

equally applicable to a prison situation—as the reviewing body for all investigational work dealing with human subjects carried on in that institution. The investigator is not a member of such a group. He may be called to present data to the group. He does not participate in the discussion of the propriety of the study.

Senator NELSON. Are these peer groups all volunteer?

Dr. LEY. These peer groups are essentially volunteer, non-pay-status individuals.

Senator NELSON. They would be informed and expected to do some oversight of the execution of the protocol that was being done by the investigator?

Dr. LEY. This is correct, including that very delicate question of whether informed consent was or was not received from the subject.

Senator NELSON. That, I take it, would be in the area of the minister or lawyer?

Dr. LEY. Also, physicians have a role in this decision.

Senator DOLE. Mr. Chairman?

Senator NELSON. Senator Dole?

Senator DOLE. Would this be in addition to your recommendations on page 11? You set up a FDA clinical investigator file, and also, No. 2, directed all inspection reports receive immediate review?

Dr. LEY. Yes, Mr. Dole, this would be in addition to these two and in the original drafting of the testimony I had those three items on page 11. We considered it more appropriate earlier in the testimony. That would be one of the three.

Senator DOLE. Then in reference to one particular investigator, Dr. Stough, I have a copy of an article from the New York Times dated August 5, 1969. The author of that article indicates he made repeated efforts to obtain a report of Dr. Stough's activities from the FDA and the implication is in the article that this information was refused. I am wondering if you might comment on that.

I would point out specifically, if you have not seen the article, there is a reference made that the information had been repeatedly sought by the New York Times when it was preparing an article on Dr. Stough's operations.

My question is, Could you comment on whether or not this information had been repeatedly refused?

Dr. LEY. Yes, Mr. Dole.

Senator NELSON. I would be willing to stipulate, Senator, that he has seen the article.

Dr. LEY. I just wanted to make that point clear, Mr. Chairman. I am acutely aware of both articles. I have met with the reporter who wrote both articles in my office, and we have had a long conference on this general subject. The information which he requested is in the form of an IND filed by a sponsor as an official document in our files. This is not in its original pristine form a document which is in the public area. However, I did feel it our responsibility to discuss with the reporter from the New York Times the features which he wished to discuss.

Senator DOLE. Is that since August 5?

Dr. LEY. Not since August 5; my interview with the reporter was a month or two earlier. He had had the material for this story for quite some time, and it was released in early August. I do have and