Senator NELSON. Would the FDA have personnel to do at least some reasonably broad sampling of the functioning of the peer group?

Dr. LEY. This would have to be sampled. I am concerned that we have not used to as great an extent as we possibly could the ancillary highly trained inspector, but nonmedical inspector, in our organization. This man has been specially trained for investigation into the clinical investigation area. We have not put him to as efficient use as possible. I believe that it will require a modest increase in manpower in this area and I am willing to commit him.

Senator NELSON. It seems to me that unless there is some oversight, every peer group may function under a different set of rules and you would not have any uniformity.

Dr. LEY. This is true. There must be some oversight apparent to the community, and I think it would also be of interest to point out to the committee that the peer groups in many of the medical centers that would be reviewing sponsored studies by firms would be the same peer groups that would be reviewing other investigational studies supported by Public Health Service research grants. The one place where this would probably not be true is in the prison situation, in which one of the findings in the Alabama report was that a peer group review is highly desirable for such a situation as that in Alabama.

Senator NELSON. You mean the Alabama Medical Association report was recommending a peer group review of that kind of activity, is that what you are saying?

Dr. LEY. Yes.

Senator NELSON. There was no peer group of any kind?

Dr. LEY. There was no significant peer group of any consequence in that situation.

Senator NELSON. How many investigators do you have in the FDA to do a field evaluation of the functions of the protocol, the performance of the protocol under the IND?

Dr. LEY. As indicated in my testimony, we have 140 nonmedical personnel who have been specially trained in this area. In the medical area, our total staff commitment not only includes Dr. Kelsey and Dr. Lisook sitting here behind me, but also includes all of the reviewing medical officers in the Office of New Drugs, into whose hands the IND studies come.

Senator NELSON. Are these field investigators?

Dr. LEY. These are not field investigators. These are headquarters personnel who perform the evaluating function that I indicated could be highly important, as in case No. 1, where adverse effects were not reported by one investigator, but strong effects reported by another. This is all part of our surveillance activity.

Senator NELSON. I understand you to say that you have 140 nonmedical field investigators. Is it their exclusive responsibility to monitor IND's or are they also your inspectors for the drug plants?

Dr. LEY. It is not their exclusive responsibility to monitor IND's. They have many other functions. As I indicated a few moments ago, I am concerned, and the staff is evaluating means by which we may involve 140 people more vigorously in the review of investigations. This is still under consideration within the Agency.

Senator NELSON. But so that I would have it straight in my own mind, are these 140 nonmedical inspectors, also the ones who do the