

Dr. GODDARD. Usually the pharmacist. The physician quite often does not get it.

Senator NELSON. What good does it do the doctor, then?

Dr. GODDARD. This same information would have to appear in the advertising. So there would be not just one channel of attempting to get this information to the physician.

Now, I also have a fair degree of confidence that this kind of information would be the subject of a paper in a scientific journal, too.

Mr. Goodrich wishes to add something to this.

Mr. GOODRICH. We also have provision in the investigational new drug regulations that all investigators be kept advised as to any adverse reactions encountered by any other investigator. Let us say one out of 100 investigators encountered an adverse reaction. We require that that information be disseminated back to us and to all other investigators.

On the approved new drugs, every hazard that is relevant is a part of the final printed labeling and that provides the base line for all promotion. By promotion I mean the direct mailing, all the sampling, and all the promotions in the journal and other media.

Mr. GORDON. My understanding is that a large part of the clinical testing is paid for by the U.S. Government, either within Government institutions as in VA hospitals, PHS hospitals, Army, Navy, and so forth, or extramurally through Government grants.

Dr. GODDARD. Under our public information policies of the Government that is available, yes.

Mr. GORDON. Is that a recent development, or has that been the situation all along?

Dr. GODDARD. I am going to have to ask counsel that because I have not been on the scene that long.

Mr. GOODRICH. I am not exactly sure of the complete extent to which this information is available, but I do know that the results of the Government-supported research are generally made available to all comers.

Senator NELSON. That raises this question. If the Government, then, has done clinical testing on a new drug and finds that the results are good, will you allow the firm which submits the NDA on that drug to incorporate your research?

Mr. GOODRICH. Yes, if it is in the public domain, of course.

Senator NELSON. And you will approve their manufacturing of the drug without going the route of testing it on animals and human beings?

Mr. GOODRICH. If the data in the public domain already shows that it has been adequately tested, of course. All we are talking about, Senator, is turning over the business information supplied by one firm to another firm. Any information in the public domain can be incorporated in a New Drug Application and relied upon.

Senator NELSON. Supposing a drug in a New Drug Application has been on the market for 5 years with good clinical results. Company A applies for a New Drug Application on the same drug. Do you still require this applicant to go through the route of testing on animals and humans or do you let him incorporate the public knowledge?

Mr. GOODRICH. We let him incorporate the public knowledge. But we want to be sure what the drug is, how it is made, how it is con-