witnesses suggest that differences in formulation of drug products were negligible or of minor significance in the effect on patients."

As far as I know, none of the witnesses before our subcommittee discussed differences in formulation of drug products. The subject we discussed was clinical equivalency. Would you explain for the record the difference in the meaning of these two terms?

Dr. LEE. The formulation of drug products—there are a variety of factors that go into that in their different dosage forms. A single drug may be prepared as a capsule, tablet or in liquid form. There are also different kinds of liquid preparations. These are different dosage forms. In the formulation of a tablet changes can also be made, for example, different degrees of compression of a tablet may produce different effects biologically or clinically.

There are a number of factors that go into formulation. In certain cases the different formulations will affect either the biologic equivalence or the clinical equivalence of a particular chemically equivalent drug. But what we are talking about when we are talking about clinical equivalence or biological equivalence, we are talking about the identical dosage forms, and we are not talking about different formulations. I think that should be made clear.

Mr. GORDON. This really tends to confuse rather than illuminate.

Dr. LEE. I would agree with your statement.

Mr. GORDON. Doctor, on page 61 of your task force report you say that one of the prerequisites for rational prescribing is knowledge by the physician of "the advantages or disadvantages of alternative forms of therapy."

As I understand it, the physician must know the relative safety and efficacy of drugs to determine which one is most suitable for his patients. Am I correct in that?

Dr. LEE. Yes.

Mr. GORDON. How can the average practicing physician make such determination, even if he had the labeling?

Dr. LEE. He bases it, of course, on various sources of information that he has. His interpretation of this information, and the particular circumstance under which he is prescribing the drug for an individual patient.

We don't have, as I indicated, in a form readily available to physicians the kind of information that is available to the British physicians through the simple, regular Prescribers Journal furnished by the Government. The Medical Letter fills that need for those physicians who utilize it. It is an excellent publication. But unfortunately most physicians don't receive it and don't read it. As a result there isn't available to most physicians an up-to-date comparative evaluations of drugs with respect to given conditions.

There are a number of textbooks that have been published and are available to physicians, but I am sure that they are not in every physician's office. Usually, when faced with a question about a drug, the physician will turn to a book that consists of paid advertising, the Physicians' Desk Reference. The material in there, of course, includes information on post-1962 drugs, and it also included information on drugs from 1938 to 1962, and even before. Because it may include data on these earlier drugs we can't always have assurance that that includes the best information available on effectiveness.