As you, Senator Nelson, have indicated several times, one of the major interests of this committee is the pricing of drugs, the actual costs to the patient or the institutional purchasing agent of the life-protecting and lifesaving drugs available. While our agency does not have jurisdiction over prices, nor have we sought it, we are concerned primarily that the American consumer receive quality drugs. The operations of the Food and Drug Administration are geared toward assuring that all drugs are reliable. The administrative work of our agency, the review of data that comes into our medical and compliance bureaus, and our constant surveillance over the drug industry are aimed toward this goal. If all drugs are reliable, then there is a basis for price competition.

I would like to state, and later discuss briefly, the factors that must operate if we are to be sure that all marketed drugs are reliable:

1. There must be honest, soundly conceived, and well-executed research to establish a drug's safety and effectiveness for its intended use before it is marketed commercially.
2. There must be proper manufacturing, packaging, labeling, storing, and shipping of the drug. In short, there must be good manufacturing practice.
3. The existence of good manufacturing practice must be checked not only by the producing firm, but also by a separate impartial agency. The FDA is the impartial agency.
4. Users must have adequate, truthful information about the drugs they employ. Drug names should be as simple and useful as possible, drug labels and advertising should be honest, and summary information about the entire drug armamentarium should be readily available to every professional in the health team.

There is, of course, an additional safeguard which needs no elaboration from me, that is the continuing communication throughout the medical community of information about the results obtained with drugs in clinical practice.

The 1962 drug amendments to the Federal Food, Drug, and Cosmetic Act significantly expanded our agency's authority over drug commerce, and for the first time placed FDA in a position to require correction of a number of abuses that were then apparent.

Senator NELSON. May I interrupt just a moment? Does your agency supply directly to physicians any information, clinical or other, that is important?

Dr. GODDARD. We rarely do that, Senator. We have, I believe twice in the past year, sent a letter directly to physicians. This is a very costly procedure for us as an agency. These were unbudgeted costs and I think each letter ran approximately $40,000 in direct costs to the agency.

Now, there is, therefore, a limitation in dollar costs in direct communications.

Senator NELSON. Would you consider it of value for your agency to have more continuous direct contact with physicians?

Dr. GODDARD. Yes; I think it would be extremely valuable if we had a continuing contact and channel of communication. A two-way channel, by the way, would be most effective between the practicing physicians and the Food and Drug Administration. We would like