For certain very serious and acute infections, the physician should have the freedom to prescribe this drug where, if he has not given it, the patient would be much more seriously ill. We feel that the physician also has the responsibility to initiate such sensitivity testing at this time as well.

The example which weighed most heavily in our committee consideration was that of a youngster with a serious meningeal infection. If you delayed therapy until the sensitivity tests are available, such a child might suffer serious brain damage. The new labeling draft which we have considered with the committee makes provision both for the initiation of therapy, and requires the sensitivity test to be done concurrently. So that I believe this one looseness in the wording of the old indications and warning section is now corrected.

Senator NELSON. The next sentence is, "Chloramphenicol should not be used when other less potentially dangerous agents will be effective."

Dr. GODDARD. That was changed in 1966 to say "must not be used when other less potentially dangerous agents will be effective."

Senator NELSON. That is the one change made between 1961 and 1966?

Dr. GODDARD. That was the one change.

That is the one change as far as the box is concerned.

Senator NELSON. Go ahead.

Dr. GODDARD. Parke, Davis was required to mail the new prescribing information to all medical doctors and osteopaths in February 1961 with a statement that the prescribing information would accompany all oral and parenteral Chloromycetin products.

Between 1963, when our prescription drug advertising regulations were first adopted, and 1966, Parke, Davis advertised Chloromycetin by reminder ads, which carried no indications and no warnings. The regulations permitted this.

Mr. GORDON. Can you give us the reason why this type of ad should be exempted from carrying the warning?

Dr. GODDARD. There is a history of this which Mr. Goodrich is more familiar with, and may comment on.

But in general, it was felt that reminder ads, which are permitted under an exemption by the Secretary, serve a useful purpose.

Mr. GORDON. Why should it have been permitted?

Mr. GOODRICH. There is a type of advertising and promotion that is used in the drug industry which features only the name of the drug and the name of the company. It does not purport to offer to the physician any indications for use, nor to indicate in any way what the drug is for. It simply is a reminder of the name of the drug and of the company that makes it.

This type of advertising was defended by the drug industry at the public proceedings which preceded the establishment of the regulations. We concluded it was reasonable to allow reminder advertising, so long as no indications for use were made, or implied directly or indirectly, and so long as nothing was said about the drug other than its name and the name of the company.

Now, we are reexamining that policy in evaluating the new regulations. And as the statement indicates, we propose to change the regulations so that Chloromycetin could not be advertised by reminder ads.