sians who graduate from medical school and complete internship and residency training.

On the other hand, in some of the other aspects of phase 1 study where the objective may be to evaluate the metabolic rate of the drug—that is, how it is broken down in the body—this type of investigative drug study would require a very much greater depth of experience and training on the part of the physician.

Senator NELSON. In this particular case, was that what the 45 IND's and NDA's were for 14 different companies, the dose-range finding test?

Dr. LEY. No, sir; in this particular case, the studies were phase 3, largely with over-the-counter type products—aspirin-containing products, cough syrups, and things of this sort.

Senator NELSON. Were the IND's on cough syrups?

Dr. LEY. There were some IND studies in this category of drug; yes, sir.

Senator NELSON. Were all of them in this category?

Dr. LEY. The majority were in the category of drugs we would classify in the general group of over-the-counter drugs. The effects which we noted, Mr. Chairman, in the studies reported by this investigator can be summarized in general terms by inadequate record keeping, rehabilitation, which is a sign word meaning that the records have been modified and changed after the original entries were made. There was evidence of actual false reporting of test results to the sponsor in this case. There was concurrent use of subjects in two trials, which is very poor technique in any investigative work; and there was in addition the fact that the investigator had been absent from his supervisory role in the studies outside the United States during significant periods when the tests were supposed to have been performed.

Senator NELSON. Did I understand you to say that these 45 IND's and NDA's for 14 different drug companies were all for nonprescription, over-the-counter, cough syrup and aspirin-type testing?

Dr. LEY. Some of these, Mr. Chairman, my staff informs me, were prescription-type products. The majority or better than half, however, were the over-the-counter type product.

Senator NELSON. Now, in the prescription-type products, what was the nature of the testing?

Dr. LEY. The testing in that area included such products as the cardiac nitrates, PETN's. The types of testing that were done there, I believe, were in the category of the dosage-range finding. They were not the elaborate metabolic studies that I referred to a moment ago.

Senator NELSON. But if I understand your statement, he was disqualified on the grounds that there wasn't a sufficient availability of patient population?

Dr. LEY. He was disqualified on much more than that, Mr. Chairman. There were indeed fewer patients than he needed for his studies. He tested two drugs at the same time in the same patient, which, as I indicated a moment ago, is a very poor practice.

Senator NELSON. Isn't it unusual that 14 companies would seek out an individual practitioner in a small New York State community to test 45 IND's and NDA's?