Should one stop its use altogether—this would surely be a wrong thing to do—because the drug is a potent antibiotic and has a well-defined usage. Should one simply continue with a warning statement in the advertising and in the package? These seem to have little if any value.

And then further in his testimony, he was willing to set up some procedure to strongly control its use.

Dr. GODDARD. Our ad hoc committee, which met Monday, also basically was in agreement with Dr. Dameshek. and Dr. Ley and myself certainly are.

We have a revision of the indications to be used, the package insert, which I have before me. We are going to discuss this with the company in the next few days. These indications markedly limit the indications for the usage of this drug.

Senator NELSON. For the package insert?

Dr. GODDARD. Yes, sir. But we are also going to take other steps which I mention in my testimony, which will not restrict this kind of information to dissemination through the package insert. As you well know, I think the package insert is an ineffectual way of getting at the transmission of information to physicians. This new information will also be required in PDR. It will be required in so-called reminder ads. These reminder ads now operate under an exemption from the Secretary which permits Parke, Davis to advertise this drug without any warning whatsoever. And so we do have steps that we propose to describe today that we think will have some impact. They may fall short of what you wish, but there are certain problems we feel need discussion.

Mr. GORDON. Dr. Goddard, I am not satisfied with the answer that I got to my question.

Dr. GODDARD. I wondered if you would be.

Mr. GORDON. Why didn't the FDA notify all the physicians in the United States about the new and additional risks which were revealed by the California study in January of 1967?

Dr. LEY. Mr. Gordon, in response to this, I have to draw upon the memory and recollection of other people who were there, because I was not there at the time.

The California study identified a level of risk between roughly 1 in 24,000 and 1 in 46,000 per death. This study was in essence within the broad limits already established for the drug by other studies. I am specifically referring to the study published in Britain in 1960, which identified a risk figure of somewhere between 1 in 10,000, and 1 in 100,000. As nearly as I can reconstruct the events that occurred at that time, the California study was weighed, evaluated, and considered not sufficiently different from existing information to require a special type of action at that time.

We are certainly——

Mr. GORDON. We are not talking about action here. It is a question of relaying the information to the physicians in this country.

The California study came up with a risk ratio of 1 in about 20,000. Before then the risk ratio was considered to be much lower.

Now, would it be your opinion that the doctors in the United States should know of these new and higher risks?

Dr. LEY. We certainly plan to include this, the study's estimate of risks, as a portion of the new labeling.