

Dr. MARKHAM. I think we can supply this. You want the total sales of Parke, Davis & Co. in 1952 and 1953 and also the sales of Chloromycetin?

Senator NELSON. Yes, and for each year as a proportion of total sales, to see what that factor was.

Dr. MARKHAM. Yes. I can only report we will all say we will try to get it.¹

Senator NELSON. All right.

In any event, discussing the risk factor, that is, a risk, if that were the factor that did cause the decline—I do not know. They were back up within a matter of 3 years to within 3 percentage points and then they jumped in 1957, more than 3 percentage points on earnings above the 1952 figure. And, they stayed 4 years in a row above the 1950 figure.

All I am saying is that this may be one risk factor. There are all kinds of risk factors and I would just point out that you could probably project a whole series of companies that did not face any product replacement, obsolescence, competition, and still experienced the same fluctuation.

Dr. MARKHAM. I will concede it did not drive Parke, Davis out of business and that it did subsequently recoup. I do not think, however, that that would lead one to the conclusion that this is not a risk that confronts pharmaceutical manufacturers. I shall continue on, sir.

Senator NELSON. Go ahead.

Dr. MARKHAM (reading). 3. The discovery that a drug can be misused in ways that create a significant social problem which then leads to limitations on its marketability or possible removal from the market.

I am told that meprobromate might be a good example of that.

Mr. GORDON. Has that been removed from the market?

Dr. MARKHAM. No, just its sales are subject to greater control.

4. Withdrawal or restriction of a drug by the U.S. Food and Drug Administration until additional evidence of safety or efficiency is produced.

I am told that MER-29 might be an example of that.

Senator NELSON. Are you going to be able to give us a series of examples? Again as with the first question, if it is an important risk factor, it seems to me we ought to see the number of examples of drugs that either had to be limited in their use because of discovered undesirable side effects not known at the time of the New Drug Application, or for some other reason. But I would think in order to prove it is a risk factor, peculiar or somewhat peculiar, as you put it, to the industry, we would need a series of examples to demonstrate that fact. If you have concluded that that is the case, you must have some examples.

Dr. MARKHAM. Yes, we are in the process of compiling such a list, Senator.²

Senator NELSON. Let me ask you a question: you referred to unanticipated side effects or withdrawal or restriction of the drug on the market.

Now, how is that risk, in terms of imposition of expense, more important, for example, than the risk of the automobile industry on auto recalls?

¹ The information had not been supplied at time of going to press.

² See Appendix III beginning at p. 2129, *infra*.