

Senator NELSON. Fine. You set the date, Senator, and I will be there.

Senator DOLE. Today we are going into an area involving a legislative matter pending in another committee. The question with reference to the peer review committees has been discussed at great length. As one member of this subcommittee, there may be some merit to this suggestion. I am not certain whether the FDA could ever be in a position to supervise all of the new drug investigations. But I was curious in reading a statement that there are some 15,000 new drug investigators. Who are these people generally? Are they engaged in phase 1 or phase 2 or phase 3 of the investigations?

Dr. LEY. Senator, they may be engaged in any one of these phases. Customarily, we find more frequently the general practitioner engaged in phase 3 testing which has as its objective, indicated in the testimony, to determine the effects of the drug as it would normally be given in clinical practice. So we do have this provision. But this is only in very general terms. We may have certain people with general medical backgrounds doing a type of work that we consider quite appropriate, what Dr. Stough is doing in Alabama.

Senator DOLE. What field is Dr. Stough in? A general practitioner?

Dr. LEY. Dr. Stough's training was that of general medicine.

Senator DOLE. Is he engaged in that practice now?

Dr. LEY. He is not. His total activities are those of drug testing. In this sense, he is unique among—not totally unique, but a rare animal among the total group of investigators.

Senator DOLE. Do you have a list or catalog of 15,000 investigators? Is that material available? Do you keep a record of those?

Dr. LEY. We have this material. It is not as convenient or accessible as we wish until we finish the computerization of it. But it is available in part in our file.

Senator DOLE. These are on a State-by-State basis, I assume?

Dr. LEY. No, we do not have a breakdown on this basis. These are some of the problems we hope to solve by the computerization of the file. It is on an alphabetical ground, I believe.

I am pleasantly surprised. The staff tells me that the names of the investigators are presently computerized. The additional information about training facility, and so forth, is not yet available by that basis. This is available, but it requires deep research of the record.

Senator DOLE. What purpose is served by your having a list of all the investigators? Do you review that list occasionally?

Dr. LEY. Two purposes, Senator, are served by this list. First of all, we may by this technique identify those investigators who have the largest numbers of investigations in progress. Second, it gives us the opportunity, if the man whom we disqualify is listed as an investigator by a sponsor, to say no, you may not utilize it. It serves these two functions.

Senator DOLE. Do you have any record of the compensation paid by, say, Dr. Stough to the clients he has?

Dr. LEY. No, that is not part of our record in any place.

Senator DOLE. There is no effort made to determine that?

Dr. LEY. I do not think that would be a legitimate item under the regulations or the law. I would have to turn to Mr. Goodrich.