larrick, succeeded Commissioner Crawford, and his administration had witnessed a long history of cooperation with the educational efforts of the Food Law Institute and bar association. It was Commissioner Larrick, by the way, who created the panel discussions between the staff of FDA and industry members. This has become an annual event in Washington, under the joint sponsorship of the FDA and FLI.

Having recorded by company's public support for the enforcement programs of the FDA, I must add that this does not, of course, mean we have always agreed with them. Our private arguments, even our litigations, have, however, always been friendly.

Growth of Regulations Becoming Burdensome

That brief recital that I have given you also describes, though I put no stress upon it, the steady growth of regulation. It is becoming burdensome, and could well become even more so. I am deeply disturbed by the far wider regulatory powers now being asked by the FDA. This additional authority—including the right to inspect, among other things, all records, files, papers, processes, controls, and facilities—is unnecessary and unwarranted.

As I said before, the contributions of the law—however great—are negative in character. And I think the time has come, or is about to, when we must begin to worry about the weight of the handicaps being placed on this responsible industry in its efforts to bring more closely together the sciences of health and nutrition and the arts of food preparation and eating enjoyment.

I do not believe that it is the spirit or intent of the law to stifle responsibility and with it, enterprise. Instead, working within the framework of the law, we must find the means whereby companies will operate for the public good, not out of fear of government reprisal—

and therefore choose to take the safe and cautious road—but because operating for the public good is second nature to the corporation.

Responsibility and Freedom

It is highly unlikely that companies from which the responsibility for safeguarding the public health and well-being has been removed, would be the kind of companies which could lead the way to the promise of the future. I can put it very simply: The future we all want can be had only by research and innovation. These can be had only in an atmosphere of freedom. And responsibility must go hand-in-hand with freedom.

It would make no sense at all if the police force of Los Angeles were to impose a nine o'clock curfew on all residents because of a handful of hoodlums.

It makes no more sense to fetter an entire industry because of a handful of sharp operators.

American Housewife's Role Important

This is even more so because while citizens may be terrorized by a hoodlum, the sharp operator can't long survive in the competitive marketplace. He is literally talked to death. When a housewife buys a product which she feels is below standard in any respect she seldom complains to the storekeeper or even the manufacturer. She simply tells her friends, her neighbors, relatives, and bridge club members about it. This is a tremendous "club" in the hands of consumers and nobody knows how to use it better than the American housewife. Make no mistake, we love her, but she isn't as helpless and unintelligent as some people would have us believe. She is a capable, fearless, astute trader, who recognizes quality and value when she sees it. She may want protection, all right, but not at the sacrifice of her freedom of choice which she not only enjoys, but insists upon. It would set off one of the biggest fusses of all time, I'm sure, if either government or industry were to attempt to restrict her in any way, or influence her free choice of the products that she, in her infinite wisdom, purchases for her family.

Reputable companies in the food business—especially those marketing well known trademarked consumer products—have far more to lose than any governmental, educational, or consumer group. These companies have millions of dollars invested in research and development, advertising and promotion so that they bend over back-

wards, far beyond any governmental requirements, to protect these priceless trademarks which are in themselves the best guarantee to the consumer for quality, uniformity and value. Their own specifications are far more exacting than could be expected from governmental regulations, which are minimal.

All right, then. I have said that I'm dead set against over-regulation. And I hope I've made the reasons sound compelling. It's easy to object, easy to complain, easy to lay the blame on government. What am I *for*?

Suggested Remedies

First and always, I'm *for* industry carrying its own responsibility and accountability for its products. And this is far from the easiest way. Once that responsibility is assumed—fully—there can be no excuses for failing to toe the mark. There can't be easy forgiveness even for well intended mistakes. There can be no passing the buck to government for not catching mistakes.

The people and the government which represents them should have every right to expect that industry furnishes sufficient and adequate internal control. The government has every right, too, to satisfy itself that their control program is really adequate, by auditing the program itself and spot-checking the output. And if it finds either wanting, it had adequate penalties and enforcement right now at its disposal. This is somewhat similar to the arrangement companies have with their outside auditors who insist on an adequate internal auditing programs, of which they approve.

Second, I suggest that careful consideration be given to a system which has worked well in other parts of the world: voluntary policing through trade associations. The best feature of this system is that self-regulation is worked out by leaders of industry, men who are experienced and practical, and who are unquestionably responsible.

Clarification and Interpretation Needed

Third, I suggest that much more needs to be done to clarify and interpret the complexities of the food law as it now stands. Government officials should be fully accessible to business people and willing to discuss what their interpretation of the law will be—before the matter reaches the point that, to use an old expression, anybody "makes a federal case out of it."

Plainly the Food Law Institute served as an important vehicle, a bridge, for more discussion and more perfect understanding between

business and government. But I am not satisfied that either business or government is using it as much as it should. Franklin M. Depew, as president of this going organization, is doing a tremendous job and deserves more widespread support than he has received to date. Certainly the Food Law Institute is making an important contribution to both research and education in our food laws.

Fourth, I strongly submit that public confidence in the safety, wholesomeness and quality of the American diet is a trust shared by both industry and government. Any action which undermines that confidence—or worse than that—panics the public into believing it is being poisoned, does great damage to our country. I am not alone concerned by the economic effects on entire industries, the fact that many entirely innocent people suffer financial loss. I am also concerned by the encouragement given to the lunatic fringe of our society, the crackpots who would send us out herb gathering our dinner. When all else has failed, public disclosure may be necessary to warn our citizens of really dangerous foods on the market. But there are many steps that can be taken to avoid so drastic a step. At the first sign of a possible problem, the businesses concerned should be called in to see what steps can be taken.

Finally, I want to reaffirm my belief in the need for a food, drug and cosmetic law. I want to say that with the tremendous development taking place in the growing, manufacturing, packaging, and distribution of food, there may be greater and not less need for regulation. But let it be within the framework of responsibility, freedom and the law. **[The End]**

HEALTH FADDIST CURBED

One of the country's leading sources of nutritional quackery has been curbed by federal court action, the Food and Drug Administration announced today. FDA said that sentencing of Royal Lee, president of the Vitamin Products Company, Milwaukee, Wisconsin, will stop distribution of over 115 special dietary products promoted by false claims for treating more than 500 different diseases and conditions.

Federal Judge Robert Tehan sentenced Lee to a one-year suspended prison term with three years probation and fined the Vitamin Products Company $7,000 on charges of interstate shipment of misbranded vitamins and proprietary remedies. Lee also consented to a permanent injunction covering all of his enterprises which prohibits the false claims for his products. FDA said the injunction also stops Lee from claiming the products are necessary adjuncts to the diet.

Lee holds a degree in dentistry, FDA said, but he has not been known to practice that profession. Instead he became one of the country's leading health faddists and a regular speaker on the subject. His "health food" business is estimated at some $3,000,000 a year.

Are Broadened Inspection Powers Necessary?

By FRANKLIN M. DEPEW

The President of the Food Law Institute, Franklin M. Depew, Presented This Talk Before a Meeting of the Flavoring Extract Manufacturer's Association in Skytop, Pennsylvania on May 1, 1962.

THE PRESENT FACTORY INSPECTION AUTHORITY of the Food and Drug Administration is found in the Amended Factory-Inspection Act which was passed by Congress on August 3, 1953 and approved by the President on August 7, 1953 (Public Law 217, 83d Cong. 1st Sess.). The inspection authority intended to have been bestowed upon the Food and Drug Administration by Section 704 of the Federal Food, Drug and Cosmetic Act as enacted in 1938 had been held by the Supreme Court not to require the owner, operator or custodian to permit entry and inspection (United States v. Cardiff, 344 U. S. 174, 1952). Therefore the FDA requested Congress to amend the section to restore the compulsory power of its FDA inspection authority. The FDA request for compulsory inspection powers was supported by industry. However, industry representatives objected to the broad inspection powers claimed by FDA under the old law and Congress further amended the section to assure a due and limited exercise of that authority.

Inspector's Authorized Actions

The amended law of Section 704 authorizes an FDA inspector to enter any establishment where foods, drugs, devices or cosmetics are manufactured or held for introduction into interstate commerce, or when they are held thereafter, upon presenting appropriate credentials and a written notice to a responsible person or agent in charge. Upon

so doing the inspector is authorized to inspect the establishment and all pertinent equipment, finished and unfinished materials, containers and labeling therein, at reasonable times and within reasonable limits and in a reasonable manner. The legislative history shows that these "reasonable" requirements were intended to assure a due administrative exercise of the FDA inspection authority, within the restricted fields specified. This authority did not reach such matters as manufacturing formulas and patents, qualifications of scientific, technical or other employees, product injury complaints or files relating thereto. The section further provides a direction that the FDA inspector give a written report of unsanitary conditions and unwholesome products assertedly found by him, but he is not required to report any other matters, nor when the inspection satisfies him.

Validity of Present Inspection

The present FDA inspection authority of Section 704 is valid in my opinion. It serves a legitimate purpose—to exclude harmful articles from interstate commerce. It does not violate the commerce clause in Article I, because it only regulates articles manufactured or held for introduction in interstate commerce, or which are held thereafter. Likewise this law does not violate the Fourth Amendment against unreasonable searches and seizures because it only authorizes an administrative inspection which is required to be made at reasonable times and within reasonable limits and in a reasonable manner. Finally, the law does not violate either the due process or the self-incrimination clauses of the Fifth Amendment for the same basic reasons. Thus, the present law is a valid one which preserves the people's fundamental right to be secure in their persons, houses, papers and effects against wrongful searches.

The FDA had contended that the law of the 1938 Act authorized inspection of formulas, qualifications of technical persons and the like, and in the Congressional hearings bearing on the amendment Commissioner Crawford testified that they believed this information was immediately relevant and pertinent to the compliance of these establishments with the terms of the law. Because of this belief FDA has undoubtedly hoped for a favorable opportunity to remove the limitations explicitly provided in the present law, and that opportunity may be at hand in view of active discussion of new food and drug legislation on the Administration level.

FDA's Recommendation

In a release dated January 17, 1961, issued by the Hon. Arthur S. Flemming, then Secretary of the Department of Health, Education and Welfare, the following proposal was advanced as representing the FDA's recommendation with respect to factory inspection:

> Amendments (a) to extend the factory inspection provision of the Act (704) to all records, files, papers, processes, controls, facilities, and things bearing on violations, or potential violations, of the Act and (b) to clarify the factory inspection provisions by expressly including consulting laboratories (the first of these is not limited to inspection relating to drugs although the immediate occasion for it arises in connection with drug manufacture, because for obvious reasons the same authority is needed for other articles subject to the Act.

The draft of the law which was attached to the release reads as follows:

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

The text of the FDA's amendment, which was reviewed earlier this year by the Budget Bureau, is even broader and is reported to be as follows:

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

President Kennedy in his 1962 State of the Union message to Congress in January of this year has given his support to some expansion of FDA's inspection powers. He said:

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

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

It is interesting to note, however, that in his message to Congress on March 15, 1962, on consumer protection he did not specifically include in his recommendation for proposed legislation a bill to expand the FDA's inspection powers.

However, in a talk entitled "The FDA and Consumer Protection" made by Mr. George P. Larrick, Commissioner of Food and Drugs, on January 23, 1962, at the annual meeting of the National Canners Association, 17 FOOD DRUG COSMETIC LAW JOURNAL 266, he stated that an additional compelling reason for increased factory inspection powers was the greatly increased use of food additives. He stated that he deemed it essential for FDA to have access to manufacturing formulas to determine that proper ingredients are being used in the proper amounts and access to control records to determine what steps are employed to guard against errors. In addition he reiterated the need to have access to complaint records and correspondence files which FDA claims are a major source of determining bad practices.

There can be no dispute about the fact that increased factory inspection as sought by FDA could be effective in some instances as a means of easing administrative difficulties. In the food additive field the FDA could check on the proper use of additives much more easily and quickly by looking at the formula cards than they can by making analyses of the products in which the additive was used. However, so far as the shady operator is concerned we believe that it is unlikely that the records made available for FDA inspection could be relied upon.

Industry's Right to Privacy Considered

The basic question, then, which is posed by this proposal is whether ease of administration outweighs the rights of reputable and responsible business men to be secure in their privacy with respect to highly confidential and essential production knowledge which they feel they should disclose to no one.

From my discussions with industry counsel and other representatives of management of a number of food companies I find that a strong industry sentiment exists in opposition to this proposal. They feel that the broad reach of this proposal involves the power to conduct fishing expeditions without any requirement of probable cause to believe that the law has been violated and without any requirement of subpoena whereby the party proceeded against can have the protection of a court. The reasons for industry opposition are well expressed by Mr. Samuel A. McCain in his speech of January 24, 1962, before the Section of Food, Drug and Cosmetic Law of the New York State Bar Association, 17 FOOD DRUG COSMETIC LAW JOURNAL 209.

This industry sentiment is reflected in the resolution opposing the proposal adopted on January 22, 1962 at the 55th Annual Convention of the National Canners Association. Those persons with whom I have discussed the matter feel that the proposal entirely overlooks the fact that most manufacturers have a high sense of public responsibility. There is no basis whatsoever to believe that legitimate industry will misuse food additives or employ incompetent people. Industry has the highest stake in making certain that our food supply should continue to be the most wholesome and of the highest quality in the world. They cannot afford to neglect their responsibility. The sentiments expressed to me are well summed up in this sentence from the National Canners Association's resolution:

> But the most significant protection for the consumer derives from the nationwide growing and processing of food through the conscientious efforts of individual enterprises to provide consumers with wholesome and fine food.

It also seems to me that this proposal overlooks the fact that the inspection powers which are exercised by the FDA are a part of a regulatory scheme authorizing inspections to encourage full and proper compliance. They are intended to protect the health and lives of the public by preventing the channels of interstate commerce from being used for the distribution of adulterated and misbranded food, drugs, devices and cosmetics. The inspections are normally a matter of routine checking, and are not necessarily or normally based on any prior suspicion or determination that any law has been or is being violated.

As has been pointed out, one purpose of such inspections is to encourage compliance with the Food, Drug and Cosmetic Act by bringing to light conditions which may cause products to be adulterated or misbranded, thus enabling manufacturers and processors to correct conditions and to withhold adulterated or misbranded products from the channels of interstate commerce.

Securing Greater Industry Cooperation

If the FDA would exercise its inspection powers in this spirit of encouraging compliance, rather than as an initial step in criminal proceedings they might find that they could secure much wider industry cooperation. If they confined their examination to the subjects authorized by the present law and then notified a responsible company manager that additional information was requested for a declared good reason it is possible they might find that there is a

large area for constructive cooperation, particularly if the requested material could be made available to FDA's scientific staff in Washington, D. C., rather than to a field inspector. While the manufacturer has just fears about disclosing confidential information to anyone, I believe that some of them might be overcome if FDA scientists furnished him with convincing reasons why disclosure would further the remedial purpose of the law. Perhaps if such FDA personnel would make full use of their powers of persuasion they might find that business men would respond to their requests. Such a policy would offer some safeguards which might appeal to industry. It would certainly be a great improvement over the present FDA policy, whereby its inspectors are instructed to ask for formulas, and other material to which they are not legally entitled. Under the present policy the FDA may be expected to place the uninformed at a great disadvantage. Such policy tends to create an unfortunate resentment on the part of industry with a resulting lack of cooperation. I suggest that if the problem of inspection is attacked responsibly by both sides it is possible that a solution may be found without the enactment of a law of doubtful constitutionality.

A Proposed Solution

Everything I have said so far has suggested that industry feels that no change in the present law is necessary. However, a legislative scheme has occurred to me which I believe would give FDA the information it needs relative to food and color additives without offending industry's right of privacy.

I suggest legislation which would authorize FDA to require an affidavit from an official corporate representative stating that an examination of the company's formula cards and processing operations kept in the regular course of business, discloses that the food or color additive named is not used in excess of a certain stated amount. This would give FDA the needed information relative to these additives that they would secure from access to the records, but without disclosure of the other confidential information shown in the records.

It is my sincere belief that this proposal should be satisfactory to both industry and government. I hope it may be looked upon with favor by the Congress as a suitable solution which will provide the FDA with the needed additional authority to protect the consumer in the food and color additive field. **[The End]**