

drug, but it is still effective. How does the physician know? What do you do about it?

Dr. GODDARD. The only way for him to know, Senator, would be through the advertising and this would be strictly controlled by the claims that are permitted in the final printed label and our enforcement of the regulations on truthful advertising. So that is the only way he would know. The labeling has to say that the drug is effective against these organisms and that—

Senator NELSON. But there is no comparative proposition there?

Dr. GODDARD. No, sir.

There is no comparative proposition there. There are other sources of information available to the physician which he may use. A Medical Letter often provides that kind of information. The AMA publication, New Drugs, often provides data on relative effects.

Senator NELSON. If the clinical evidence reveals that a new drug is half as effective as other drugs on the market for treating the same disease, why doesn't the FDA require the advertising to state that it is half as effective?

Dr. GODDARD. We do in that instance.

Senator NELSON. You do?

Dr. GODDARD. Yes, we have.

Mr. GORDON. How do you notify the doctor of this relative efficacy you are talking about?

Dr. GODDARD. In this instance, it is by implication. I would like to give you an example. Say an ad for a drug which is only 50 percent effective against pneumococcus, is advertised in such a way that it is misleading. We would cause the sponsoring firm to send out to the medical profession a "Dear Doctor" letter which says in effect "The FDA has determined our ad to be misleading and we have failed to provide certain information about this drug; namely, that this drug is only effective in 50 percent of the instances of pneumococcal infection." The physician already knows that he has other agents that are of a higher level of effectiveness.

Mr. GORDON. Is that correct, that a physician really knows that there are other agents that are more effective?

Dr. GODDARD. Well, I can only go on averages, Mr. Gordon. I hope he knows. That is what the practice of medicine is about. He has had ample experience with these other drugs in the marketplace. He certainly, in the instance of the antibiotics, uses enough of them to have experience.

Mr. GORDON. Well, practically all our medical witnesses have testified that this knowledge is unavailable to the ordinary practicing physician.

Dr. GODDARD. In an organized, systematic fashion, yes. Now, I am very much interested that we do a better job of providing the practicing physician with good information on therapeutic agents that he is using. I asked the PMA a year ago to revive their interest in a drug compendium. They had at one time asked my predecessor, Mr. Larrick, to permit individual member firms to drop the publishing of the package insert and in return for this exemption, they would cause to be published a drug compendium. Mr. Larrick said he would agree with this, I am told, provided that there was a year's experience of publishing the drug compendium and distributing it to physicians before the package inserts were dropped.