man leaves with the physician is also considered labeling, and it must also contain that same warning promptly displayed.

Senator NELSON. Is he required to leave the material containing this warning with the doctor?

Dr. GODDARD. No, he is not.

Senator NELSON. If you require the package insert, why wouldn't it be helpful at least to require him to leave it with the physician?

Dr. GODDARD. If he leaves anything, the warning must be included. But he is not required to leave the drug or the warning upon the occasion of detailing. He may simply discuss the drug with the physician.

Mr. GORDON. It is the oral presentation, however, which is the most potent presentation, is it not?

Senator NELSON. Doctor, I have to go over to the Labor Committee to help them make a quorum for an executive session. We will recess for 10 minutes.

(At this point in the hearing a short recess was taken.)

Senator NELSON. We will now resume the hearings. Go ahead, Doctor.

Dr. GODDARD. In 1955 Parke, Davis requested a deletion of part of the warning statement. The firm's letter pointed out that some patients with blood disorders attributable to Chloromycetin had received only a few capsules. The company regarded the warning, which referred to prolonged or intermittent therapy, as a legal liability in litigation.

We rejected this proposal, and while strengthening the warning was suggested, the decision was made to continue the warning as recommended by the scientific committee.

In December 1959, one of our physicians, who was also in private practice, was visited by Parke, Davis' detail men who claimed that there was no more danger of blood dyscrasias with Chloromycetin than with any other antibiotic. The company was informed of this impropriety, and gave assurance that the statement was both unauthorized and contrary to company policy.

In April of 1960 the Council on Drugs of the American Medical Association made another report on blood dyscrasias associated with chloramphenicol. The report said that although the warning had been in use for a long time, physicians continued to use the drug indiscriminately for minor infections, including those associated with the common cold.

FDA asked the National Research Council in November 1960 to again consider the chloramphenicol problem in light of a new evidence accumulated since 1952. FDA wished to obtain the council's opinion as to whether chloramphenicol should be allowed to remain on the market, whether its use should be restricted to hospitals if it were to remain on the market, and what label changes the council would recommend if the drug was allowed to remain on the market.

The recommendations of the council were received by FDA in January 1961. The council concluded that, due to its therapeutic value, chloramphenicol should remain on the market; due to some of its proper indications for use, home treatment, as opposed to hospital treatment exclusively, was reasonable; due to its serious effects, further warnings and increased education of the medical profession were necessary.