

I am told the package inserts, the printing and the packaging, thus required to insert costs the major PMA manufacturers about \$6 million a year. I am perfectly willing to drop the package insert requirement at the moment a good drug compendium is distributed to the profession—the pharmacists, the physicians.

Senator NELSON. Drop what requirements? The insert?

Dr. GODDARD. The insert for all except intravenous and parenteral drugs.

Senator SCOTT. What would the compendium provide and how would you handle the distribution?

Dr. GODDARD. It would be distributed free of cost to every physician, pharmacy, and hospital in the United States. It would be assembled by a distinguished board of editors in the scientific community and, hopefully, paid for by the members of the pharmaceutical firms. Both the drug and allied products field and PMA have had these subjects discussed with them. There does not seem to be too much interest on their part in going this route, I am sorry to say. I had hoped they would exert leadership in this field.

Senator SCOTT. Now, with regard to what it would comprise.

Dr. GODDARD. On composition, the drugs sold in interstate commerce, listed by both generic and trade name; a brief description of the drug, its action, its recommended dosage, indications for usage, side effects, contraindications, and warnings, in brief. Now, this is not a compilation of the current package labeling as some people have misunderstood me to be recommending. This is a well done, in brief summary that could be useful to the practicing physician, just as PDR now is.

Senator SCOTT. It would seem to me that industry and the profession would be helped, would be glad to have such compendium. You said there did not seem to be much interest. What efforts have been made to enlist interest in this proposal?

Dr. GODDARD. Senator, let me comment if I may, first on your remark about the practicing physicians and others involved viewing this as being desirable.

For 10 years, the council on drugs of AMA have said this would be desirable. I know that for 4 years at least that the National Academy of Sciences Drug Research Board has recommended such a compendium.

Now, as to what has been done. There have been meetings held with the PMA leadership, both between FDA and PMA and the FDA and National Academy of Sciences and PMA. Specific recommendations have been made and no action has been taken.

Now, I am very dismayed by this, because I would like to see this done by the private sector of our economy. It would have to have FDA approval, because it would constitute labeling of sorts. We are perfectly willing to do this and to drop immediately the requirement that packaged circulars accompany every drug sold in the marketplace.

Now, I think that this is one of the most important things that could be done in terms of enhancing communications on therapeutic agents to those who need this kind of information.

Senator SCOTT. Have you made that statement before with regard to dropping immediately the package insert?