

been approved in advertising or promotion, it would be a criminal offense. We also have an administrative mechanism for discontinuing the certification of an antibiotic, where it is being promoted for conditions contrary to what has been agreed upon between us and the company in certifying the lot. Chloramphenicol is an antibiotic, so there are rapid mechanisms for dealing with such a problem.

Senator HATFIELD. Have you used that power that you have?

Mr. GOODRICH. Yes; we have.

Senator HATFIELD. Frequently?

Mr. GOODRICH. Not frequently, but it has been used decisively in a number of instances.

Senator HATFIELD. Have you used it more or less than opportunities provide? In other words, have you been conservative in the exercise of this authority, or have you been liberal?

Mr. GOODRICH. Quite conservative.

Senator HATFIELD. Do you feel that perhaps if you were a bit more aggressive or less conservative in your application of this power, it might be helpful in policing the industry that you are required to police?

Mr. GOODRICH. I expect the drug industry would say that we have been quite liberal in the exercise of the authority, but I think that, we hope that, we have struck the proper level of enforcement, but maybe we haven't been strong enough at some and perhaps too strong at other times. But there are mechanisms for dealing with the problem.

Senator HATFIELD. You feel you have adequate authority?

Mr. GOODRICH. Yes.

Senator HATFIELD. At this time, to deal with any situation that might arise in which you are called upon to protect the public?

Mr. GOODRICH. We think so. We examined our authority in great detail, when the Kefauver investigation was on, and made our recommendations. Now, since then, as you know, the President has recommended the enactment of legislation to provide for the issuance of a compendium which will provide one of the points Senator Nelson was talking about, that is, an on-the-desk, authoritative unbiased viewpoint of drug prescribing information.

Congress hasn't acted on that yet. But we are hopeful that something can be done.

Senator HATFIELD. On the matter of keeping control over the promotional program of these pharmaceutical houses, what is and what is not included in your review as far as promotion materials are concerned?

Mr. GOODRICH. Both the package material, all direct mailing, catalogs, movies, tape recordings.

Senator HATFIELD. Charts?

Mr. GOODRICH. All that, charts, visual aids, all that material which has been classified, as we were authorized to classify it by the Kefauver-Harris amendments, as labeling requiring full disclosure.

We also have authority to regulate the advertising of prescription drugs, but not the advertising of over-the-counter preparations. We initiated our prescription drug advertising program early in October of 1963, soon after the Kefauver-Harris amendments were passed. The regulations were placed into effect, I believe, in January of 1964. They have been successful in bringing about significant changes in