Dr. LEY. I have rough figures here, of a total of 79, in addition to the fatalities, who experienced a leukopenia, and 79 who had a bone marrow depression.

Senator NELSON. From what?

Dr. LEY. From the chloramphenicol.

Senator NELSON. What statistics?

Dr. LEY. This is a summary from the California report.

Senator NELSON. One of the doctors who testified yesterday related that in his relatively small town of 16,000 people, he became aware of four cases of aplastic anemia at one time. And we have heard of similar situations through the mail that is coming into our office from little towns of 800, 900 people. I have five or six from my own State. These letters are from people who just notice something in the paper about these hearings and write.

It seems to me that the California study tends to give the physician a whole lot more security in prescribing this drug than the facts, as we know them, would justify.

You have a risk of one death in 24,000. How many cases are there of permanent injury?

Dr. GODDARD. As I said, Senator, I do not believe anyone has realistic figures on this. The incidence of nonfatal side effects which may be of long duration is probably higher than the incidence of fatalities, if the usual course of events is held to follow in this instance.

However, the British study, which we think has certain deficiencies, points out that fatalities occur as often as 1 in 10,000 patients receiving the drug. One has to be very careful in carrying out studies of this type, because aplastic anemia, as you well know, occurs from other causes—they may be idiopathic. And to simply relate all cases of aplastic anemia to chloramphenicol is not proper nor supportable. But nonetheless, I have to go back to my original statement and say that the CMA study is the best one we have seen so far.

Now, that does not mean that the incidence may not be higher. It simply reflects a lack of good data, Senator.

Senator NELSON. But why is our data so poor?

Dr. GODDARD. Senator, this is true in almost this entire field. We do not have good reporting. Hospital record systems vary throughout the United States. There is no requirement for reporting these kinds of episodes. It is done upon the initiative of a few physicians.

We have had great difficulty in getting good reporting in our adverse reaction reporting system, even in those instances where we paid the resident physician $5 for submitting a report. It is extremely difficult.

Now, as we progress with the usage of computers in hospitals to store patient data, the kinds of activities that are being carried out in Michigan by Dr. Virgil Slee's organization, and at a number of large hospital centers, it is going to be possible to extract much more significant information from existing hospital records.

But in the present situation, where we are totally dependent upon the physician assuming—upon his own initiative—the burden of sending a report to a firm, the FDA, or the AMA, we do not get good reports. The AMA in fact has discontinued its adverse reaction reporting system simply because of the lack of interest of participating