

Senator NELSON. Are you satisfied that you have sufficient knowledge, have sufficiently analyzed the problems so that you could, in fact, undertake to develop a compendium in a reasonable amount of time?

Dr. GODDARD. I believe it can be done. As I say, the best way to do it is outside of the Government, in my opinion. It is important enough to me that if it is absolutely necessary, then we can do it as a Federal agency.

Senator NELSON. You would have to be a cooperating agent, anyway, wouldn't you?

Dr. GODDARD. Yes. And I would still prefer, if we had to assume the direct burden, to have much of the work done by contract.

Senator NELSON. And supposing the industry decided they would go ahead, they would, of course, work with you?

Dr. GODDARD. Yes.

Senator NELSON. Do you have any notion, as a practical matter, as to how long it would take to develop and publish an acceptable compendium?

Dr. GODDARD. I think about 18 months would be realistic. It is a large undertaking. Of course, I am optimistic. I think we can do it in that period of time. There are some techniques now available that would lend themselves readily to the production of a volume of this type—the computerized storage of information. Of course, as Mr. Goodrich reminds me, and I bring up once again, the NAS summary is now coming to us, and this will be an integral and important part of that task.

Senator NELSON. What are those summaries?

Dr. GODDARD. These are summaries of their judgments as to efficacy of the drugs marketed between 1938 and 1962. And these represent the opinions of some of the top scientists in the United States who met and discussed drugs that were grouped in 27 categories; 3,000 drugs were involved.

Mr. GORDON. Dr. Goddard, when you talk about efficacy, this is not relative efficacy, is that correct?

Dr. GODDARD. No, sir.

Mr. GORDON. This is merely efficacy as compared to a placebo—better than nothing, is that it?

Dr. GODDARD. Well, they are making judgments, sort of putting these drugs in pigeon holes, if you will, of efficacy. There are no doubts about digitalis you see, for example. We have good direct measuring capabilities that say digitalis changes the heart rate, slows up the heart, increases the force of it.

So we have good information. And with those that are probably efficacious like digitalis, where there is a body of experience in literature, the firms were given the opportunity to pick the best references that supported their claims for review. And, of course, this is primarily a review of the claims that are made for the drugs, too.

So the next category would be probably "nonefficacious" and then "not efficacious." "Efficacious but" is another category. That would refer to trimming back some of the claims that are made, you see.

So the judgments are made against the promotional claims the firms have advocated for this particular drug, not relative evidence.