and it is a baseline we are trying to establish in the mind of the industry. It should be their benchmark in keeping their claims within the approved concepts concerning the nature and effectiveness of the drug. It is the official document, negotiated for all drugs of this type, the so-called package insert.

Senator NELSON. Do I understand you correctly that they may use words in ads that are not in the package insert, but they may not make claims for the drug's performance that extend beyond the authorized claims that they are able to make in the package insert?

Dr. MCCLEERY. Right; we are saying if this kind of information appears in the scientific literature, or as a result of research, the company has a very good legal method to begin to use this in advertising. They should gather together this kind of information and submit it to the Food and Drug Administration as a supplement to their New Drug Application, have this evidence judged and agreed on between the manufacturer and the agency, and get it into the package insert, and then they may indeed use it in their advertising. But the way not to do it is through the route of advertising.

Senator NELSON. If this is correct, what you are saying is that you have the legal authority to prohibit them from putting in an ad a claim for the drug that extends beyond the approved claims made for it in the package insert?

Dr. MCCLEERY. Yes, sir. I believe that is true.

Senator NELSON. I am not familiar with your authority on that. Is there any question about the law on that?

Dr. MCCLEERY. May I ask you to ask Mr. Goodrich?

Mr. GOODRICH. No, no question on that, Senator.

Senator NELSON. What are the penalties for violation of the law on that point?

Mr. GOODRICH. The same penalties for shipping any other misbranded drug, which is a maximum of a thousand dollars, and in the case of an individual up to a year in jail. But the regulations, the authority to specify what should be in the ad, is granted to us by the Kefauver-Harris amendments, and our regulations provide, acquiesced in by the industry, that in advertising drugs that had been cleared through the new drug procedures, the only permissible claims were those that had been approved.

Here the point is that the claim that this product is effective in most cases and gives predictable results were not approved. We went over yesterday, in connection with Dr. Hodges' statement, the points made at the time of approval, in which the limits of the claims were spelled out. The record yesterday will show that the breadth of this claim was not permitted.

Senator NELSON. Well, I would assume that anybody reading the package insert, and reading the ad could easily see that the ad is making a claim beyond what is authorized in the package insert.

Mr. GOODRICH. We think so. That is the simplicity of our regulatory scheme—to have the approved label as an identifiable, usable benchmark for all promotional efforts—advertising or direct mailing.

Senator NELSON. Do you have the authority to require that an ad be submitted for approval in advance of publication?

Mr. GOODRICH. In extraordinary circumstances, yes.

Senator NELSON. What are those circumstances?