CASE NO. 8

An assistant professor of medicine at an eastern school had conducted 24 studies for nine drug companies.

An FDA audit showed:

1. Patients who died while on clinical trials were not reported to the sponsor.
2. Dead people were listed as subjects of testing.
3. People reported as subjects of testing were not in the hospital at the time of the tests.
4. Patient consent forms bore dates indicating they were signed by the subjects after the subjects died.
5. Recordkeeping was otherwise totally inadequate.

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

CASE NO. 9

A general practitioner in the East who was named in 16 IND's and NDA's for six different drug companies submitted reports of laboratory work that had not been performed.

He has been declared ineligible to receive investigational drugs and is still ineligible.

ATTACHMENT "A"

SOME FACTORS USED BY FDA TO SELECT INVESTIGATORS FOR INSPECTION

1. Question of 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 would originally be done.
4. Reporting of studies on large numbers of patients with a disease which does not normally appear at that level.
5. Complaints received from sponsor firms.
6. Publications of summaries of studies in scientific journals, etc., which appear to exaggerate or misrepresent reported conclusions. These would include claims not authorized for the drug.

The clinical investigator is committed by the regulations to:

1. Maintain adequate records of the disposition of all receipts of the drug, including dates, quantities, and use by subjects, and if the investigation is terminated to return to the sponsor any unused supply of the drug.
2. Prepare and maintain adequate and accurate case histories.
3. Maintain the records of disposition of a drug and the case history for a period of two years following the date of approval for the new drug application; or if the application is not approved, until two years after the investigation is discontinued and the FDA so notified.
4. Will at reasonable times make such records available for inspection and copying.
5. Certify that the drug will be administered only to subjects under his personal supervision or under the supervision of investigators responsible to him. The drug will not be supplied to any other investigator or to any clinic for administration to subjects.
6. Certify that the investigational drug will be used by the undersigned or under his supervision in accordance with the plan of the investigation.
7. Certify that he will inform any subjects, including subjects used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subject, or their representatives, except where this is not feasible or, in the investigator's professional judgment, it is contrary to the best interest of the subjects.
8. The investigator is required to furnish his reports to the sponsor of the drug and report adverse effects promptly. An adequate report of the investigation should be furnished to the sponsor shortly after completion of the investigation.