of blood dyscrasias. Several doctors testified in the *Love* v. *Wolf* case, in California, that Parke, Davis' detail men told of the virtues of Chloromycetin and minimized its dangers.

Do you really accept the firm's assurance that the statement was both unauthorized and contrary to company policy?

Mr. GOODRICH. They supplied us with instructions that they had sent to their force, and they are a part of the record in the Kefauver hearings, as you know. All that correspondence is included in the Kefauver records. I would not mean to imply in any way that the detail men were not making these presentations. Indeed, the detailing of our own physicians showed they were. But we took steps to call it to the company's attention.

Now, the point of monitoring detailing is a very, very delicate point with us. We have no way, really, to monitor what goes on between the detail men and the physician in his private office.

We do have control over the printed and promotional material, so that the message will come through loud, clear, and repeatedly in the promotion about what the drug is for and what warnings should be observed.

Senator NELSON. It has not in the case of this drug come through very loudly or very clearly, obviously.

Mr. GOODRICH. Since 1960, there has been this warning, and the current PDR, if you look at it, has a black box warning right at the top of the column, which has Dr. Dameshek's warning. This discussion of Chloromycetin has been before the profession some time. Now, it is not effective, I know that, and I know that there is room for improvement. We are planning to do that.

Dr. GODDARD. It is probably the strongest drug warning that exists, Senator. And in spite of that it is still being misused. The warning does not work.

Senator NELSON. So where do we go from there?

I wanted to ask you a question.

The FDA has the authority to require and does require the package insert. Am I correct in that?

Dr. GODDARD. That is correct.

Mr. GOODRICH. And it has done so for Chloromycetin since the 1960 ad hoc committee. Up until 1961, I believe it was, we allowed package inserts to be made available on request. But in response to the 1960 ad hoc committee recommendations, one of the conditions was that package insert be included in all packages.

Now, there has been on the bottle, on the carton, on the bottle containing the capsules, a warning since 1962 about blood dyscrasias. This is the one Dr. Goodard just read:

> Warning, blood dyscrasias may be associated with intermittent or prolonged use. It is essential that adequate blood studies be made.

That has been on the bottle since 1952.

Senator NELSON. For capsules, not injectables.

Mr. GOODRICH. For all containers, yes sir.

Senator NELSON. But, the package insert in almost all cases goes to the gentleman who does not prescribe, that is, the pharmacist—so that does not help to warn the physician at all.

Dr. GODDARD. Except this. All the detailing material that the detail