quality control inspections within the manufacturing plants of the drug companies?

Dr. LEY. Many of these are and many of these investigators are functioning in a very important role in our intensified drug inspection program in the field in that they focus attention on the studies reported to the Department by the investigator right as they exist in the investigator's file.

Senator NELSON. Excuse me, what was that again?

Dr. LEY. These 140 people are basically drug inspector personnel within the Food and Drug Administration. They have been exposed to a highly specialized additional training course which qualifies them uniquely for investigative work in the area of clinical investigation This means not only recordkeeping in the investigator's files and his method of conducting the laboratory work and the other work involved in the investigation itself, but it means they are also expert in evaluation of the sponsor's method of processing this type of information in their preparing it for submission to the FDA. These people have many functions to perform. However, they have unique training, they represent a large pool of personnel from which I believe we can divert a significant part of their effort into more intensive investigation of the investigator and investigation.

Senator NELSON. I am trying to get at the question really, of how many inspectors, how many man-hours are spent by your inspectors directly in the field evaluating the performance of the protocol by the investigator, not the inspector's work within the plant, not his inspection of the data that comes to the plant, but going out to the investigator, giving surveillance to his performance. On that question, I would also like to have you tell me how many IND's you have in—give us the last couple of years, and specifically, how many of those investigators were inspected for the performance at the place of the experiment, how many actually had a visit from the investigator, how many advisers had a visit to him directly and a review of how he is carrying out the protocol? Do you have that?

Dr. LEY. We can submit this information for the record, Mr. Chairman. It is in more detail than I have it here.

Senator NELSON. Yes, I understand.

Dr. LEY. I think it is important to point out that the man-years involved in the total process of supervising or oversight of the investigator and the investigation is in three separate categories—one, headquarters staff including the Office of New Drugs review of the investigational study submitted to us; second, in terms of the field staff. We can provide figures for both. Both figures are necessary to interpret the total effort we are putting in this area.

Senator NELSON. What I would like to know is if there are at any one time, in any one year 500 IND's pending, with experiments going on on 500 different drugs—in how many of those 500 experiments has an investigator gone to supervise the performance of the protocol by the investigator? How much time was spent on this task?

I am getting at this because I am concerned, as a consequence of the testimony of many witnesses, that there is inadequate supervision. If that is the case, I would like some estimate of what the Department thinks would be necessary in additional personnel to perform this function so that we may have, perhaps, some evidence on which to