

pendium would have to be in existence for some time before he would entertain the idea of discontinuing the package inserts.

More recently, the Drug Research Board of the National Academy of Sciences has had for the last year or 18 months a series of meetings with interested parties. That is not just the FDA, and it is not just the PMA. It includes the American Medical Association, the American Pharmaceutical Association, the American Society of Hospital Pharmacists.

Those conferences have been held to answer five or six specific questions. Is an additional compendium necessary—and mind you, there are compendia now on the market and available. If it is necessary, what should its format be? Should it be published by private sources or by the Government? What is its estimated cost, and how should it be financed?

Now, despite the fact that Dr. Goddard sincerely believes that all these questions have been answered to everybody's satisfaction, they have not to the satisfaction of most of the parties involved and they have not been to ours.

We have a serious question as to whether or not existing compendia, such as the U.S. Pharmacopeia, the National Formulary, New Drugs, put out by AMA, or the Physicians' Desk Reference, possibly could be revised to make acceptable document for the physician.

I have been personally at every meeting that has been held by the Drug Research Board on this question. I know the nature of the discussions.

I have yet to hear what the doctors think about this proposed compendium.

I happen to believe, in view of my past employment, that doctors are not in agreement with this compendium as now proposed. And I think, since we are talking about a tool for physicians, the best thing we could do is ask the doctor—What do you need or what do you want in the way of a compendium?

They are not, despite what was said last week, in agreement that this compendium should be initiated.

Frankly, if we are going to be asked to pay the bill, we think we should have the answer to such things as, What is the format of this book going to be; are all drugs going to be listed; are they going to be listed generically; is there going to be a classification for a group of therapeutics; how are they going to be handled? Will all dosage forms be accommodated or not?

Now, I know that the objection to the PDR is that it is a document paid for by the industry. In other words, these are allegedly ads put in this book.

Senator NELSON. They are ads; aren't they?

Mr. STETLER. They are paid for. But they are labeling—that is why these "Dear Doctor" letters have gone out. They have got to comply with FDA regulations.

Senator NELSON. Just to have it clear—they don't go in the PDR unless they are paid for.

Mr. STETLER. That's right. I am not denying that.

Senator NELSON. So it is a paid ad.

Mr. STETLER. If PDR is vulnerable for that reason, would any compendium be suspect if industry paid for it?