In announcing the reinstitution of certification for chloramphenicol, FDA said:

> The administration has weighed the value of the drug against the capabilities for causing harm and has decided that it should continue to be available for careful use by the medical profession in those serious and sometimes fatal diseases in which its use is necessary.

Senator NELSON. In what year was that done?

Dr. GODDARD. 1952.

The FDA characterized its experience as "an impressive reminder that highly potent drugs must be treated with extreme care and should not be employed unless there is a clearcut indication that they are needed."

The Kefauver Subcommittee on Antitrust and Monopoly subsequently reported that these warning measures were diluted by Parke, Davis instructions to its detail force, which the subcommittee said presented the report of the National Research Council as a blanket clearance of the drug.

Nonetheless, the use of the drug dropped off markedly after the new warning issued. This was a short-term reaction; however, and use of the antibiotic increased during the years that followed.

Senator NELSON. I realize you were not the Commissioner at that time. But I have read the Kefauver testimony, and I presume you have read it. It is a very impressive example of clever advertising language being used by the company to circumvent the statement of caution that was suggested by the FDA at that time, was it not?

Dr. GODDARD. Yes.

Senator NELSON. And as I recall the testimony before the Kefauver committee the company claimed that the drug had been completely cleared by the committee of the National Research Council or words to that effect.

Mr. GOODRICH. This was in terms of instructions to the detail force. Now, you will recall, Senator, that prior to the enactment of the Kefauver-Harris amendments in 1962, we had no right to obtain that information by inspection. We had no right to records of these drug companies. And we learned about this detailing through the material subpenaed by Senator Kefauver's committee.

Now, we did have one of our own physicians detailed improperly in 1959, and we, on the basis of our own experience, contacted the company immediately, calling attention to this misuse of a piece out of the literature to dilute the aplastic anemia warning. The company, from their president on down, gave assurance that that type detailing was not authorized.

Under the existing law, we do have the right to inspection to obtain records of this sort. And we have asked, within the last few days, what detailing pieces there were, and we are told that there are none—no specific detailing pieces.

Mr. GORDON. Yesterday one of our witnesses who is a physician, Dr. Watkins, testified that a detail man misinformed him about the dangers of Chloromycetin. Two days ago Dr. Hewson, from Philadelphia, testified that in his own experience as a general practitioner, he could not recall a Parke, Davis detail man ever discussing the relationship between administration of the drug and the development