

MINNESOTA RADIO TAPE OF MARCH 18, 1964

FOR BROADCAST WEEK OF MARCH 22, 1964

Ladies and gentlemen:

This is Senator Hubert Humphrey, reporting to you from my office on Capitol Hill in Washington

Today I would report a story on the testing of drugs. Drug safety I am sure, is a matter of vital concern to every American. Although my report concerns help I was able to give in getting a dangerous drug removed from the market, my aim is to reassure people that we have the best protective system in the world. Moreover, it is improving all of the time.

Handwritten: 2 -

Recently ~~I~~ was able to help remove from the market, a drug that has taken possibly as many as 100 lives in this country. The story illustrates how by the alertness of a single Doctor, the cooperation of governmental agencies, and the help of a Senator, a dangerous drug was removed. The price of safety as well as liberty, is eternal vigilance. It is also cooperation.

Handwritten: ORA-bi-lex

The drug was Orabilex. It was used in some X-ray processes. Most people were not harmed by it. For some persons however, it could be and was injurious. Some deaths resulted.

Let me emphasize that drugs are important. The marvelous advances made in drug therapy have saved millions of lives. Children and adults that would have been given up for lost only a few years ago, are now saved and restored to health quickly by use of the proper drugs.

Nevertheless there are some hazards that develop from time to time. To detect these the Federal Food and Drug Administration has a competent team of scientists and inspectors. They have an outstanding record.

They cannot predict, no more than can drug companies and doctors, when unanticipated reactions in patients will show up. Absolute safety is impossible. We want, of course, and we must have, the highest safety level possible.

ORA-bi-let
The drug Orabilex was introduced in 1958. Not until 1961 did some reports show up indicating that the drug at times was injurious. It later developed that some reports of deaths were not made to the Food and Drug Agency as quickly as the law required.

The Food and Drug agency had a difficult decision: to weigh the benefits which were considerable, against the risks. Early in 1963 it sent out a letter of warning, without however removing the drug. In December, 1963 John Wennberg, a physician at Johns Hopkins University in Baltimore wrote to me about the drug. He presented evidence which he thought sufficient to judge that the drug should be taken off the market.

Immediately I forwarded this to the Food and Drug administration. I did not recommend that they remove the drug. No layman is competent to weigh the scientific evidence. The Food and Drug people responded immediately to me, not finding the evidence as yet sufficient. I sent their reply to Dr. Wennberg, who again promptly replied with additional evidence.

In the meantime I had written to President Johnson about the problems of drug regulation and cited this instance. He immediately asked his scientific advisors to look into the matter in general and the evidence on this drug in particular. The President's advisor's concluded that Dr. Wennberg's evidence was substantial. Almost at the same time the Food and Drug Administration concluded the same thing, and withdrew the drug from the market.

The net result of two months of effort was a real victory for Public Health. All of us have reason to be grateful to Dr. Wennberg for alert and devoted effort. President Johnson and his staff are to be commended for excellent follow-through. The Food and Drug Administration which is the best in the world, was helped. It learned in the investigation that its original warning letter had been misinterpreted. It discovered that some reports had not been made to it as promptly as they should have been. It is closer today to the goal we all seek: drug hazards reduced to a minimum; drug benefits increased to the maximum.

I was pleased to have a small part in that process. Meanwhile I do assure you that the U.S. has the highest drug standards in the world. Our federal regulatory system is the best. Our American drug industry is the most advanced, and our medical profession is the most interested in drug safety and efficiency.

As we cooperate together, it will remain so.

Thank you.

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