

Dr. MOSER. No, sir. I must confess that for the last several years I have not been reading the journal advertisements.

Senator NELSON. If a doctor opens up Goodman & Gilman, or any such source of information, and reads any article on the use of chloramphenicol, he will probably find that the specific limited indications of its use are listed very carefully. The package inserts that go with the medicine, which probably most doctors don't see because it goes to the pharmacist, lists the indicated uses and precautions and dramatic side effects in certain instances.

What I am curious to find out, if all this information is available, why has it been so widely misprescribed, if the testimony of these doctors is correct?

Dr. MOSER. Of course I cannot answer that, but one partial explanation resides in the fact that the average physician, in the course of a lifetime, may never see a case aplastic anemia. The incidence has been quoted at from 1 in 20,000 to 1 in 100,000 administrations of chloramphenicol. The rationale, as far as I can figure it, is that a physician may say, this is so rare it just isn't going to happen to me.

And chloramphenicol is a good drug. It is quite an effective drug. In fact, it is one of the most effective oral antibiotics that we have. Unfortunately, it has this potentially devastating complication.

I suspect that a physician will be tempted to prescribe this drug when it is not absolutely indicated because he just hasn't seen a case (aplastic anemia) himself. And there is a great tendency in medicine to rely on one's experience. This is dangerous; that is why we have the medical literature.

Senator NELSON. I think there is a problem with that statistic from the California study, which was about 1 in 20,000, I believe, nobody knows what percentage of cases are reported. Obviously, if a doctor uses it for acne, sore throat, headaches, upper respiratory problems, gum infections, hangnails, all of which are specific cases for which it has been used, and aplastic anemia results, which it has in all of these cases, he is not going to report it when he is liable in a lawsuit for the damage done. And there have been some very dramatic lawsuits in the past and many on the way now. We have testimony from doctors here that nobody is going to report that themselves.

So when you say 1 in 20,000 it may be 10 or 15 or 100 times that figure. The figure is high, but even so, even though the testimony is that it is an excellent drug, it is for such a limited number of indications that if you just read it once, you wouldn't use it as a broad spectrum antibiotic for which it obviously is being used.

Dr. MOSER. I do not feel that chloramphenicol should ever be used outside the hospital. It is a drug that should be used on inpatients for the treatment of very specific infections.

Senator NELSON. Thank you.

Dr. MOSER. Now, getting back to the discussion of the compilation of adverse reaction data, the AMA Registry continued to gather and tabulate its information until 1964, when it was decided that the data should be transferred to computer storage. And unfortunately this conversion never came to fruition. Also anticipated plans for free communication between the AMA and the FDA programs also never achieved a working reality. Through both programs it has been estimated that roughly 1 percent to 2 percent of adverse reactions that