

dividual firms would probably not be listed in such a compendium. But we are interested in having those firms that produce and distribute nationally and even regionally included.

Senator NELSON. How many drugs would be involved?

Dr. GODDARD. Well, there are 21,000, approximately—

Senator NELSON. Different or—

Dr. GODDARD. Different dosage forms of the some 7,000 drugs in the marketplace today. These would all be included.

Senator NELSON. And would a compendium and the drugs included have the approval of FDA?

Dr. GODDARD. It would have to be approved by the Food and Drug Administration since it does serve as a form of labeling. The best possible outcome as far as I am concerned, would be for PMA to exercise leadership in this area, assume the burden and use, if such could be arranged, the format of the PDR, if the owners of PDR were willing to engage in that. I say this because PDR has a great level of acceptance in the country, and this would become competitive, you see.

If such a marriage, if you will, could take place, I think it would find instant acceptance on the part of the practicing physicians. They would receive this volume each year, as they always have, and it would provide them with comprehensive information in terms of coverage of the drugs, as opposed to today's PDR which is on the basis of paid advertising. Even the major firms do not include all of their drugs in today's PDR. So I think it would be a marked improvement and everyone would benefit.

Senator NELSON. All the drug products listed there would have the approval of FDA?

Dr. GODDARD. Of course, the drugs have to have our approval to be in the marketplace.

Now, if you are saying that we would be offering an implicit warning or guarantee that they are efficacious, until the academy review is completed, we could not offer such a guarantee. Until we are in a better position to apply therapeutic equivalency than we are today, we could not offer the physicians such a guarantee.

But that is our goal. It is an achievable goal, and I think it is one that we can accomplish by 1971, as I have indicated in other testimony.

Senator NELSON. Am I correct in saying that to get approval to be introduced into the marketplace at all, a prescription drug has to meet USP standards?

Dr. GODDARD. If it exists in the USP or NF, yes. Combinations are not in USP, of course, so there are many combination drugs in the marketplace today, too.

Mr. GORDON. Well, there are FDA standards, too, aren't there; for example, on antibiotics?

Dr. GODDARD. Yes, there have to be standards, and we do certify them on a batch-by-batch basis.

Mr. GORDON. Perhaps you cover this later, but how useful and effective are the package inserts—do the doctors really read them?

Dr. GODDARD. Most of the time the physician does not receive them, so he does not really have an opportunity to read them.

I have some here, for example. Here is a package insert. I do not think many physicians are going to read this, if he even gets it.