

Mr. GORDON. You mean the incidence per 1,000 treated?

Dr. SCHEELE. That is right, but I mean the idiosyncrasy within the patients themselves to have this happen if he is given the drug.

Mr. GORDON. So that the record may be clear, then, you have accumulated additional information; but do I understand you to say that you do not have any more information about side effects now than you had 10 or 12 years ago?

Dr. SCHEELE. That is correct, and the physician who uses it does it on the basis that the disease he is treating, the risk—that is, the need for the drug is greater than the hazard as far as he is concerned in prescribing the drug.

Mr. CUTLER. Mr. Chairman, you might want to have the record show that Dr. Scheele is the former Surgeon General in the United States and not without experience in this.

Dr. SCHEELE. I helped gather some of the data for the FDA some years ago.

Senator NELSON. The record will show that because I saw the reporter writing it down.

I would like to ask you a question about something that puzzles me.

You were aware of the occurrence of serious blood dyscrasias, even fatal blood dyscrasias 5 or 10 years ago.

Your ad in 1960, an ad in the Antibiotics and Chemotherapy magazine, was a one page ad that we will submit for the record which says: "True broad-spectrum coverage, proved clinical efficacy, Chloromycetin, outstandingly effective against a wide range of pathogens," and so forth. It compares various other antibiotics A, B, C, versus Chloromycetin.

Then the written legend is: "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, as with certain other drugs, adequate blood studies should be made when the patient requires prolonged or intermittent therapy."

There is nothing here that would scare anybody. Your claim was for a potent therapeutic agent and because certain blood dyscrasias had been associated with its administration, you simply said that the drug should not be used indiscriminately.

(The advertisement follows:)