Senator NELSON. What kind of work are the PMA companies doing on the NDA's as compared to the work submitted by the non-PMA's?

Dr. GODDARD. We did this kind of analysis in preparation for the hearing because in a recent meeting, the president of the PMA said there were two drug industries. He raised the issue, so I thought it was a fair way to analyze this kind of data. I can submit the record if you wish, to comparable applications for each category. In general, the PMA did about as well as one would expect on a representative basis, except in two categories where the performance was indeed superior. That was with respect to composition and components, where their percentage of deficiencies were 29 and 23 percent, respectively. Now, in animal safety, PMA member firm submissions had deficiencies of 49 percent, clinical safety, 60 percent. Clinical efficacy, 56 percent.

Senator NELSON. These are deficiencies?

Dr. GODDARD. That is right, in the incompletes: Composition and components I mentioned earlier. In manufacturing they also did better, 46 percent; samples, 44 percent; and labeling, 51 percent.

Now, the number of incompletes in fiscal 1967 from PMA was 137 out of 258.

So PMA had 53 percent of all incompletes that year. Their overall percentage of performance was about 53 percent, about which one might expect. So you see, it is not a function of size.

Senator NELSON. They were not any better off than the others?

Dr. GODDARD. That is our evaluation and I am prepared to defend this before the scientific community by letting the scientists evaluate any 10, 20, or any number of applications we rejected as not being complete.

Senator SCOTT. Of those rejections how many would you think would be due to differences in interpretation between the FDA and industry scientists?

Dr. GODDARD. We, of course, Senator, feel we are correct in our judgment and are willing to place it on the line with the scientific community and let them be the final arbitrator.

Senator SCOTT. In your opinion, are industry scientists on the whole capable and well directed? What do you think?

Dr. GODDARD. Well, I must admit we have had considerable dialoge since I have been Commissioner with the industry scientists and I have explained about the quality of IND's and NDA's. I have asked industry scientists to review our IND requirements and suggest improvements. We have talked at meetings involving industry scientists about the quality of submissions and that quality had to be improved, that we were coming into a different era of drugs; therapeutic agents that were more potent, intended for longer term usage. I just do not find this to be an acceptable record of performance from the pharmaceutical industry. I am not differentiating between large and small and I am trying to be fair about this, Senator.

Too often the research offering in the IND's and NDA's seem to have been designed to get the drug to the market with the minimum data that the manufacturers think we will accept; they are not generally models of scientific planning and clinical execution to produce the evidence that will promptly admit drugs to the market on the basis of proven safety and effectiveness. This is the only conclusion I can draw to explain the large number of applications that are