Senator NELSON. Have you requested that they agree to submit these applications to review by the scientific community?

Dr. GODDARD. I did this morning in my testimony. I suggested that we could settle this difference of opinion about our subjective judgments by taking the last 10 or 20 IND's that we have deemed to be incomplete, have the PMA get from its member firms permission to open up this scientific data to acceptable review groups in the scientific community and, then, let the judgment be made by those groups. So in that fashion, I think we can get a pretty good fix on it.

Senator NELSON. That sounds fair.

You said there have been a few cases in which false data have been submitted to the agency. Was this data intentionally false?

Dr. GODDARD. Well, it is difficult to make a judgment of intent, Senator. There were only about five cases involving the submission of false data in a recent period of time. I cannot really ascribe intent in these instances. I have tried to point out, and I think it is significant, that with 25,000 investigators on our file, we have only had five such instances.

Senator NELSON. I think that is a good record.

Dr. GODDARD. I think it is a good record, too. I am not saying that there might not be others that exist, but I think there are very few.

Mr. GORDON. On page 5 of your statement, you talk about the quality of research in connection with the NDA's. In your opinion, does the poor quality of research in connection with the NDA's, apply also to other research conducted by the industry?

Dr. GODDARD. Are you talking about the IND?

Mr. GORDON. The IND's and the NDA's.

Dr. GODDARD. The IND's are the precursors of the NDA's and it is during the investigation and new drug exemption stage that these clinical studies are carried out. Of course, we think by initiating closer surveillance over the IND submissions and review of these at an earlier point in time, we can have a better understanding of the drug and perhaps will have a little better scientific data finally come into us. This, of course, is where we have in our meetings with the scientists in the industry been urging placement of greater emphasis on the need for better science. I submit that we are entering into an entirely different era of therapeutics—an era of more potent agents, as I mentioned before, agents intended for long term usage. We have to have rather exquisitely detailed knowledge of the effect of these drugs at the cellular level. We do not get that very often and I think it is just going to be absolutely mandatory that this kind of information be developed.

Mr. GORDON. Then would it be fair to say that a large number of drugs submitted to you are only minor modifications of old drugs developed in order to be able to secure patents?

Dr. GODDARD. I cannot, again, know why they are—whether they are submitted for us to——

Mr. GORDON. I did not ask why. I said is it correct?

Dr. GODDARD. You said in order to get patents.

Mr. GORDON. All right, let's forget that. They are just minor modifications rather than really interesting developments?

Dr. GODDARD. I said this morning that out of the 83 new drugs, 69 of them were not what would be described as new chemical entities,