Statement by Hon. James J. Delaney, M.C. on H.R. 4014 and H.R. 4015, before the Subcommittee on Health and Science, March 29, 1957.

Mr. Chairman, and members of the committee, I want you to know how much I appreciate this opportunity to appear in support of H. R. 4014 and H. R. 4015. The first of these bills is for the purpose of protecting the public health by amending the Federal Food, Drug and Cosmetic Act so as to provide for the safety of chemical additives in food, and the second, for the safety of chemical additives in cosmetics.

In the 83rd Congress I introduced two similar bills, but they were not heard at that time. Last year, the committee held hearings on my bill, H. R. 4475, and other bills relating to chemical additives in food, but no action was taken. I appreciate the committee's renewed examination of this subject, and I hope that protective legislation will be enacted in this Congress.

I believe that most of you know the reason for my interest in chemical additives, and to save your valuable time I shall not go into it in any detail on this occasion. It should be enough to recall to you that in 1950, 1951 and 1952 I was chairman of a select committee which investigated the use of chemicals in foods and cosmetics. The committee held extensive hearings in various parts of the country and heard testimony from qualified experts only. The investigation established beyond question the need for regulatory legislation in this field.

As you know, under the law as it now stands, chemical additives do not have to be tested to establish their safety for use before they may be introduced into foods or cosmetics. In practise, responsible companies do make such tests, but the public has no official assurance of the adequacy of the tests, and, of course, the public has no assurance of protection against the practises of less conscientious companies.

The Food and Drug Administration estimates that today, in foods alone, there are at least 150 chemical additives in use, whose safety has not been definitely established.

Think what this means. Since practically every item on our foodshelves contains chemical additives, it means that every day, you and I, and everyone in the country, are eating food containing substances whose effect on the body, on a long term basis, is not definitely known. The question of acute poisoning is not involved to any great degree. However, the question of chronic toxicity is very much involved.

All of this is now generally recognized. Physicians, scientists, the food and chemical industries and the consumers agree that chemical additives should be pre-tested for safety. The issue is not the need for legislation, but the form the legislation should take.

It is my position that the public must have the fullest measure of protection. I believe that any legislation providing less than that would be indefensible.

H. R. 4014 was carefully drawn up to conform with the recommendations of the select committee. It affords protection for the public and at the same time it safeguards the legitimate interests of the food manufacturers and processors.

I should like to comment briefly on certain features of H. R. 4014.

1) Unlike some of the bills considered by the committee last year, it does not contain a "grandfather's clause" which would exempt doubtful chemicals now in use from pre-testing requirements. No one wishes to cause the industries unnecessary inconvenience or dislocation, but it is my conviction that the public health must come first. If a chemical is dangerous for human consumption, it is dangerous - period. The criterion should always be: "Is this chemical safe?"

2) In Section 5 there is a requirement that a chemical additive must serve a purpose which will be useful to the consuming public. This provision is important, and is necessary for the purpose of maintaining the highest nutritional standards of our foods. Chemicals are now used as substitutes for more costly natural food ingredients. These chemicals have no nutritional value, and the foods in which they are employed have had their nutritional standards lowered. Any legislation on chemical additives should contain a "useful to consumer" clause to insure that the public will have food of the highest nutritive content.

3) Section 5 also contains two procedures to protect the legitimate interests of the food and chemical industries. The first provides that anyone adversely affected by an FDA ruling on chemical additives in food and cosmetics may petition to have the ruling referred to an advisory committee of qualified experts for their recommendations and report. The second provides for judicial review of any contested ruling.

Mr. Chairman, at this point I should like to bring to your attention a recommendation which has recently been made, and I believe it merits careful consideration in the study of this proposed legislation.

Although, as I said earlier, H. R. 4014 was carefully drawn up to conform with the recommendations of the select committee, I have no particular pride of authorship, and, on many occasions, I have been in touch with physicians and medical societies asking them for any suggestions they might have relative to this legislation.

Along this line, late last January I had a conference with a noted cancer researcher, Dr. William E. Smith, of Englewood, New Jersey. To identify him, I might say that since his graduation from Johns Hopkins University in 1938 as a doctor of medicine, Dr. Smith has devoted his career to cancer research. He has been a full-time member of the staffs of first , the Harvard Medical School; then, the Rockefeller Institute for Medical Research; and following that, the Sloan-Kettering Institute for Cancer Research. Until 1956, he was associate professor of industrial medicine at New York University.

At the present time, Dr. Smith is executive secretary of the Cancer Prevention Committee, which is devoted to the study of environmental factors in cancer, and he now holds a fellowship from the American Academy of Nutrition for study of nutrition in relation to cancer.

As a result of our conference, at my request, in February Dr. Smith wrote me a letter in which he analyzed, from his point of view, the various chemical bills which were introduced in the last Congress. In addition, he urged that my present bill, H. R. 4014, be amended to specify that no known cancer-inducing substance may be added to food.

I have provided each of you with a copy of Dr. Smith's letter, and I earnestly request that you read it in full. However, here I shall try to give briefly the reason for Dr. Smith's concern.

The wording of Section 409 (c) of H. R. 4014 would seem to prohibit the introduction into food of any known cancer-inducing substance. However, a comparatively recent FDA ruling on a pesticide known as Aramite has prompted Dr. Smith to urge that any chemical additive legislation should specifically prohibit the use in food of any carcinogen.

As I understand the case, in 1955, under the authority of Public Law 518, 83rd Congress (the pesticide amendment), FDA ruled that a zero tolerance should be established for residues of Aramite - in other words, that no residue of Aramite should be permitted on vegetables and fruits.

In accordance with a provision of that law, the U. S. Rubber Company asked that the ruling be referred to an advisory committee of experts selected by the National Academy of Sciences for recommendations and report.

The advisory committee met on July 27, 1955, and after considering all the evidence, recommended that a residue tolerance of 1 part per million be established for Aramite. The committee also advised the U. S. Rubber Company to secure more data on the chronic toxicity and carcinogenicity of Aramite and recommended that the whole problem be reviewed again this year, at which time further laboratory and other data should be available.

Although the advisory committee thus tacitly admitted that in 1955 it did not have sufficient evidence to completely establish the safety of using Aramite as a pesticide, FDA followed the recommendations and published a residue tolerance of 1 part per million for the chemical. So, for nearly two years, Aramite residues have been permitted, although Aramite is considered a carcinogen.

Now, Dr. Smith's point is this: As the result of his long experience in the field of cancer research, he is strongly convinced that the presence of any carcinogen in food is dangerous and he fears that the Aramite decision will set a precedent that may make possible the introduction of so-called safe quantities of cancer-inciting additives into food.

Dr. Smith's position is in line with the views of the International Union Against Cancer.

Last August, in Rome, the Union held a symposium on potential cancer hazards from chemical additives and contaminants to foodstuffs. Over 40 cancer experts from some 21 countries participated. A unanimous report was issued, ending with this general conclusion - and I quote:

"The Conference recommends that, as a basis for active cancer prevention, the proper authorities of various countries promulgate and enact adequate rules and regulations prohibiting the addition to food of substances having potential carcinogenicity."

I have written various medical groups, including the New York Academy of Medicine, the American Public Health Association and the American Cancer Society, asking them for their views of Dr. Smith's recommendation, and after they have been received I hope to have the opportunity of submitting them to this committee.

I have confined most of my remarks to H. R. 4014, since H. R. 4015 is very similar, except that it provides for the regulation of chemical additives to cosmetics.

Mr. Chairman, interest in this subject is countrywide. I have received literally thousands of letters from people in every state of the Union and from various countries abroad. These letters come from people in all walks of life and they all agree on one thing - there is urgent need for protective legislation.

I know of no issue of more immediate importance than that which is under consideration here. The health and power of our nation depend in large part on its food and I feel that no time should be lost in bringing this chemical additives situation under control.

Thank you, Mr. Chairman, and gentlemen, for your courtesy.

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Statement by Hon. James J. Delaney, M. C. before the Subcommittee on Health and Science, April 16, 1958.

Mr. Chairman, and members of the committee, it was a little over a year ago that I was heard in support of my additive bill. Since that time, you have listened to a great deal of testimony, and I appreciate this opportunity to recapitulate and reemphasize some of my views on chemical additive legislation.

May I say that I also appreciate the amount of time and the serious consideration you have been giving the additive bills. I am sure that by now you can have no doubt as to the necessity of protective legislation in this field.

However, the question remains - what form should the legislation take?

My bill, H. R. 7798, has but one purpose - to give the public the fullest measure of protection possible. I know that various of its provisions do not please the industries involved, but I am much more concerned with the public health than I am in accommodating the industries.

I believe that H. R. 7798, together with Mrs. Sullivan's H. R. 7938, offers greater protection than the other bills before you, and I should like to comment briefly on certain salient points. (Hereafter, when I speak of H. R. 7798, I also include H. R. 7938.)

Grandfather's Clause

As I have previously stated, the bill contains no grandfather's clause. Industry representatives at these hearings have frankly admitted that they want such a clause, but I feel strongly that no exemptions should be granted.

As you know, the Food and Drug Administration has estimated that there are at least 150 chemical additives now in use that are in a sort of "scientific no man's land". That is, their safety has not been proven beyond a doubt.

If these chemicals are not brought within the scope of any legislation enacted, the very reason for the legislation will be by-passed. What sense would there be in your protecting me against new poisons if I am forced to keep on ingesting old poisons?

The FDA bill, H. R. 6747, has a provision which seems to have some grandfather possibilities. It would exempt an additive if it has been shown to be safe through "prolonged use" in food. However, it does not define "prolonged use".

Just how long is "prolonged use"? Two years. Five years. Ten years? And if adequate tests have not been made, how can a criterion be established for safety through "prolonged use"? In the case of some chemicals, it might take as long as 20 years for their accumulative effect to be felt.

Other bills (H. R. 8390 and H. R. 366) do not specifically give exemptions, but they deal only with "new food additives", thus

conveniently ignoring those now in use. H. R. 10404 exempts chemicals in use before January 1, 1958.

Mr. Chairman, I do not wish to appear unduly critical of the other bills, but I do want to have my opposition to a grandfather's clause thoroughly understood.

Usefulness to Consumer

There is a provision in my bill which is not contained in the others, and I feel that it is an important one. That is, a chemical additive must serve a purpose which will be useful to the consuming public.

This provision is extremely unpopular with the industries. They have even quarrelled with the rather vague requirement in the Administration bill relating to an additive's "functional value", although it does not state whether the additive should be of functional value to the consumer or to the industry.

Considering the present practices of many of the food industries, a "usefulness to consumer" requirement is needed to insure the nutritional standards of our foods.

For instance, chemical emulsifiers and synthetic egg colorings, which have no nutritive value, are widely used in place of natural food ingredients, especially in baked goods. Baking soda has been added to sour milk to make it appear sweet when used in the making of ice cream. Synthetic sweeteners are used to replace sugar. These are but a few illustrations.

The substitution of inexpensive chemicals for valuable natural substances cannot be justified on any grounds. The nutritional standard of our food supply must be jealously guarded, and a "usefulness to consumer" provision is essential.

Carcinogens

H. R. 7798 is the only additive bill which contains a specific provision prohibiting the introduction of any carcinogen into food.

I am aware of the fact that conflicting scientific opinions have been expressed here regarding this provision, but my testimony of March 29, 1957 gives the reasons why I felt impelled to include such a provision.

In this field, I am a layman, and I do not claim to have any special knowledge of medicine. However, when the public health is involved, and the experts disagree, then, as a legislator, I feel I must support the experts whose opinions appear to most strongly safeguard the public health.

The carcinogen prohibition in my bill follows the recommendations made by the International Union Against Cancer in Rome, in August, 1956. It is supported by the three emminent cancer researchers who appeared before you last year and who are on the Cancer Prevention Committee of the International Union - Dr. W. C. Hueper, Dr. William E. Smith and Dr. Francis E. Ray. The committee has a letter from the American Cancer Society, also in support.

Mr. Chairman, it is appalling to think that one out of every four persons in this country will at some time or another suffer from cancer.

The part that chemical additives play in the cancer picture may not yet be completely understood, but enough is known to put us on our guard. The safety of the public health demands that chemical additives should be pre-tested specifically for carcinogenicity, and this should be spelled out in the law. The precedent established by the Aramite decision has opened the door, even if only a little, to the use of carcinogens in our foods. That door should be slammed shut and locked. That is the purpose of my anti-carcinogen provision.

Irradiation and Animal Feed

I should like to touch briefly on two or three other points.

For several years, experiments have been going on to find a way to successfully preserve food by the use of irradiation. While apparently this does not cause the food to become radio-active, I understand that it has not yet been determined what chemical reactions may result, and what the effect of those chemical reactions might be. Since irradiation may become accepted as a new method in the processing of food, in any legislation now being considered, it seems only prudent to include radio active material in the definition of chemical additive. Both the FDA bill and H. R. 7798 do this.

Also, both these bills would cover chemical additives in feed given to animals destined for human consumption, and food derived

from animals. The addition of stilbesterol to cattle feed and the use of antibiotics as additives in feed are now common practice. Urea, a synthesized product made from carbon dioxide and ammonia, is being used in increasing amounts in rations for food animals. Other chemicals are in similar use, and still others are being experimented with. There is a definite need to have these chemicals subject to any legislation dealing with food additives.

I believe it is not necessary for me to go into the appeal provisions of H. R. 7798. You have heard the views of Judge Biggs on the appeal provisions of the various bills, and I think the procedure indicated in my bill conforms in essential respects to the recommendations of the Judicial Conference of the United States, which Judge Biggs represented.

Mr. Chairman, I have no exaggerated pride of authorship. I have tried to make H. R. 7798 a good bill, and I believe it is a good bill. But I do not consider it a perfect bill. If the committee can improve it, I shall welcome the improvements. What I have tried to do today is to highlight certain provisions which I feel any food additive legislation should contain. I recognize that this is a difficult subject on which to legislate, and it is impossible to anticipate all contingencies; but in the bill I have tried to give the public the maximum protection possible.

The public is deeply concerned with the food additive problem and is increasingly aware of the issues involved. The letters which I continue to receive from people all over the country

express this concern. The writers cannot understand why action has been so long delayed.

Certainly there is nothing of greater importance to any nation than the health of its people. I am confident that the committee shares this view, and it is my earnest hope that strong food additive legislation will be enacted in this Congress.

Thank you, Mr. Chairman, and colleagues, for your courtesy.

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