Dr. LEY. We have very recently completed a detailed review of all results Dr. Stough obtained in his studies in the Alabama prison system. In our context and in our framework—that is, in the framework of the investigational drugs followed—comparing his results with other results of other investigators, looking at comparable results from related drugs, and so forth, we find in the sense of a scientific investigation no reason to question the basic validity of Dr. Stough's observation. Indeed, in several instances, he was highly critical of drug products because of adverse reactions which he reported and which were reported by other people. So we have conducted a review. But it is not in the context of a commission report.

Senator NELSON. Let me understand you—the review was done on the written material submitted to the FDA?

Dr. LEY. Right.

Senator NELSON. My question is: Has the FDA sent its own team of investigators to do an on-the-spot evaluation of the performance of the protocols he has?

Dr. LEY. This we have, Mr. Chairman.

Senator NELSON. A team?

Dr. LEY. A team. I think at this point, my statement would be very appropriate, because it tells you what we have done.

Senator NELSON. All right. So you may wish to have in mind some points raised by the medical association, let me give you a couple of points from there.

As to your review and your conclusion as to the adequacy of the written material you have, what's your response to the story in the New York Times that, for example, they are paying the prisoner—he gets paid $1 a day—and I understand from the story that his monthly stipend is 50 cents. It was a strong motivation to get the $1 a day. How can you tell from the studies you reviewed, the written materials submitted to your office, how can you tell that the side effects on these prisoners were reported when the reporter says that one of these prisoners, or maybe more, was sick from the drugs, but declined to report it because he did not want to lose the $1. How do reports from your office discover that?

Dr. LEY. Our reports and our investigations do not specifically approach this type of question. This is a question of not only the quality of informed consent, because the money provided to the patient offer an unusual stimulus for him to stay in the program and an unusual stimulus for him not to exercise his right as a subject to withdraw from the experiment if the effects were exceedingly unpleasant or unsatisfactory to him.

The points raised in the Times article are more matters of consideration by an appropriate peer review group in the Alabama situation. The questions that were raised there are not questions that can be answered by our investigative team of an inspector in a position to visit the prison for a day or two. It is impossible to get that type of information by an outsider coming in for a relatively short period of time. The appropriate group for resolving the questions raised in terms of remuneration would be a peer review group.

Senator NELSON. What about the question of the prisoner not reporting toxic side effects which would certainly be critical to an evaluation