product. It is also planned to develop a directory. Dr. Rice noted that the FDA is a source of valuable data on toxicology and has made strides in making this information available, FDA will logically be a prime contributor and client of the bank at the TIP.

Dr. Rice's plan includes; (1) The establishment of a registry of sources of information. (2) The establishment of a center for the dissemination of literature including technical reports, working papers, etc., and (3) The establishment of a program for critical evaluation of literature.

Dr. Allan B. Lisook spoke next on prison facilities for clinical investigation. He raised questions about what constitutes adequate records, how closely an investigator should be associated with the study and with other investigators, and how carefully should the progress of the investigation be monitored. In tracing the history of investigations which have been questionable he pointed out that in 1962 the work of one investigator was found to be fraudulent and he was eventually convicted for submitting false data to the Government. At present, an investigator's exemption can be revoked by the FDA if his work is determined to be questionable. The Bureau of Medicine is especially interested in the Phase I investigations being performed in prisons. Dr. Lisook noted that the investigational set-up at the McAlester Penitentiary under the University of Oklahoma may be considered a model for good drug investigational procedures.

Dr. Minchew pointed out that FDA guidelines have been developed for the handling of possibly falsified data so that an investigator is brought in for discussion and has several oportunities to explain his manner of conducting drug studies before the Commissioner might take action to withdraw his exemption.

Dr. Kirby noted that the FDA's high standards have upgraded research and Dr. Richardson wondered if ultimately some sort of certification of investigators will develop.

Dr. Wentz stated that industry has trouble getting good studies done. Reference was made by Dr. Minchew to the recent publication of a synopsis of the New Drug Regulations, copies of which had been distributed to the Board members.

Dr. David B. Leof next reviewed the 1967 first phase training program for the new Scientific Associates. In his estimation the course provided a good introduction to the work at FDA. He urged an ongoing professional education program in the Bureau of Medicine. Dr. Ethridge of George Washington University, who was present during this presentation, concurred. Dr. Minchew felt that the Bureau will have to have some type of course annually. Dr. Richardson commented that such a course would be a good opportunity for Fellows in clinical pharmacology as well.

Mr. Julius Hauser, of the Office of the Associate Commissioner for Compliance, next reported on the comments received from the public on the proposed new advertising regulations. Twenty-three such comments had been received to date, prominently lengthy comments from the PMA and the Pharmaceutical Advertising Club of New York. The PMA comments consist of a 27 page letter discussing the regulations in detail and a 46 page legal brief. Mr. Hauser quoted from some of the comments and noted that of them all those of the PMA were the most intelligent and constructive. He indicated, however, that a hearing would likely be necessary on the subject. Dr. Dowling suggested that the opinion of the Board members as to the answers received be solicited again either by mail or at the next meeting of the Advisory Board. There seemed to be general concurrence.

In answer to a question, Mr. Hauser stated that he did not think the advertising regulations would result in a decrease in advertising since the pharmaceutical firms need to promote their own brand name product.

On the second day of the Advisory Board meeting, Dr. Ley presided as Chairman.

Dr. Ley opened the discussion by soliciting comments on a proposed "Dear Doctor" letter on sulfonamides which had been distributed to the Board members on the close of the previous day's meeting. The FDA purposes to send this letter to all physicians. Essentially, the letter points out that sulfonamides, while recognized as effective in the *prophylaxis* of streptococcal infections, have not been shown to be effective in the *treatment* of streptococcal infections so as to prevent subsequent occurrence of Rheumatic Fever. The Board members requested some discussion of the papers on which the conclusions presented in the letter had been based. Dr. Ley pointed out that these papers had been reviewed both by FDA staff and by the American Heart Association. Several of