and a certain percentage of the cases will go on to develop aplastic anemia or other dyscrasia.

Senator NELSON. Regardless of the fact that you may not be able to discover any bone marrow problem from blood studies, should blood studies always be made when chloroamphenicol is administered?

Dr. WESTON. Always be made.

Senator NELSON. Always be made.

Dr. WESTON. Yes, sir.

Senator NELSON. Regardless of whether one dose or several doses are given?

Dr. WESTON. That is correct.

This warning did not begin with words of caution but with a glowing tribute to the efficacy of the drug. Also the types of bone marrow dyscrasias involved were not enumerated as they were by the Federal Food and Drug Administration. Further, the words "it is essential" were deleted, detracting from the emphasis on the requirement for blood tests and the expression "as with certain other drugs" was added, thereby equilibrating the toxicity of Chloromycetin to that of other, unnamed medications. The Parke, Davis warning was not, at this time, placed at the top or beginning of this literature but was placed well down in the writing and often in small print. Witnesses in at least one malpractice action have testified that the Parke, Davis warning was no different from the warnings on many other drugs which led them to use Chloromycetin freely and without reservation.[1] This refers to the *Incollingo* v. *Ewing, Parke, Davis and Cucinotta* trial in which I appeared in the Philadelphia court, in which Dr. McGehee was present as a hematologist expert and he not only testified to the fact that this had quite a contrary effect on the warning, it was equated with what one might anticipate with the sulfonimides, aspirin and a variety of common household medications which were used quite commonly, and to see it put in that same wastebasket was, in effect, saying that you are dealing with a drug which only very occasionally will give you an untoward reaction.

I will cover more of Dr. McGehee's other testimony as we get on in the statement.

Following the issuance of the FDA warning, the sales of Chloromycetin dropped precipitously. However, by 1960, sales of the drug reached a level even greater than that of its peak years in the early 1950's. This resurgence was due in large part to the promotional efforts put forth by Parke, Davis & Co. through its advertising and detail men. This vigorous overpromotion was made despite the well-documented toxicity of the drug, by this time. Chloromycetin, it was urged, was still the most effective antibiotic in a wide variety of infections, with minimal side effects. The Parke, Davis campaign to bring Chloromycetin back into widespread use for a multiplicity of clinical conditions was evidenced very early. In November of 1952, just 4 months after the FDA warning requirement was issued, a letter was sent from the sales department of Parke, Davis to its professional sales staff. Included with the letter were "suggested details" and "ideas and suggestions" for promoting the use of Chloromycetin to physicians.

[1] *Incollingo* v. *Ewing, Parke Davis and Cucinotta,* Philadelphia Court of Common Pleas No. 6, December Term, 1961, No. 3248.