Dr. EDWARDS. Mr. Chairman, we have gone on in our testimony to indicate what the Department of Health, Education, and Welfare has done as it relates to the list of ineffective drugs which I will not go over at this point in time, but will conclude by answering specifically the questions that you posed in your invitation that we appear here.

Namely, we have learned that constant attention must be given to all forms of drug promotion to keep it current, reliable, and useful. We believe that a future NAS–NRC evaluation can only be avoided by constant surveillance and timely action. Federal policy toward rational prescribing requires attention to drug quality, to sound medical documentation of all allowable promotional claims, and to greatly improved communications with the physicians prescribing these drugs. Government, as a major purchaser of drugs, should and must insist upon the least expensive of equivalent drugs and upon rational choices among different drugs which satisfy the same medical needs. Our role is to assure the reliability of all drugs available in the marketplace and the dissemination of fully informative labeling and promotion to enable the prescribers to make wise choices among the array of products available to them.

Thank you.

Mr. GORDON. What lessons have we learned from the drug efficacy study?

Dr. EDWARDS. Well, I think as I indicated in my concluding remarks, I think that we have learned that, first of all, the two subjects of safety and effectiveness have to be considered together and you cannot consider one without the other, and I think that unfortunately, this was not appreciated prior to 1962 and put us in the position that we are in right now.

I think it also indicates, as indicated to us, that a far better definition has to be had of such subjects as what are adequate and well-controlled studies, and the meaningfulness of monitoring. I think all of these things have been highlighted in this drug efficacy study. Dr. Simmons, do you want to add anything to that?

Dr. SIMMONS. I think in addition to what the Commissioner has already said, basically what we learned was that there are many problems that currently exist in therapeutics that need solutions. I think it taught us that the old system of having authority only to pass on safety was not adequate to the task, that somebody needed the authority to pass on efficacy.

We also learned that the uncontrolled observations and testimonial endorsements are not adequate to the needs of the 20th century, that we do in fact need substantial evidence, well controlled evidence, before we know what we are doing with drugs.

We learned that, as the Commissioner already mentioned, labeling in the past has generally failed in the primary purpose of letting those who have to use the drug know how to use it intelligently. I think it also told us that the combined efforts of the Federal Government and the private sector can help improve this system and in fact, is necessary. I think the most important thing it showed us was that the medical profession needs a better, more balanced and objective source of good drug information.

This is what we hope to be able to provide in the months ahead.