vide more reliable data which could be reviewed much more rapidly by the FDA staff.

The use of consultants and advisory committees also could be increased.

We have under development a proposed regulation that would require that all investigational studies conducted in an institutional setting be subjected to the same type of peer review and evaluation that is currently required for research work funded by the Public Health Service.

Let's now turn our attention to another aspect of drug testing. One of the vital links in the evaluation of new drugs is the drug investigator. Sponsors have designated approximately 15,000 clinical investigators since mid-1966. This number obviously is too large to permit routine inspections. Consequently, we have developed our own ways to help us select clinical trials for field audit. I have attached to the statement an outline labeled "Attachment A" which summarizes the guidelines involved. I think it would be of interest for me to briefly indicate the six major factors involved in the choice of a particular investigation to audit on the part of FDA.

1. A question about the qualifications of the investigator to perform the particular study outlined in the protocol;
2. Suspicion of irregularities based on the quality or nature of the data submitted in IND's or NDA's;
3. A large volume of work over given periods by an investigator, raising question as to whether the work can be done within the time period involved;
4. Reporting of studies on large numbers of patients with a disease which does not normally appear with this frequency or at that level;
5. Complaints received from sponsor firms; and
6. Publications of summaries of studies in scientific journals, et cetera, which appear to exaggerate or misrepresent reported conclusions. These would include claims not authorized for the drug.

Onsite inspections of clinical investigators and their facilities, including medical data, are conducted by an FDA physician accompanied by an inspector. If violations are found, FDA may take one or more of the following actions:

1. Issue warning letter calling for corrective action.
2. Hold an informal conference with the investigator to point out deficiencies that need correction.
3. Proceed to disqualify the investigator, that is, find him ineligible to receive investigational drugs.
4. Lastly, and the most severe action, is to recommend criminal prosecution to the Department of Justice.

Since 1962, the Commissioner has declared 11 investigators ineligible to receive investigational drugs. One investigator, a general practitioner of Silver Spring, Md., was prosecuted by the Government for knowingly submitting false data to the FDA.

Senator NELSON. This is 11 out of 15,000?

Dr. LEY. Yes, sir; this is 11 out of 15,000 that had been declared to be ineligible.

In 1962, we learned that the investigator had submitted data to a number of NDA's and IND's and had undertaken projects beyond his