

Senator NELSON. And I understand you are reviewing that now?

Dr. GODDARD. I would propose if the exemption is to be permitted to continue for Chloromycetin that the warning box be incorporated in the reminder ad itself, or the exemption be dropped completely.

Senator NELSON. Thank you.

Dr. GODDARD. Now, that of course has to go through the procedures that we described earlier.

Senator NELSON. Which?

Dr. GODDARD. Opportunity for public hearing, and review by the courts.

Senator NELSON. Yes. But have you made that decision as to the reminder ad?

Dr. GODDARD. On this drug, basically, it has been made.

Mr. GROSSMAN. Doctor, would that hold up for other drugs?

Dr. GODDARD. It could, if there was an indicated need.

We are reexamining the entire issue of reminder ads—not just this one.

In 1964 the company decided to advertise the drug promotionally. That means the more routine type of advertising. They met with our medical advertising group to consider how this should be done. Our physicians noted that the package insert had no "Indications" section, but instead described the broad range of antimicrobial activity of the drug. To correct this, an indications section was devised and other changes made to emphasize that the drug was only indicated for, and should be prescribed in accordance with, the important information in the "warning box." In 1966, the company made the requested changes and discontinued the reminder ad campaigns.

And I would add as a postscript that for a large part there may be still some reminder ads.

Dr. LEX. Few only.

Dr. GODDARD. The labeling was reviewed again in 1966 by the Acting Deputy Director of the Bureau of Medicine and the "box warning" was changed to say that the drug must (instead of should) not be used to treat trivial infections or in any other conditions except as described in the box.

Despite these label revisions, editorials in the Journal of the American Medical Association, and warnings in other publications such as the Medical Letter, the use of chloramphenicol has increased and continues to increase. Most of this use, we believe, is for medical conditions for which the drug is not indicated or for which it is expressly prohibited such as acne, the common cold, simple infections, and the like. We are disappointed by a current advertisement in the Reader's Digest by the Pharmaceutical Manufacturers Association, which describes chloramphenicol as a prime member of a "class of drugs that fights 100 diseases" and characterizes it as a "broad spectrum" antibiotic effective against dozens of diseases, causing only occasional and sometimes serious side effects in some patients.

Senator NELSON. Doctor, you state that the use of the drug continues to increase?

Dr. GODDARD. Yes, sir. As measured by sales, the amount that is being certified by the Food and Drug Administration through batch-by-batch certification.