

general advertising for prescription drugs, but they still pose some problems.

Last year we took the initial steps to improve the quality of advertising messages. We received objections from pharmaceutical manufacturers and the advertisers and a lot of other people.

Senator HATFIELD. This was on a continuing basis?

Mr. GOODRICH. Right.

Senator HATFIELD. As well as on—

Mr. GOODRICH. To bring these regulations up-to-date to deal with the problems that had emerged under our experiences with the regulations placed in effect in 1964.

We highlighted in the revised regulations those points of most concern and the points of failure that we had seen in actual practice.

Now PMA opposed that, and notwithstanding, we have taken efforts to resolve our difficulties. The matter now stands that they have objections in and it will have to go to a public hearing.

Senator HATFIELD. So that you have both the initial authority to deal with their advertising and promotional material as they introduce a drug, and then the continuing responsibility.

Mr. GOODRICH. Yes.

Senator HATFIELD. To review any additional or modified or changed—

Mr. GOODRICH. Yes.

Senator HATFIELD (continuing). Modifications or changes in their advertising and promotional materials.

Mr. GOODRICH. Yes.

Senator HATFIELD. Then as I understand it, you have control over everything except what may be stated orally by the detail men?

Mr. GOODRICH. Well, the opinion that Senator Nelson put into the record yesterday from the Library of Congress indicates some doubt about our authority to deal with oral detailing of this kind. I have no such doubts.

As Senator Nelson's opening statement said, in 1961 when we promulgated the full disclosure regulations, we provided that a drug, a prescription drug would be regarded as misbranded unless its labeling contained adequate directions for professional use for all the conditions for which it was advertised or represented. Now, that included oral detailing. That regulation has been in effect since 1961, was specifically called to the attention of the Congress in 1962, and was recently sustained in a criminal case in Chicago on whether we had the authority to promulgate such a regulation. So I don't have the doubts and fears that the Library of Congress opinion does. I will be glad to supply the committee with our views, if you would like to have them in detail.

Senator HATFIELD. But the point I am trying to get at is, that actually unless there is evidence shown from the oral presentation by say, a detail man that he has misrepresented the drug to the doctor, it is difficult then to enforce or police other than that which you have as now the existing authority on the printed and visual and all the other kinds of—

Mr. GOODRICH. Sure it is difficult. There is no question at all about that.

Senator HATFIELD. Yes.

Mr. GOODRICH. And this is why we have put our priorities first on making all the public promotion that goes in such great volume, both