

need for this. Such a capability does exist. The costs at that time were considered to be perhaps excessive. We are also exploring at the present time the possibility of a communication system using the phone, with a number listed here in Washington that physicians could call from, say, 9 in the morning until 10 at night and let us at FDA know their experiences with drugs. Hopefully, this sort of system could someday be expanded to provide information to the physicians upon their request. I would say in direct answer, yes, we do visualize the possibility someday, but no, the price of such a system would not be justified by our need to communicate, but rather, as the communications capability develops in the medical community, we wish to take advantage of it.

The 1962 drug amendments, as I said, significantly expanded our authority over drug commerce and put us in a position to require correction of a number of abuses that were then apparent.

For example, enactment of the 1962 law:

- Required new drugs to be proved effective, as well as safe before marketing.

- Provided better means for withholding or withdrawing approvals of new drugs.

- Gave us authority for the first time to make complete inspection of factories making prescription drugs.

- Required drugs to be produced under current good manufacturing practice.

- Authorized us to establish simple, useful common or generic names for drugs.

- Established an effective control over prescription drug advertising and placed it under FDA.

- Extended batch certification to all antibiotics for humans.

The 1962 law also expressed the desire of Congress for more and better control of drugs being tested clinically on man, and required strengthening of revised regulations that FDA had proposed that same year.

Let me now discuss those four factors that must be present if our Nation is to have a good drug supply.

Senator NELSON. Is there any reason why batch certification of all drugs used on humans would not be feasible? Is there anything peculiar about antibiotics?

Dr. GODDARD. You recall antibiotics are used in what one would have to term lifesaving situations. The antibiotics developed largely after World War II in terms of the number that were being marketed, and it was felt that careful control had to be exercised because of the complex production process. Thus these controls were put into effect and batch-by-batch certification has been carried out now since 1962 for antibiotics. I believe that insulin batch-by-batch certification preceded that in 1941. These were the basis for batch certification.

Senator NELSON. Are there any other drugs that ought to be batch tested?

Dr. GODDARD. We did propose to Congress last year, Senator, that the Secretary of Health, Education, and Welfare be given the authority to extend batch certification to those drugs that were significant drugs or for which the health of the public might be more directly protected under such circumstances—such potent medications as corti-