I would appreciate the opportunity, with the chairman's permission, of reading into the record a short statement which I believe summarizes the agency's position on the article.

Senator NELSON. I wonder if you would withhold that. I wanted to finish in the record the peer group proposal. We have a series of questions on the article referred to by the Senator, but in order to get clear what the peer group proposal is about, and have it run continuously in the record, I would rather leave aside the Stough incident. I have here also a report from the Alabama Medical Association, which I am sure you are familiar with.

Dr. LEY. Yes, sir.

Senator NELSON. In order to maintain continuity in the record I would like to finish the peer group questions.

Senator DOLE. I have another committee meeting where I have something involved and would like to pursue also some questions with reference to Dr. Stough. How long will it take on the peer group?

Senator NELSON. Just a couple of minutes. I also have another committee meeting.

As to the peer group, who would select the peer group?

Dr. LEY. The peer group would be selected by the institutions in which the study was conducted.

Senator NELSON. How does the peer group function in relation to your remote rural New York physician who had 45 IND's?

Dr. LEY. This is the still remaining loophole, Mr. Chairman. It bothers me, but I am also practical enough to recognize that having a peer group under circumstances of this sort would be near to impossible. It would also raise in our minds, the minds of our staff, the very important question that those individuals who did not have a peer group associated with their investigation would require very careful special monitoring above and beyond the other. The requirements for a peer group have been published. We, Mr. Goodrich and I, worked very carefully with the Public Health Service grant program personnel back late last year and early this year. These requirements as now published by the PHS research grant group require the same type of informed consent that our regulations require. It came rather forcibly to the attention of both my staff and myself during the review of the Stough incident and also in preparation for this testimony that there was an important gap in the protection of the patient or the subject of medical investigation in the new-drug area in that he or she was the only such patient or subject which did not have the peer group working to review and to evaluate the conditions under which the experiment studies were done.

Senator NELSON. I note that, just about 22 months ago, there the whole business of investigational new drugs was discussed in a very fine speech by the then Commissioner, Dr. Goddard. He said:

> I can say that I have been shocked at the quality of many submissions to our IND staff. The hand of the amateur is evident too often for my comfort. So-called "research" and so-called "studies" are submitted by the carton full and our medical officers are supposed to take this all very seriously.

I will put the whole speech in the record.

I am raising the question as to whether all of this has changed in the last 25 or 26 months. In that speech, which I ask to be printed in full in the record, Dr. Goddard states:

> In addition to the problem of quality, there is the problem of dishonesty in the investigational new drugs stage.