field of competence. We learned also that he had done little or none of the work reported. In fact, he had been in Florida during part of the period when his alleged work was done in Silver Spring. He was convicted and received a suspended sentence.

A New York drug testing firm and its president, a physician, were disqualified and the firm went out of business. We investigated the firm after we received information that the signature of a prominent New York pediatrician had been forged on individual case reports on a cough syrup. Our findings disclosed that 13 of the 26 patients reported in the study denied participation. Investigation of two additional studies disclosed similar forgeries and falsificatons. The firm and its head have been disqualified from further investigational work.

I am submitting for the record summaries of the additional instances in which we have found it necessary to disqualify investigators. Briefly, highlights from some of these cases are:

One involves a Boston physician who had done very poor work on new drugs prior to 1962. Our records showed that he and his associates were named as investigators in 82 IND's, 55 of which were active at the time of the investigation; 28 sponsors were involved. The details are provided in case 1, which is attached for the record.

The other case involves a general practitioner in a small New York State community who had been named as an investigator on 45 IND's and NDA's for 14 different drug companies. We doubted the availability of the patient population sufficient to participate in some of the studies submitted. (See case 2.)

Three investigators were reinstated after taking steps to insure that they would be in strict compliance with the investigational drug regulations in the future. I am submitting summaries of the three cases for the record. (See cases 3, 4, and 5.)

I am submitting for the record summaries of the remaining investigators who were never reinstated. (See cases 6 through 9.)

In the period since 1963, the regulations governing investigational new drug studies have been modified as indicated to protect the subjects of clinical trials. For example, in 1966 following an investigation which showed that a significant percentage of patients receiving investigational new drugs were not giving informed consent, we revised the regulation to delineate the need for this and to define how it was to be achieved. Another change we have made is to establish a procedure whereby inadequacies in the handling of investigational new drugs are called formally to the attention of the investigator and the sponsor before decision is made on disqualification. I am submitting a copy of the up-to-date regulations for the record. These are appended to the statement.

Mr.Chairman, I need not tell you that clinical investigation of drugs is an inexact science. There are very few cases of clinical drug investigations where all conditions are perfect.

In the last 3 years, I think we in the Food and Drug Administration have continued to move forward in our efforts to create the best possible conditions under which drugs can be tested safely and effectively.

At the same time, we realize the need for further improvements. Accordingly, we have:

1. Set up an FDA Clinical Investigator File in the Division of Science Investigation. This file will contain in a central place such items as correspondence, inspection reports, food and drug