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It gives me pleasure to be with you today to discuss consumer protection under the Federal Food, Drug and Cosmetic Act. As you know, the primary function of the Food and Drug Administration is to protect the health, welfare, and pocketbook of the consumer.

When we stop to think about it, Federal laws to protect the health of the Nation's people are of relatively recent origin, having been preceded by laws enacted by a number of States.

It was through the efforts of public-minded crusaders, such as Dr. Harvey W. Wiley, with the substantial aid of consumer groups and others, that the original Federal Food and Drugs Act was passed in 1906. Most of the American people today take much for granted and do not remember that only a few short decades ago our food supply was not generally safe. We had to exercise the same unusual care domestically in the selection of foods and the places where we ate as those who now travel abroad in some countries.

We are proud of the fact that today the American food supply is tremendously improved. This undoubtedly contributes to our national well-being. These advances did not just happen. They resulted, in part, from industry's constant efforts to improve the food and drug supply. Consumer demands and competition for favor of the consumer are powerful influences in this direction. And in part this progress has resulted from the type of food, drug and other health laws we have in this country. The Food, Drug, and Cosmetic Act, passed in 1938, has been a major factor in the improvement. Consumer groups have played and continue to play an important role in securing passage of necessary protective legislation, and in supporting active enforcement.

Five years ago, the Secretary of Health, Education, and Welfare appointed a committee of public-spirited individuals, known as the Citizens Advisory Committee, to study the programs of the Food and Drug Administration and make recommendations concerning the amount and kind of enforcement of the Food, Drug, and Cosmetic Act and related statutes, which would best serve the interests of the country. This committee, after very searching inquiry, made approximately 100 recommendations covering three broad areas: (1) Personnel and facilities to insure consumer protection, (2) new activities or activities which should be expanded, and (3) planning and administrative changes. A large part of these recommendations have been or are currently being carried out. Full accomplishment depends upon availability of funds and personnel. The most important recommendation was for a three to four-fold increase in personnel and facilities within a five to ten year period. To date, we have accomplished approximately a two-fold expansion.

A headquarters building was proposed to consolidate FDA's Washington activities, which are now scattered in six different locations. The site has been acquired and the plans drawn. The 1961 budget will, if approved by the Congress, provide funds for construction.

In keeping with the Committee's recommendation that we enlarge and improve our consumer information activities, we have enlarged the Division of Public Information.

Additionally, we have expanded what we call a consumer consultant program. It has three principal objectives:

1. To provide a channel of communication through which consumer views in matters relating to foods, drugs, and cosmetics can reach FDA and thus promote more intelligent programming of enforcement work.
2. To provide a source of comment and criticism by which an evaluation may be made of the effectiveness of FDA's activities from the consumer's point of view, and
3. To inform consumer groups regarding the protection afforded by food and drug laws and to promote more intelligent action on their part in buying and using products covered by these laws.

Just recently, we appointed Mrs. Carla S. Williams as our Consumer Programming Officer. She is charged with the planning and coordination of the activities of our consumer consultants located in FDA's 17 field districts. Incidentally, we are fortunate in having Mrs. Frances Satterlee of Minneapolis as the consumer consultant in this area. I am sure that she would be happy to discuss with you any problems of mutual interest.

The great technological advances that have occurred in the food, drug, and cosmetic fields require improved controls. They have been responsible for such recent changes in the Federal Food, Drug, and Cosmetic Act as:

1. The Pesticide Chemicals Amendment, which is concerned with limiting pesticide residues on raw agricultural commodities to amounts that will be completely safe for consumption, and
2. The Food Additives Amendment which provides for the establishment, by scientific means, of the safety of additives before they may be used commercially in food.

As indicated, both of these amendments require us to find that the residues of chemicals that may be permitted in food will be safe. We are advised by responsible scientists engaged in cancer research that it is not possible with present procedures to determine a safe feeding level for a substance that produces cancer when fed to laboratory animals. So it is our view that both amendments forbid the establishment of permitted tolerance levels for such cancer producers in food. The Food Additives Amendment has a cancer clause specifically forbidding us to establish tolerances for cancer producers.

Within recent months, two developments have focused public attention upon the cancer question. A cancer-producing pesticide used to kill weeds in cranberry bogs was applied improperly by some growers so that residues of the chemical remained in harvested cranberries. When the error first occurred in 1957, the National Association of Cranberry Growers was able to impound suspect lots and withhold them from distribution. A similar error occurred in 1959 by which time we had learned that the chemical does produce cancer when fed to rats, but this time the growers were unable to keep contaminated lots off the market. So it became necessary for the Department to warn the public last November of the existence of contaminated berries and to establish a mechanism for examining lots on the market and properly branding those that were free of the poisonous chemical.

The second development stemmed from the use of a synthetic hormone-like chemical, stilbestrol, in chickens. Stilbestrol is a new drug so its proposed use in chickens had to be cleared by us before it could be marketed commercially. We did grant clearance on the basis of evidence which led us to believe that no residues of the drug would be left in edible portions of treated chickens. Newer testing procedures showed later that this conclusion was in error, that when used in accordance with directions the stilbestrol would leave small residues in the liver, kidneys, and skin fat of treated birds. Consequently, we found it necessary to request the manufacturers of stilbestrol to discontinue its production for use in poultry raising, the poultry raisers to discontinue its use, and retail grocers to discontinue handling treated birds.

No doubt you have recently seen a number of stories in the press relating to the presence of antibiotic and pesticide residues in milk. Penicillin residues, as you may know, result primarily from the use of penicillin preparations in the treatment of mastitis. DDT and other pesticide residues result from the use of these pesticides for the control of insects around the barnyard as well as on feed and forage crops. We believe that milk, which constitutes an appreciable part of the diet of infants and invalids, should be free of poisonous residues. Beginning in 1954 and continuing in 1955 and 1956 we carried out a series of surveys collecting and examining samples of milk from different areas. We found small quantities of penicillin and DDT in a significant number of samples.

During and subsequent to this period we conducted an intensive educational program in cooperation with the U. S. Department of Agriculture, the U. S. Public Health Service, State and local food law enforcement officials, and milk producers and distributors in an effort to eliminate the problem.

Another similar survey carried out during 1958 disclosed a drop from 11.6% of samples showing penicillin contamination to 3.7% and a drop in significant pesticide residues from 19.5% in 1955 to 2.5% in 1958. This justified the conclusion that our educational activities had resulted in a noticeable reduction in the occurrence of penicillin and pesticides in the milk samples in 1958 as contrasted with the earlier surveys. Unfortunately, it also demonstrated that the problem was not being solved by educational means alone and it was necessary for us to set up a program involving regulatory action as a supplement to the educational program.

This proposed program was announced and initiated during the latter part of 1959. We have not yet found it necessary to seize shipments of fluid milk, but a lot of butter containing DDT has been seized and we are in the process of seizing some evaporated milk with the same adulterant.

About 10 years ago we started training our inspectors and chemists to deal with radioactivity in foods. In 1956, with the splendid cooperation of consumers, we obtained many samples of foods packed prior to the first atomic blast in 1945. In this way, we determined the naturally occurring radioactivity and are able to measure any increased radioactivity in our food supply as a result of weapons testing or industrial uses of atomic materials. We are continuing the monitoring of our food supply to make sure that the radioactivity levels of all products remain within allowable limits.

Synthetic colors have come in for a certain amount of discussion recently. As you know, the law provides for the listing and certification of synthetic colors which are harmless and suitable for use in foods, drugs, and cosmetics. We, and the courts, have held that the term "harmless" must be interpreted literally. Thus, for a color to be eligible for listing or to remain on the list, it must be truly harmless. Within the past few years, new scientific testing methods have shown that some of the synthetic colors which were certified for use as "harmless" are, in fact, capable of causing harm when fed to animals in test concentrations that are deemed proper. Accordingly, steps have been taken, or are being taken, to delist them. Some of these colors may be safe for use under tolerance restrictions but the present law does not authorize us to establish such tolerances. This situation is responsible for causing alarm in the food, drug, and cosmetic industries, such as that set off by the manufacturers of lipstick. Congress is presently considering legislation providing for the establishment of tolerance limitations and other conditions for safe use of colors which we hope will clarify this situation.

We need your interest and help in dealing with problems such as those already discussed. But we particularly need your active assistance in other areas. I have in mind quackery. It is one of the Nation's biggest consumer health problems. We can deal with only one phase of the problem - interstate commerce in foods, drugs, medical devices, and cosmetics that are worthless or dangerous for their intended purpose or which are misbranded by false or misleading promotion. States and communities, and citizens as a whole must deal with other aspects.

In recent years, three types of quackery have become of major importance. These are: 1. worthless cancer remedies; 2. worthless therapeutic devices represented for the prevention and treatment of serious diseases; and 3. nutritional quackery. The latter may take any one of several forms. Lectures by self-styled "experts" on nutrition, door-to-door promotion of over-priced vitamin-mineral combinations with extravagant claims of prevention or treatment of disease, and promotion of food supplements by misleading advertising and labeling are among the most common. The American Medical Association estimates that the public wastes over 500 million dollars a year on nutrition nonsense.

For some years we have been engaged in an intensive educational program against nutritional quackery. The American Medical Association, the National Better Business Bureau, and many other organizations are cooperating. The aim of this program is to provide the facts by which persons may evaluate the claims of the nutrition "quack," and thus help dry up the market for the worthless or misrepresented product.

As we look into the future, we see many opportunities for further work to protect consumers. Better control of hazardous household substances that kill many people, particularly children, every year, is urgently needed. Therapeutic devices and cosmetics should be tested for safety by the manufacturers before they are marketed. Drugs that permit the user to escape from reality, principally barbiturates and amphetamines, are illegally distributed in bootleg channels in large quantity. A better method of regulating them is needed. And, as I mentioned, a better method is needed to control color additives used in foods, drugs, and cosmetics. Legislation designed to bring about improvements in some of these fields is already before the Congress.

At the time that the Citizens Advisory Committee made its recommendation in 1955 for a three to four-fold expansion program for the Food and Drug Administration we translated it into terms of a staff of approximately 4,000 people. Since then we have been given other pressing duties that will require additional staff - for example, obligations to control pesticides and chemical additives in foods. It is apparent that we need and will continue to need the utmost support from consumers throughout the country if we are to do an adequate job of protecting the consumer of foods, drugs, and cosmetics.