

Dr. LUECK. I do not know in what frame of reference you are phrasing the question. If you mean Chloromycetin and all chloramphenicol products have official labeling approved by the Food and Drug Administration, required statements on the labeling, that include indications for use, how to use the product, with warnings, actions, and side effects, that information is explicitly—

Senator NELSON. Maybe you did not understand the question. I said I understand that your product, Chloromycetin, has been responsible for deaths from bone marrow disorders. Is that correct or incorrect?

Dr. LUECK. I do not know in what reference you are phrasing that question. I know that Chloromycetin, the Parke, Davis brand of chloramphenicol—

Senator NELSON. Has never resulted in any deaths?

Dr. LUECK. No, I did not say that.

Senator NELSON. Maybe I did not put the question correctly.

Some people have died from the administration of Chloromycetin, I understand. Will you tell me what you know about that?

Dr. LUECK. I understand that Chloromycetin has been alleged to be related to or associated with some serious side effects, some serious reactions. Those things are related and detailed in considerable length in the package information, in the labeling, Mr. Chairman.

Senator NELSON. You say you understand. You really are not sure that any deaths have resulted from this drug?

Dr. LUECK. I think that there have been instances where some reactions can be related to the use of Chloromycetin.

Senator NELSON. Have you ever read the warning that your company now belatedly puts in its advertising for this drug? Here is an ad from the Journal of the American Medical Association, February 20, 1967:

Warning: Serious and even fatal blood dyscrasias aplastic anemia, hypoplastic anemia—

And so forth—

are known to occur after the administration of chloramphenicol.

Were you aware of that?

Dr. LUECK. Yes, sir.

Senator NELSON. That was my question, Doctor: Do you know of any cases of fatal side effects occurring after the administration of Chloromycetin?

Dr. LUECK. I was attempting to respond to your question by referring to this warning statement in the labeling, which is precisely identical to that in the advertising. I am sorry if I misled you.

Senator NELSON. You did not mislead me. You are aware, then, that deaths have occurred in this case?

Dr. LUECK. Absolutely.

Senator NELSON. What has Parke, Davis done about quality control to overcome that problem?

Dr. LUECK. I would like to state, Mr. Chairman, that Chloromycetin, like many other drugs, is a very potent drug. As the packaging infor-