munity supports me, that there are classes of drugs for which we can write today very clearcut, definitive protocols of exactly what tests are required, exactly how many patients on which the tests have to be done, and exactly what statistical procedures have to be used to prove efficacy. One of the classes of such drugs I would present for the committee's consideration, is that of diuretics. I believe that the Academy, working in concert with the scientific community, with advisers from the FDA and industry, will be able to develop a set of guidelines for the evaluation of the efficacy and the safety of diuretics that can be applied across the board, with a very major saving both in terms of the numbers of patients and in terms of the risks to which these patients are subjected.

Diuretics are not the only such drugs that can be so evaluated. But again I do not wish to present this as a sole and major cure for the problem as I see it. There are other kinds of drugs, such as tranquilizers, for which such a protocol would be difficult, and indeed, I fear it would be impossible to design at this point in time.

Senator NELSON. Do I understand that you are going to proceed to establish peer groups throughout the United States?

Dr. LEY. That is our intent. I have a draft here that is not yet in completed form because of questions internally within the staff, which our General Counsel has prepared for my consideration for regulation-making requirements.

Senator NELSON. You have made the decision to go ahead?

Dr. LEY. I have. I must listen, however, to the comments that will arise in response to the proposal. I do not think it will be a welcome proposal.

On the other hand, I do not believe, Mr. Chairman, that we can exclude the subjects and patients of drug investigational work from this type of protective influence that every other research-oriented group in the country now requires.

Senator NELSON. The Public Health Service now uses peer groups?

Dr. LEY. Definitely. Throughout its entire program, internal and external.

Senator NELSON. Who did you say would select the peer groups?

Dr. LEY. The peer groups are selected by the institutions in which the studies are done. The selection of the peer groups is made an official matter of record and the minutes of the meetings of the peer group are available for inspection at any time.

Senator NELSON. Will the FDA require that the minutes of the actions of the peer group be submitted as a part of or independent of the IND?

Dr. LEY. This is a point that is currently under consideration, with several views on the part of my staff. I cannot answer this at the present time.

Senator NELSON. How would we know whether the peer group was just a perfunctory——

Dr. LEY. There would have to be as part of the submission of the investigational institution to the sponsor and from the sponsor to us a statement that such a peer group existed, that such a peer group had reviewed the material and that the minutes of the group were available and where. This is the minimum, it seems to me, that would be essential. This is the pattern that the Public Health Service would follow.