should have been used. Thus, the widespread, irresponsible prescription of Chloromycetin, although apparently accepted by a majority of the medical profession, was not reasonably prudent, or legally condonable, use of the drug. In other words, the general use of the drug was deemed not to be accepted legal use. The usual legal standard of the act of the reasonably prudent man under the circumstances was not met. These were not reasonably prudent physicians, nor was this reasonably prudent use of the drug. At least the jury so found.

Historically, Chloromycetin was first introduced in 1948 as a broad-spectrum antibiotic of great efficacy and minimal side effects.

Senator NELSON. It is still so advertised; is it not?

Dr. HEWSON. It is still very much so advertised, and I think every one has testified that it is a very effective drug, but that does not mean it should be used widely. There are other effective drugs, probably almost nearly so effective, and without the serious side effect of toxicity to the bone marrow.

Unlike the tetracyclines—Terramycin, Aureomycin, et cetera, which were also broad-spectrum antibiotics, Chloromycetin caused little gastrointestinal upset. Also, it was more effective in the treatment of certain diseases, such as typhoid fever. Sales of the drug increased markedly from 1949 to 1952. However, reports of aplastic anemia resulting from the use of the drug appeared during that time, and the Federal Food and Drug Administration asked the National Research Council to submit a report on the toxic aspects of this antibiotic. The National Research Council, which was composed mainly of eminent physicians, I believe, recommended that a warning be placed on Chloromycetin containers and the circular within. Parke, Davis & Co. followed the recommendation of the Food and Drug Administration; but the warning was required only on the circulars accompanying the injectable preparations, which are actually seldom seen by the prescribing physician. The injectable form of Chloromycetin is used in hospital practice for the most part; so that only the pharmacists were exposed to the FDA warning. The modified warning which Parke, Davis placed in most, but not all, of its promotional literature for Chloromycetin was weakened or diluted in at least five aspects from the recommended statement.

Senator NELSON. Are you saying that the injectable preparations are not used very often in physicians offices?

Dr. HEWSON. That is correct. The injectable preparation at that time had to be used every 4 to 6 hours and, even as a starting dose, it was not feasible to use it in office practice. A later preparation was to be used every 12 hours or even 24.

Senator NELSON. Is it still more commonly administered orally in office practice than it is by injection?

Dr. HEWSON. Oh, yes; very much more.

Senator NELSON. It is a tablet; is it not?

Dr. HEWSON. It is a capsule or a liquid pediatric preparation.

Senator NELSON. The package insert which contains the warning goes directly to the pharmacist at the drugstore; does it not?

Dr. HEWSON. Senator, from 1952 to 1961 there was no circular with the oral preparation. After 1962 it was required with the oral preparation, also; but that still goes to the pharmacist and he dispenses it without the circular enclosed, of course.