

Early in our report, we likened our task to that of observing and commenting upon a "play" in a theater. Perhaps it is not inappropriate to pursue that analogy.

It has been our privilege to sit on the front row. We have observed a drama that has displayed certain minor aspects of comedy and many features of melodrama. But the major impact has been that of tragedy. There has appeared, over and over again, conflict between right and right.

From our posts of vantage we have watched the entrances and the exits of the characters and the unfolding of the plot of this drama, we have constantly asked ourselves one question: "Who if anyone, is the villain in the Play?"

From time to time we have made tentative judgements as indicated earlier in this report, but our final judgement indicates that our search has been successful and that the greatest villain has been identified. At times, he brazenly occupied the spotlight; at others he has been seen flitting in the shadows. More often his presence has been felt even while he remained hidden in the wings. That villain is human nature. The same character is also the knight in shining armour, the hero of the play.

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Senator NELSON. I would like to ask this question: You have, I understand, taken a careful look at the Alabama study.

Dr. LEY. I have.

Senator NELSON. Do you have any reason or any evidence that would refute any conclusions or any statements made by the Alabama Medical Association in this report?

Dr. LEY. This is a very difficult question to answer off the cuff. Much of the criticism or comment of the Alabama commission is aimed at specifically this area of informed consent, the degree of stipend or the amount of stipend available to the prisoners—all items which, technically, fall outside the present existing regulations of the Food and Drug Administration. So that when the statement appears here, "The work of Dr. Stough and to some extent of Dr. Long is bluntly unacceptable"—I must caution the committee and any other persons interested in the subject that this sentence, although it may be quite appropriate when you consider everything that was considered by the commission, is not appropriate on the basis of our review of the scientific details of the reports of doctors found in our file. However, it is very difficult to go line by line and make this sort of comment throughout the report.

I believe that in general, the major thrust of this report is that there was inadequate, incomplete understanding on the part of both Dr. Stough and on the part of the institution, the prison, of some of the responsibilities which each had in this particular situation in which prisoners were used for investigational studies.

Senator NELSON. But they make a substantial number of observations which, of course, are not related to paperwork that was submitted in the studies by Dr. Stough.

Dr. LEY. One of them that bothers me specifically, Mr. Chairman, is the remark about the quality control procedures utilized in the clinical laboratory, performing laboratory studies on blood specimens of the patient. Even the commission, however, recognized that the laboratory personnel were minimally trained for the work, but were probably no different from the majority of personnel in most medical laboratories in the State of Alabama.