distributed without cost to the physicians, pharmacies, hospitals, et cetera, would be a significant step forward in educating the health professions to the safe and effective use of therapeutic agents. It could also relieve the drug industry from the burden of printing the voluminous package inserts as such a compendium could appropriately replace this type of labeling.

The content of package-insert type of labeling is initially approved by FDA during the new-drug clearance procedure and is constantly reviewed by our medical staff to insure that the labeling is consistent with current knowledge. Often the package insert is the only source of such necessary data on medicines which are prescribed daily.

Unfortunately, this information seldom reaches the physician; it remains on the local pharmacist's shelves. Proper utilization of this information is further hampered by the present format of the package inserts.

Senator NELSON. May I interrupt a moment?

Dr. GODDARD. Certainly.

Senator NELSON. Do you have an estimate on the cost of printing, preparing, and supplying these inserts along with the drugs?

Dr. GODDARD. I was advised by the Pharmaceutical Manufacturers Association—this subject was first raised by them, I might add—when they asked would I consider a drug compendium to replace the package insert, that the program presently costs industry about $6 million a year.

Senator NELSON. $6 million?

Dr. GODDARD. Yes, sir.

Senator NELSON. Do I understand you to say that the Pharmaceutical Manufacturers Association raised the question of the preparation of a compendium in place of this?

Dr. GODDARD. Yes. This was in April of 1966. And they pointed out that the matter had been discussed with my predecessor, Commissioner Larrick, and his position was that they could publish a compendium but would have to also continue the use of package inserts for 1 year in order to evaluate the effectiveness of the compendium.

Now, they were anxious to move ahead with this program but didn't see the necessity for running two programs in tandem for a year.

I agreed at that time that we would not require the package insert for the year after the compendium was published.

This was the beginning of our discussions on the drug compendium.

Now, we have had nothing but discussions since that time, and I am hard put to understand the recent statement of the president of the PMA where he was critical of my testimony before a committee of Congress where I expressed my displeasure with the foot dragging—I think I characterized it as that. He said, "Why, we are discussing that matter right now."

Well, they are going to discuss it to death. And I think we stand at a unique point in time. With the National Academy of Sciences efficacy review reports beginning to come back to us, these can form the basis for much of what will be needed in the compendium on the drugs that were marketed between 1938 and 1962. So we truly have an opportunity that is well perceived by the members of the Drug