

was that certain cases of serious blood dyscrasias had been associated with chloramphenicol—that was 1952—and still an ad in the General Practitioner, in March 1954, did not mention this fact.

Do you have a copy of that? This ad only said in 1954 that:

Since its introduction over four years ago, Chloromycetin has been used by physicians in practically every country of the world. More than eleven million patients have been treated with this important antibiotic, truly one of the world's outstanding therapeutic agents.

That is all that is there.

How do you explain that at that stage, even 2 years after the National Research Council's statement about side effects that there is no warning at all in the ad?

Dr. LUECK. Mr. Chairman, I would like to point out that the warnings and so forth on Chloromycetin were introduced into the official labeling and were delivered to practicing physicians by Parke, Davis and Co., following the first report from the National Research Council.

Senator NELSON. I did not follow that. What about the physicians?

Dr. LUECK. That the physicians, a major attempt was made to inform the physicians of the information then included in a warning statement on Chloromycetin and it is our firm belief—

Senator NELSON. In what way were the physicians informed?

Dr. LUECK. Both by letters to the physicians—

Senator NELSON. Every physician in the United States received a letter?

Dr. LUECK. Yes.

Senator NELSON. That was at the direction of the FDA?

Dr. LUECK. With the cooperation of the FDA.

Senator NELSON. Well, was it at their direction? Did they order it?

Dr. LUECK. I do not know whether they ordered it or not. It would not have made any difference to Parke, Davis whether they had ordered it or not. It is a means of communicating this information.

Senator NELSON. Do you have a copy of the information you sent?

Dr. LUECK. Just a moment, please.

I have a copy of the letters that were sent to physicians in the country. I would be happy to submit it to the chairman for the record if he pleases.

Senator NELSON. Do you have the date of the letter?

Dr. LUECK. It will be all on the letter.

Senator NELSON. You do not know the date?

Dr. LUECK. Just a moment. I think I can remember some of the letter.

Mr. Chairman, there are three letters and the different letters are required for this purpose: One went to the medical profession, one went to the osteopathic profession, and the third to the pharmaceutical profession. The letters are dated February 15, 1961. They include a letter with the current package insert.

Senator NELSON. A letter and what?

Dr. LUECK. And the package insert, the official labeling.

Senator NELSON. That was in 1961?

Dr. LUECK. That is February 15, 1961.

Senator NELSON. Those letters will be printed in the record.

(The material referred to follows:)