

Dr. LEY. Mr. Chairman, the most effective measures to correct such problems as exist in the operation there is the peer review committee. That is, to my way of thinking, after reading very, very carefully the Alabama Commission report, the one major item that would have made that event in Alabama unlikely.

On the other hand, I do not wish to give the impression that I can or should attempt to place fault at any one level in the complex system that is responsible for oversight of such studies. Dr. Stough had certain responsibilities. The institution or prison had certain responsibilities. The Alabama Medical Society in turn had responsibilities, the sponsor did, and last but not least, we in FDA did.

Senator NELSON. What is the legal responsibility of the Alabama Medical Association?

Dr. LEY. The Alabama Medical Association does have an oversight function here in terms of the physicians operating within their State. They did become involved in what amounted to a peer review of the Alabama prison operation at the request of the warden. This is the responsibility that they perhaps should have been fulfilling earlier.

Senator NELSON. Do I understand, then, that you will make a proposal for a peer review committee?

Dr. LEY. That is correct.

Senator NELSON. Is this under statute?

Dr. LEY. This is a part of our regulations. I would propose that this be published as a proposal, with 30 days for comment. We undoubtedly, as I indicated, will have considerable comment. But I see no reason why the establishment of a peer review structure in experimental drug testing should not and can't be applied in this area.

Senator NELSON. Would it be one of the first orders of business, then, that once a final decision to establish peer review committees was made, they will be used in the experiments being conducted in the prisons in this country?

Dr. LEY. It would indeed.

Senator NELSON. I have read, as I know you have, a very comprehensive 22-page—what amounts to a peer review, I guess you would say—report from the Alabama Medical Association, signed by six persons, three of whom are M.D.'s, one a Ph. D. and one a lawyer and another one identified as Mr. Patterson, but not identified as to his profession.

Let me say that I read it as a very damning indictment of the conduct of studies by Dr. Stough. The medical group states on page 14: "The work of Dr. Stough and to some extent Dr. Long is, bluntly, unacceptable."

I would like to ask, because I could not get it straight from reading the news stories, as I understand it, Dr. Stough was doing drug IND studies for ethical drug houses, correct?

Dr. LEY. This is true.

Senator NELSON. He was also doing studies for the Division of Biological Standards, is that right?

Dr. LEY. I cannot speak for this, because I am not that familiar with the record. I do not believe that that operation, as I believe Dr. Murray told me, was in the Division of Biological Standards.

Senator NELSON. He was, as the news story appears, extensively collecting blood plasma.

Dr. LEY. This is correct.