Mr. GOODRICH. Yes, we do. We have had this authority on the package insert since the beginning of the new drug provisions. We have not had control over the claims of effectiveness. But all warnings essential for safe use has been wtihin our authority, under the new drug provisions since 1938—in the case of new drugs—and since 1945 for antibiotics, when the first antibiotic was brought under certification.

We have indeed specified in our antibiotic regulations, in the case of chloramphenicol, the precise box warning which now appears in PDR and in the labeling and in all the promotional material for this drug, except reminder advertising.

It is the very warning that Dr. Dameshek recommended, and that our committee recommended in 1960. And we are, we think, improving on it now with the benefit of another committee.

Dr. GODDARD. But, Senator, we do not control the text of every advertisement that is produced.

Mr. GOODRICH. But in the sense that he was asking, as I understood, if this became necessary, did we have the authority to do that. And the law says that the ad shall include such information about side effects, counterindications, and effectiveness as we shall specify in the advertising. Now, we started off with a system which required that the advertising limit its promotion within the claims authorized by new drug clearance or by antibiotic clearance. We could become more specific if that is necessary, and we have become more specific in the case of Chloromycetin.

Senator NELSON. So you do have the authority to specify exactly the language as to safety and effectiveness.

Mr. GOODRICH. Right.

Senator NELSON. So that if there is an exaggerated claim, you can simply direct the company to change the language; is that correct?

Mr. GOODRICH. The company has hearing rights and other protections that go with this. But we have the ultimate authority to resolve the question.

Senator NELSON. And before whom is the hearing conducted?

Mr. GOODRICH. Before a hearing examiner in our department, with judicial review in the courts of appeal.

Senator NELSON. Has there ever been a case where the drug company disagreed with what the FDA directed, and asked for a hearing? And, then, have there been cases where they asked for a hearing and later appealed the decision of the hearing to the courts?

Mr. GOODRICH. There have been cases in which there was a request for a hearing. There have been—in other settings, but not that particular one—appeals to the courts.

But in general, the companies have not exercised their hearing rights in developing labeling and promotion for drugs. They have become convinced, I believe, that no drug can gain a place in medical practice or retain a place except on its scientific merit. And therefore the——

Senator NELSON. Who is this?

Mr. GOODRICH. The drug industry. They could not really press a drug onto the market over the objections of the Bureau of Medicine where there were scientific reservations. And so the way the procedure works is that the differences are resolved through the new drug procedures, or through the antibiotic procedures.