seriously deficient, except for the few cases in which false data have been submitted to us.

Senator Nelson, I have not been satisfied with the research results presented to us. We have taken some steps to try to help industry improve the quality of its NDA submissions; it seems that still more steps are necessary. The high percentage of poor applications must be greatly reduced. There is no reason why a manufacturer cannot do the job properly the first time. Poor new drug studies and applications are wasteful economically; but much more important, they are wasteful of the very limited scientific talent and resources available for conducting and evaluating clinical trials. Such poor work delays the introduction into medical practice of valuable new therapeutic agents, and increases the cost of research with no benefit to the public.

We have taken a number of corrective steps such as:

Working with industry scientists to explain the requirements for good testing.

Outlining improved methods for organizing and submitting NDA's.

Terminating clinical trials where necessary, and in a few cases barring certain investigators from the privilege of participating in further trials.

We are inaugurating a further step that may be of some help; we are going to resort routinely to more formal procedures. Heretofore, we have usually advised firms informally of the deficiencies found in their NDA's and given them an opportunity to correct them. The result often has been a time-consuming series of phone calls, conferences, or memorandums, meetings.

Henceforth, we plan to file each application submitted—unless there are obvious gross deficiencies immediately apparent—and then make a formal decision on that application. This we believe is the procedure the law contemplates. If a manufacturer knows he may not be able to make continuing corrections in his submission, he will have a greater incentive to send us the best possible submission the first time. Further, where the situation warrants such action, our rejection of a poor NDA will be with prejudice to the resubmission of that particular document or its further use if the firm still wants that drug approved.

Senator SCOTT. Right there, doctor, when you say these will be rejected with prejudice, does that mean with prejudice also to those whom the drug might help if it is ultimately accepted?

How do you handle that?

Dr. GODDARD. You are talking about the patients who are being thus denied the benefit of the drug?

Senator SCOTT. Yes, sir.

Dr. GODDARD. Sir, I submit if we are not in a position to evaluate properly the material the manufacturer has submitted, if it is so poorly done, then there must be real doubt in our minds as to whether the patients will benefit. It may ultimately be proven that they will, but we cannot tell the future. We just have to have the proper kind of data.

Senator SCOTT. You are making the decision there?

Dr. GODDARD. Yes, sir. That is reason for administrative review, Senator, that is available in such instances and we have used this