be informed if an experimental drug is going to be used in treating them?

Dr. GODDARD. Yes, except in those two instances.

Senator NELSON. In what two?

Dr. GODDARD. Where it was not feasible because of the state of the patient in terms of either his consciousness or awareness, and second, when it would be detrimental to the best interests of the patient.

Senator NELSON. Then those cases which we have read about where physicians actually either falsified the record, or didn't ask the patients, were clearly violations of the law?

Dr. GODDARD. They would have to be construed that way, sir. I would like to point out that in terms of physician investigators, the agency has had relatively few of these whose data has been falsified. This has only happened in a handful of cases, and we do have 25,000 investigators of record at this moment. So by and large, I would have to say that the physicians have conducted themselves in an exemplary fashion.

Senator NELSON. 25,000?

Dr. GODDARD. Yes, sir.

Senator NELSON. Full-time investigators?

Dr. GODDARD. No, sir. Not full time. You see, the firms, particularly in large pharmaceutical manufacturers, who sponsor much of the research, use large numbers of investigators, particularly in phase 3 investigations, when they are trying to test the drug under conditions of usual usage. They may go to 100 obstetricians and gynecologists to try a drug that would be particularly useful in their practice. Then there may not be occasion for that particular company or any other company to call upon that group of physicians for some time—several years or even longer. So there are a large number of persons whose names are on our files as active investigators, "active" in quotes.

Senator NELSON. You are not talking about investigators who review the work done by the physician who experimented with a new drug?

Dr. GODDARD. No, no.

Senator NELSON. I see.

Dr. GODDARD. They are clinical investigators.

The agency keeps current on investigators, either from reports or through inspection, requires that the studies be carried out according to a rational plan, requires modification of the plan if necessary, and occasionally orders the investigations discontinued if the plans were not adequate, were not being followed, or if the investigation produced evidence that it was unsafe to continue.

Currently, the Food and Drug Administration has 2,188 active investigational new drugs—IND's—on file, with an annual entry of new IND's running at a current rate of approxmiately 700. Thus, about a third of the IND's on file at any one time are new for the year; another quarter will be discontinued within the year.

The point which I wish to make here, Senator Nelson, is that with the IND procedure, FDA has a chance to follow drug research from the beginning; we are thus better able to react when the manufacturer requests that we approve commercial marketing of the new drug. The manufacturer requests such approval in an application which we call a New Drug Application, or simply an NDA. The NDA contains or