Davis, either in letters to doctors or in advertising, adopted warnings on its own?

Dr. HEWSON. Oh, yes. After 1952, when the FDA warning was required on the package inserts and in the cautionary statements on the boxes, Parke, Davis did include a warning on most of its promotional literature, but not on all. This was not the same type—not the same warning, in effect, and certainly not in the same words that the FDA recomended.

Mr. GORDON. It was required by the FDA; was it not?

Dr. HEWSON. I do not believe so.

Mr. GORDON. Adopted on their own?

Dr. HEWSON. That is right. They did adopt it on their own but they did not adopt the FDA warning. Their warning, and that was one of our arguments in the *Incollingo* case, was considerably diluted or watered down, weakened. In at least five aspects we felt it was changed and our experts so testified.

Senator NELSON. Was the FDA warning just a suggestion to the company?

Dr. HEWSON. That is the way I read it, a recommendation, and they could only recommend it for the package inserts with the parenteral forms and for the enclosing boxes. Parke, Davis, itself, had to put it, of its own volition into its advertising, but they chose to present it in a changed form.

Senator NELSON. Did the law not authorize FDA to require warnings approved by them?

Dr. HEWSON. The warning which they put in their literature?

Senator NELSON. Yes.

Dr. HEWSON. No.

Senator NELSON. In their advertising, either?

Dr. HEWSON. I am sorry. That is what I meant by their literature, too. Yes; did not require them to put——

Senator NELSON. Are you saying the FDA——

Dr. HEWSON. We are talking about the period 1952 to 1961?

Senator NELSON. Yes.

Dr. HEWSON. Correct.

Senator NELSON. The FDA during that period did not have the legal authority to veto any specific advertising, so to speak, or to require any specific language in the advertising between 1952 and the Kefauver-Harris amendment in 1962; is that it?

Dr. HEWSON. I understand they had a recommendatory authority only. They did not have the legal power to require it.

Senator NELSON. Have you studied the law as to what authority they now have?

Dr. HEWSON. No. I know only of what it is from 1962 from reading the cases and listening to the Parke, Davis defenses.

Mr. GORDON. Can you tell us the five aspects in which Parke, Davis watered down, diluted the FDA warning?

Dr. HEWSON. Oh, yes. The FDA warning began with the statement certain blood dyscrasias have been associated with the use of Chloromycetin.

Senator NELSON. Now, this is the suggestion that FDA made?

Dr. HEWSON. That is correct. This is what was put on the boxes and in the circulars with the parenteral forms of Chloromycetin. The first