change that was made was that Parke, Davis started their warning with "Chloromycetin is a potent therapeutic drug" which, we argued, is a self-serving statement which tends to dilute what follows.

Also, in their warning they did not delineate the specific blood dyscrasias which were parenthetically enclosed in the FDA warning. In the part of the warning that referred to the taking of blood studies to determine bone-marrow changes, they added the phrase "as with certain other drugs," tending to equilibrate the toxicity of Chloromycetin with certain other unspecified drugs.

The FDA warning contained the words, relative to the required blood studies, "It is essential." The Chloromycetin warning deleted "It is essential."

The FDA warning was required to be placed at the top of the literature in the injectable circular. The Parke, Davis warning was usually placed well down in its advertising in relatively small print.

Following the 1952 investigation by the National Research Council and the ensuing warning, sales of Chloromycetin dropped precipitously. However, recovery was successful to the degree that the sales in 1960 were greater than the peak of any previous year. In 1960 enough Chloromycetin was sold to provide courses of therapy for nearly 4 million persons.

Senator NELSON. What is your estimate of the number based upon?

Dr. HEWSON. That, I believe, came from the Kefauver investigation.

Senator NELSON. I see.

Dr. HEWSON. There is literature on this. There are graphs which show these sales.

These sales were made despite the statements in leading journals from knowledgeable physicians and from American Medical Association councils that the drug should be used only for typhoid fever and other salmonella diseases or for diseases caused by organisms proven to be resistant to other, less potentially harmful, anti-infective agents. The increased incidence of staphylococcal infections in the middle and late 1950's account for but a small part of the resurgence in the use of Chloromycetin; for staphylocci had been shown to develop resistance to it, and other, more effective, and less seriously toxic antibiotics were developed to combat these bacteria. The enthusiastic promotion of Chloromycetin by Parke, Davis & Co. apparently played a significant role in the increased use of the drug.

The advertisements for Chloromycetin emphasize its great versatility and effectiveness, along with its ready tolerance and minimal side effects. And that applies to the advertising today.

This approach by Parke, Davis became evident soon after the FDA recommended the addition of the 1952 warning to the Chloromycetin literature. In Parke, Davis' "President's Letters," "Director's Letters," and "Ideas and Suggestions" to its promotional staff, as well as in its advertising, Parke, Davis asserted that the indications for the use of Chloromycetin were unchanged—this is after 1952—that it was still the most effective and versatile antibiotic, and that it was well-tolerated, with rare side effects. The statements inferred that the toxicity of Chloromycetin was akin to that of other drugs. Appeal was made to the doctor to base his evaluation of the drug on his past experiences with it. Detail men were to use a positive approach in