Dr. LEY. Not quite, but I do wish, with your permission, to place into the record a summary of the Stough matter as I see it at this particular point in time.

Senator NELSON. Do you have a separate summary there?

Dr. LEY. I do, sir.

Senator NELSON. The committee has not had copies, is that correct?

Dr. LEY. I do not believe this has been provided to the committee earlier. I do have two copies additional here.

(Summary referred to follows:)

The New York Times recently has run two feature stories on drug testing by Dr. Stough in the Alabama Prison System.

Dr. Stough was engaged in doing the more routine parts of phase 1 studies for a number of drug sponsors. He was administering investigational new drugs to volunteers in the prison, drawing blood samples to determine the amount of drug that entered the blood stream and doing other associated laboratory studies. This is dosage range finding and gross toxicology. He was not engaged in the more sophisticated types of clinical pharmacology.

FDA personnel visited the Alabama facility in 1964 and our physician-inspector teams visited the facility again in 1967, and most recently in 1969 after a story about it appeared in the Alabama papers.

The findings in 1964 were that there were a number of minor discrepancies—poor record-keeping, inaccuracies in some of the records, and inadequate physical examination and medical supervision of the volunteers in the investigation. These deficiencies were discussed with Dr. Stough.

By 1967 these problems had been corrected except for minimal physician-subject contact. There is no requirement in the regulations which defines the degree of physician-patient contact for investigational studies.

The Bureau of Medicine concluded that the findings were not serious enough to warrant any action against Dr. Stough and his associate as investigators, based on current regulations. The studies going on in Alabama were providing useful information that was not available in other than prison environments.

The inspection report and the Bureau of Medicine evaluation were not required to be forwarded for review by the regulatory personnel. We are taking steps to see that in the future such reports are examined by compliance personnel.

Moreover, as previously noted, we are proposing an amendment to the investigational new drug regulations to require the establishment of review committees, of the type required in research funded by the Public Health Service, for institutions such as the Alabama Prison System where volunteers are involved in drug testing. This will better protect the welfare of the volunteers and assure a better quality of research data.

Senator NELSON. Was your memorandum from yourself to the Acting Director, Bureau of Medicine, subject, Austin R. Stough, dated July 29, 1969—was that released?

Dr. LEY. That memorandum from Dr. Jennings to me was in response to a request from my office to summarize the information as of that date. That was released to the press. I would have preferred that it not be released until I had the statement I have today. However, it did reach the press and did result in the second New York Times article.

The work that Dr. Jennings indicated was necessary I believe has been completed. You may wish to discuss this matter with him in terms of whether or not any of these studies were pivotal to a new drug approval. The evaluation was that they were not.

Senator NELSON. Well, from that memorandum, I would like to quote a sentence and ask your observation on it. I would ask that the memorandum dated July 29 from Dr. Jennings to Dr. Ley, subject, Austin R. Stough, be printed in full in the record.