had in hand reports from their investigators cautioning them about serious side effects and yet the company, in their own memos, advised that they seek out a couple of particular investigators who would report to them what they wanted to hear. This was and continues to be a terrible catastrophe to thousands of people in the world and it could have occurred in this country as a consequence of the system in which you may have even one company which is intellectually dishonest. Is not the public health of such great consequence that something must be done to eliminate catastrophes of such dramatic consequence? Some place in the world this is going to appear again, and on the same grounds—lack of integrity of the sponsor.

Dr. LEY. I grant, Mr. Chairman, that the thalidomide episode has been a very startling and shocking experience in drug development. I would hope, and I have seen many instances where hopes have been well founded, that the majority of pharmaceutical firms in this country would recognize that they have a significant and a major responsibility to insure that a thalidomide episode does not recur in the United States.

Senator NELSON. I would agree and believe that that is the case. But that does not protect us against the recurrence.

Let me give you another example with which you are very familiar—MER–29. MER–29 was marketed without a disclosure of serious side effects. It was on the market for 2 years and subsequently there was indictment for criminal conspiracy and subsequent conviction. That happened to be in this country. It will occur again. All I am getting at is how do we insure integrity in the system against that special case that has occurred in the past, that exceptional case that will occur again, unless there is independent sponsorship where you can't select somebody, you cannot hide the results, and there is no interest in hiding the results?

Dr. LEY. The two cases the Senator has quoted both took place prior to the passage of the amendments.

Senator NELSON. Which amendment?

Dr. LEY. The 1962 amendments, the thalidomide and the MER–29 were largely set before the amendment.

Senator NELSON. May I ask what element is there in the 1962 act requiring proof of efficacy which gets at the question of failing to disclose serious side effects? This was illegal in both cases. The act does not correct that.

Dr. LEY. But the act gave to the Department and to the FDA far greater resources to conduct the type of monitoring and overview functions which are our proper responsibility. I can recount, within the past year that I have been Commissioner, two major firms voluntarily coming forward to me, presenting adverse data on their product, being a little bit reluctant, of course, to take the drastic action which we requested. The action taken, however, was very appropriate and proper in terms of the protection of the public health. I think there has been in the years that have passed since the amendment a very great increase in the sense of responsibility of the firms. Part of this, Mr. Chairman, I grant may be not solely an increase in responsibility, but a fear of legal action which might be taken by the agency against the firm if disclosure were not made.

Senator NELSON. There has always been the remedy of a legal action if there is a fraud and failure to disclose.