

Senator NELSON. If it were in tablet form, the usual procedure would be that the prescription would be written by the doctor and dispensed by the pharmacist, so the doctor does not see the package, is that not correct?

Dr. WESTON. It could well happen. I don't know how many times—he could well have not seen the warning. I have seen or have heard the statement of several doctors who said they weren't aware there was a warning put into the drug at this particular period in its chronology.

Senator NELSON. But in the ordinary procedure of prescribing, the doctor writes the prescription and, unless it is in a hospital, the patient takes it to the pharmacist. The package containing tablets now contains a warning but the doctor ordinarily does not see the drug or the package at all, unless it is administered in his office, does he?

Dr. WESTON. That is correct, yes.

Immediately following this announcement by the Federal Food and Drug Administration, Parke, Davis & Co. issued "President's Letter No. 4" on August 12, 1952. Despite the obvious limitations placed on the use of the drug by the warning, the statement was made in this letter, over the signature of the president of Parke, Davis & Co., that Chloromycetin had been "officially cleared by the Federal Food and Drug Administration and the National Research Council with no restrictions" on its use. In an open letter, published in the Journal of the American Medical Association, in August of 1952, Parke, Davis & Co. stated that the above warning would be included in all their Chloromycetin literature in the future. However, from 1952 to 1961, the advertising for Chloromycetin contained only the following words: I will comment on these after I read the warning:

Chloromycetin is a potent therapeutic agent, and because certain blood dyscrasias have been associated with its administration, it should not be used indiscriminately or for minor infections.

Furthermore—

And it is stated right in its warning—

as with certain other drugs, adequate blood studies should be made when the patient requires prolonged or intermittent therapy.

Senator NELSON. When it says adequate blood studies should be made if a patient requires prolonged or intermittent therapy, what is your judgment as to what blood studies should be made? That is, should they always be made when chloroamphenicol is administered or only under certain circumstances?

Dr. WESTON. Well, let me bring into text the chronology of this thing.

At this particular time they were not aware of the fact that a single, as little as 1 gram of chloromycetin would have caused the dyscrasias. This pretty much became apparent later on in the history. Of course, now we know that with 1 gram of Chloromycetin there may not be an alteration in the bone marrow. On the other hand, there may well be an alteration in the bone marrow and actually, practically speaking, there is no way of detecting this if you want to be strictly honest about it. However, with prolonged therapy you may see a morphological alteration in the bone marrow. I am sure Dr. Dameshek testified to this,