

Mr. GORDON. This is new labeling, and you are planning to do it now. But it was January of 1967 when this report came out, almost a year and a half ago.

Dr. GODDARD. The answer is that it would have been better to have done it then. That is the only answer I can give you. I have no reason for it not being done, other than the judgment that was made at that time, that there was a general knowledge that the risk was between 1 in 10,000 and 1 in 100,000.

Mr. GROSSMAN. Doctor, that is a pretty wide gap, isn't it?

Dr. GODDARD. Yes, sir, and I think it reflects again the problem we have in not having available good data.

Mr. GROSSMAN. That is what I wanted to ask you. How do you feel about some kind of a coordinated national—nationally enforced reporting system. Is it possible to do something like this? In other words, it does not seem we are getting anywhere. On the point you raised before—some doctors report if you pay them \$5, some others do not. This does not seem to be a very effective way of effectively finding information. I would like to find out how many people who got the drug and should have gotten it ended up with some problems, as well as those who should not have gotten it.

Dr. GODDARD. We would like to know that, too. But the development of an effective national reporting system is an extremely complicated problem, one that we have worked on. Dr. Ley may wish to speak to this. We have made some changes recently to try to get better drug data from a variety of sources.

I know of no way to enforce—from the national level—a reporting system.

Mr. GROSSMAN. What about regionally enforced, State enforced?

In other words, isn't it time we tried something else—because the present systems just are not working.

Dr. LEY. I think two facts should be pointed out.

As far as the present legislation is concerned, the manufacturer is required to report to us all reactions reported to him. There is no requirement for any physician to report reactions to the manufacturer. But those that are reported, which are not any more than the top of an iceberg, must be reported to us.

Senator NELSON. How many have been reported to you by Parke, Davis?

Dr. LEY. Over the period from July of 1963 to the end of 1967, which is the end of our tabulation, a total of 93 hematologic reactions have been reported from Parke, Davis to us, of which 59 are reported as aplastic anemia.

Senator NELSON. That is really just a ridiculously useless figure. Everybody knows it is more than that.

Dr. GODDARD. Senator, in answer to the previous question, let me say I have also had some experience with the reporting of other diseases which is required by law. Reporting of syphilis is required by law—by the States. It is completely ineffective. You get about 1 case out of 11 reported by the practicing physicians. Even though it is a legal requirement.

Now, I do not know how we can do anything to get physicians to report adverse reactions to drugs when we cannot get them to report