and vomiting, and yeast or other intercurrent infections. Chloromycetin soon became a very popular, widely used drug. From 1948 to 1952 its sales rose markedly, and it has been stated by the company that over 8 million patients were treated with the drug during this period. However, reports began to come in which noted that blood dyscrasias were associated with its use. Of these blood dyscrasias, aplastic anemia was the most common. The Federal Food and Drug Administration requested that the National Research Council make an investigation into the problem and submit a report of their findings. The Council, recognizing the potential and serious toxicity of the drug recommended that the following warning be placed on the packages and in the circulars distributed with Chloromycetin.

The Federal Food and Drug Administration concurred: Warning to be placed at the top of the circular was as follows:

Certain blood dyscrasias (aplastic anemia, thrombocytopenia purpura, granulocytopenia and pancytopenia have been associated with the administration of Chloromycetin. It is essential that adequate blood studies be made when prolonged or intermittent administration of this drug is required. Chloromycetin should not be used indiscriminately or for minor infectons.

To appear on immediate container label:

Warning: Blood dyscrasias may be associated with intermittent or prolonged use. It is essential that adequate blood studies be made.

These warnings were subsequently placed by Parke, Davis on the appropriate packages and in the circulars enclosed with the parenteral forms of Chloromycetin, but no circulars were included in the packages containing the oral preparations.

Senator NELSON. You state that the circulars with the printed warnings were enclosed in the package forms; is that correct?

Dr. WESTON. With the form for parenteral administration, that is injected.

Senator NELSON. That is an injectible?

Dr. WESTON. Yes, sir. It was not included in the material that was distributed for oral consumption initially.

Senator NELSON. That meant that the injectibles that went directly to the doctor did have the warnings; is that correct?

Dr. WESTON. Yes, sir.

Senator NELSON. And that the packages containing the tablet form of Chloromycetin which went to the pharmacist did not, is that correct?

Dr. WESTON. That is correct.

The injectibles, of course, may have been handled by the pharmacists as an intermediary.

Senator NELSON. But even the warnings that went to the pharmacist weren't seen by the doctor anyway, is that correct?

Dr. WESTON. Not necessarily.

The ones that were packaged, some of them were put on the label proper. There are two types of warnings, one was put on the label proper, and one was put in the literature that the instructions included.

Senator NELSON. If it were an injectible, of course, it ended up in the doctor's hands for his administration, is that correct?

Dr. WESTON. Yes, sir.