officer memoranda and investigational findings and evaluations of investigators and facilities.

2. Directed that all inspection reports of clinical investigators will receive immediate review and evaluation in the Bureau of Medicine which will transmit its recommendations to the Associate Commissioner for Compliance in my office for final review.

Mr. Chairman, my staff and I will be happy to answer any questions you may have.

(Attachments to Dr. Ley's prepared statement follows:)

CASE No. 1

The investigator operated a large commercial drug testing facility in the Northeast. He had worked on 82 investigations for 28 sponsors.

An FDA audit showed:

1. Patients who died, left the hospital or dropped out of the study were replaced by other patients in the tests without notification in the records. Forty-one patients reported as participating in studies were dead or not in the hospital during the studies.
2. Administration of drugs and maintenance of records were intrusted to nonmedical personnel.
3. Laboratory facilities were not adequate for performance of test reported.
4. Record-keeping, supervision and observation of patients in general were grossly inadequate.

The investigator was declared ineligible to receive investigational drugs and is still ineligible.

CASE No. 2

This general practitioner in the Northeast had been named as investigator on 45 NDA's and IND's for 14 drug companies.

Audit showed gross defects in the clinical testing program, such as:

1. Inadequate record keeping.
2. Records had obviously been "rehabilitated" after original entries were made.
3. False reporting of test results to the sponsor.
4. Concurrent use of subjects on 2 or more trials.
5. Absence of the investigator from the U.S. during significant periods when tests were supposed to have been conducted.

The investigator was declared ineligible to receive investigational drugs. He is still ineligible.

CASE No. 3

This case involves an associate professor of medicine at a large eastern university.

During the audit, serious deficiencies were discovered. These included:

1. Failure to properly identify test drugs and placebos.
2. Failure to keep accurate records of adverse reactions.
3. Failure to keep records of subjects used in the tests.
4. Simultaneous use of subjects in more than one test.
5. Reports that studies continued for weeks after they were stopped.
6. Conduct of studies by untrained or inadequately trained personnel.
7. Lack of supervision by supervisory personnel.
8. Conduct of more studies than could be handled by available personnel.

The physician was declared ineligible to receive investigational drugs.

Later, major improvements were instituted. Among other things:

Record keeping was placed on a sound basis, only trained personnel conducted tests.

Volume of work was drastically reduced. Good medical supervision was effected. Proposed studies, as well as ongoing studies, were audited by a peer group of specialists not otherwise associated with the facility.

The investigators' eligibility to receive drugs for clinical testing was reinstated when a new audit by FDA showed that the various deficiencies had been corrected and the Commissioner received adequate assurance that future testing would be properly conducted.