

If you knew 10 years ago what you know today, why, in 1967, do you have a severe warning boxed in heavy print:

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

And so forth—

are known to occur after the administration of chloramphenicol. Blood dyscrasias have occurred after both short-term and prolonged therapy with this drug. Bearing in mind the possibility that such reactions may occur, chloramphenicol should be used only for serious infections caused by organisms which are susceptible to its antibacterial effects.

Do you consider these to be equivalent warnings?

Dr. LUECK. The second warning is an exact duplicate of the package insert and, in my opinion, would be considered a stronger warning, Mr. Chairman.

Senator NELSON. I bless you for that.

Dr. LUECK. I would like to repeat that all of the ads on Chloromycetin were reviewed by Parke, Davis & Co. with the Food and Drug Administration since 1952 before they were published or submitted to a journal or any advertising media.

Also, I would like to—

Senator NELSON. Let me say at this point, if I may, that I do not have any higher opinion of the FDA's judgment in permitting this kind of advertising than I do of the company's running this ad. I do not think it protects you any to come up and say the FDA approved of a lousy ad. Most of the industry is attacking the FDA most of the time, anyway.

Dr. LUECK. Well, I think if Parke, Davis & Co. had improper ads, we would have been cited by the Food and Drug Administration, as some people have, and we have not. So our advertising of all our products—

Senator NELSON. I am sorry, I have another vote. It is 12:45. Why not take 45 minutes for a long lunch?

(Whereupon, at 1:45 p.m., the hearing was recessed, to reconvene at 1:30 p.m., this same day.)

AFTERNOON SESSION

Senator NELSON. Doctor, would you resume?

STATEMENT OF DR. LESLIE M. LUECK ET AL.—Resumed

Dr. LUECK. So, Mr. Chairman, I think our advertising of all our products has been much in order with the keeping of the day and regulatory requirements appropriate to advertising the product and to inform the advertising.

Senator NELSON. Well, my questions have been directed at the proposition that the evidence was available several years ago that there were some major serious side effects, and that the ads did not indicate it. For example, there had already been known deaths—I think that is indisputable—by 1954.

The National Research Council in 1952 made statements which were brought to the attention of the industry and Parke, Davis, in particular. You read some of the conclusions of the Council, one of which