REMARKS OF THE HONORABLE JOHN E. FOGARTY, M. C., SECOND CONGRESSIONAL DISTRICT, RHODE ISLAND AT THE LUNCHEON MEETING OF THE NETOPIAN CLUB ON OCTOBER 31, 1962.

For many years now as a member of the Appropriations Committee of the House of Representatives I have especially been concerned with the programs of the Government in the areas of public health, education and welfare. In fact, the subcommittee of which I have the honor of being chairman, handles the appropriations for the U. S. Department of Health, Education, and Welfare as well as the Department of Labor. And so, I have been concerned with buying health, and better education, and better economic security for the American people. And I have been concerned with getting our money's worth in these important areas of the public welfare.

I could give many illustrations of the benefits from these programs. One of the most interesting and dramatic

examples is one you have been reading about in the papers quite recently. This was the action whereby a woman doctor of the U. S. Food and Drug Administration was able, by applying the requirements of the law, to prevent a terrible medical tragedy from occurring in the United States.

Through the newspaper stories about this case, millions of people have learned for the first time about one of the most important responsibilities of this government agency - the clearance of new drugs for safety before they are allowed to be marketed commercially. The FDA medical scientists study the scientific data that is submitted by the manufacturer and they decide whether it is adequate to show that the new drug is safe to use according to the directions in its labeling. Such a new drug application was assigned to Dr. Frances Kelsey of the FDA Bureau of Medicine. It was for a drug called thalidomide.

Thalidomide was developed in Germany where it had rapidly gained popularity as a sedative and for other purposes. It was considered so safe in Germany that it was allowed to be sold without prescription. An American drug firm the Richardson-Merrell Co., Inc., acquired the right to sell it in the United States. But Dr. Kelsey was not satisfied with the information the company submitted to her. She was uneasy

about the chemical structure of the compound. She noticed it did not affect the experimental animals as same as humans -- it did not make them sleepy.

Apparently it had no harmful effects on the animals but Dr. Kelsey became concerned when she read an article in a British medical journal concerning reports of neuritis in the hands and feet of some of the people who had taken the drug. And so, although the company repeatedly urged the FDA to take action, Dr. Kelsey with the backing of her supervisors steadfastly insisted on more information. And so the new drug application was not officially filed by the Food and Drug Administration. The effect of this technicality was to delay clearance which could otherwise under the law have become automatically effective in from 60 to 180 days.

It was early in 1961 that Dr. Kelsey learned about the reports of neuritis from the British journal. It occurred to her that this might mean that there was a chance of injury to an unborn infant. The manufacturer was advised to submit evidence showing that the drug would be safe during pregnancy.

Meanwhile, in Germany, a desparate search was going on for the cause of a mysterious outbreak of phocomelia -- a peculiar and previously very rare type of birth deformity in

which the arms, legs, sometimes all of them were stunted or missing. German physicians began to suspect that thalidomide might be the cause. During this time, the American licensees were continuing to distribute the drug to medical investigators. When the reports came from Germany the American doctors who were testing the drug were first advised not to give it to women of child-bearing age. In March 1962 they were told to stop using the drug and to return or destroy all unused supplies. Nevertheless there have been several deformed babies born in the United States to women who received thalidomide from their doctors, or who got it while in Europe or from people who brought it back from Europe.

Thalidomide was never distributed through regular commercial channels in the United States. It was kept off the market through the alertness and professional integrity of Dr. Kelsey and her associates in the FDA Bureau of Medicine. As a result the American people have been spared a tragedy which struck thousands of families in Germany and to a lesser extent in England and other countries where it is estimated that over 5,000 armless and legless babies have been born because an apparently harmless sleeping pill was taken by their mothers.

Dr. Kelsey has received from the President the award for Distinguished Federal Civilian Service, the nation's highest honor for civilian Federal employees.

It is an interesting fact that the law that made it possible for the Food and Drug Administration to prevent a major medical tragedy from thalidomide was itself the result of a tragedy which did happen here 25 years ago. At that time there was no requirement in the law that medicines had to be tested for safety before being put on the market.

Through a mistake in the formula a poisonous drug was distributed that killed over 100 people before it was possible to determine what was causing these deaths. As a result, Congress hastened to pass new and stronger food and drug legislation which at that time had been under consideration for nearly 5 years. Included in this legislation was a new provision, the New Drug Section, requiring drugs to be proved safe before commercial distribution.

That is where the protection began. But that is not the whole story. In order to have safe drugs or foods or cosmetics we need to have not only adequate laws and regulations but likewise trained and dedicated scientists to enforce them and the laboratories and other facilities needed for their work.

Today history is being repeated. The regulations dealing with the distribution of drugs for purposes of scientific investigation are being tightened up and Congress has enacted legislation greatly strengthening basic provisions of the law with reference to prescription drugs. And now we must consider the question of the funds necessary to make this new protection effective.

What does it cost to provide the protection furnished by the Food and Drug Administration? This year it is about 15 1/2 cents for each man, woman, and child in this country. And what does this 15 cent insurance premium pay for? In addition to helping to insure the safety and reliability of drugs it protects the consumer in many other ways. Did you know, for example, that it is the Food and Drug Administration that is responsible for checking up on the use of pesticides, food additives and coloring materials that are allowed in foods, drugs and cosmetics in order to make sure that they can be safely used?

They test all batches of insulin, the drug that is literally a necessity of life for so many diabetic persons. They also test the critically important antibiotic drugs and this program will be greatly increased under the new legislation.

They set up standards that guarantee the composition and real value of food products in the interest of the consumer.

They check up on the imports of foods, drugs, medical devices and cosmetics to make sure that they comply with the law.

They enforce the provisions that require truthful and informative labeling on all these different kinds of products.

They enforce the law against illegal sales of dangerous drugs that are restricted to prescription. They inspect thousands of establishments which produce or distributes foods, drugs and cosmetics.

In the fiscal year of 1961 they had 1,326 enforcement cases in the Federal courts. They took more than 21 million pounds of spoiled or contaminated foods off the market -- over 200 tons a week.

I can't begin to tell you in this short speech all the different things the Food and Drug Administration does to protect the health and pocketbook of the American consumer. This is the kind of protection that the housewife cannot provide for herself. She could hardly set up a laboratory in her kitchen to test the products she is buying. She needs a Government scientific agency to do this for her. And so we have here another illustration of

the principle of Government which Abraham Lincoln stated so well when he said:

> "The legitimate object of Government is to do for a community of people whatever they need to have done but cannot do at all, or cannot so well do for themselves in their separate and individual capacities."