Dr. LEY. There was a very significant change written into the 1962 amendments which is drastically new. This was a requirement for records and reports on the part of the firms to be filed with the FDA on a periodic basis. That eventually passed after the drug was 3 years old. This was never required before.

Senator NELSON. In the case of Panalba, your Department found four studies done by the companies own investigators which showed that it was not efficacious as a combination. This was not reported to FDA.

Dr. LEY. That work was completed, sir, prior to the passage of the amendments. The firm did furnish the information to us when we found it and insisted that it be furnished. I do believe there was no legal requirement for it to furnish data that had been placed in its files prior to 1963.

Senator NELSON. The FDA, based on the 1962 amendments, asks for all pertinent data. This is pertinent data but it was not supplied.

Dr. LEY. It was pertinent data, Mr. Chairman, I grant that definitely. It was not supplied. There is a legal technicality here that our counsel can refer to better than I. Whether it was technically legally required, I am not so convinced. It would have been very nice to have had the data earlier, I grant you.

Senator NELSON. Well, I submit that I still have heard nothing that is in the law, no protection against the kind of case in which the sponsor of the drug in a rare instance decides not to disclose findings that have been made. It only takes one thalidomide—one of these serious things. That is why one asks why follow a system in which the sponsor who has an interest in a drug has nothing to do with the IND? That is what I am getting at. Why should we not do that?

Dr. LEY. There are other answers which I have suggested in the testimony today that are intermediate between the present system and the system which you and some of the witnesses before you have proposed. One of the very significant features in our testimony here today is our statement that we have in preparation a proposed Federal Register statement that would make all investigational studies conducted in phase 1 and 2 studies and those phase 3 studies in institutional setting subject to review by a peer group committee. This would not only be for initial approval of the study, but on a continuing basis to insure that the results developed by the investigator are sound and medically, scientifically justified. This element of involvement of the local community, the medical and scientific community, in the evaluation of an investigational study, would be a very important factor of protection in that, if serious adverse effects are found and seen by the review committee, this review committee would, in itself, I think, become an instrument in notifying us if the sponsor did not.

This area—that is, investigational drug testing in man—is the only area in medical research funded by or overseen by the Federal Government that does not have the requirement for a peer group committee today. I think it is time that such a committee be established.

Senator NELSON. How would the peer group function? Who would they be?

Dr. LEY. The peer group, sir, set up by the Public Health Service is a group of physicians, lawyers, ministers formally appointed by the institution—the hospital in the present contract, although it would be