

(The information follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
July 29, 1969.

U.S. Government Memorandum.

To: Herbert L. Ley, Jr., M.D., Commissioner of Food and Drugs.

From: Acting Director, Bureau of Medicine.

Subject: Austin R. Stough, M.D.

Dr. Stough is a clinical investigator who with his associate Irl Long, M.D., has been named in 139 IND's and 36 NAD's to date. A tabulation of these documents is appended hereto.

Dr. Stough first came to our attention in June 1964 in conjunction with a hepatitis epidemic in the Alabama Prison System which was subsequently proven to be caused by his poor technique in the conduct of a plasmapheresis program.

Dr. Stough has no formal training in clinical pharmacology or any specialty, but is a general practitioner who began work in the McAlester Penitentiary in Oklahoma in 1938. He performed an increasing volume of drug testing there until December of 1963 when unfavorable publicity and press criticism led to his expulsion from the Oklahoma Prison System. He subsequently set up shop in the Alabama Prison System, ultimately forming Southern Food and Drug Research, Inc., a corporation principally engaged in Phase I testing of investigational new drugs. In September of 1967, Dr. Lisook visited Drs. Stough and Long for the purpose of evaluating their facilities and techniques for the testing of investigational drugs. He concluded that Dr. Stough's practices were adequate under our regulations, although there was less physician-subject contact than would be desired.

In January of 1969 the *Montgomery Advertiser* and its editor-publisher, Harold E. Martin, ran a series of expose type articles concerning Dr. Stough's drug testing operation. Because of this adverse publicity Dr. Lisook undertook another visit to Montgomery on February 11, 1969. During the course of that visit he met with a special committee appointed by the Alabama Medical Association at the request of the State Board of Corrections. (See attached memo of conference)

The February 1969 inspection of Southern Food and Drug Research, Inc. was not materially different from that of 1967. Physician-subject contact again appeared to be minimal and the execution of the studies was primarily left up to medical technicians. Physical examinations appeared to be performed as required although they were somewhat cursory in nature. The administration of medication appeared to be properly policed. Laboratory records and progress reports appeared to be complete, for the most part, and in original form. There was no evidence to indicate that the tests were not actually performed, or that inmates were participating in the selection of subjects. The use of convicts to draw blood samples was acknowledged, but such practice was discontinued in the wake of the January 1969 publicity. It was noted that the interviews for subjective complaints by medical technicians were excessively brief.

On May 30, 1969, the *Birmingham News* carried a front-page story headlined "Medical Probers Assail Prison Drug Testing; Board Halts Program." Essentially the same information was found in a *New York Times* story of June 1, 1969. The basis for this publicity was the report of the special committee entitled "The Use of Prisoners for Drug Trials in Alabama."

The front-page story in *The New York Times* today, July 29, 1969 seems to be a recapitulation of previous newspaper articles and to contain no new information.

Dr. Lisook's memo to me dated June 11, 1969 is somewhat more detailed than this memo and he has more back-ground material in his files if you require further information.

Although Dr. Lisook's two investigations of Dr. Stough's operations disclosed no violations of our regulations, obviously we should be concerned that such an operation can exist under current regulations of FDA and DBS. Aside from the welfare of the subjects, the question of validity of the studies may still be raised—especially the possibility of concurrent testing of drugs.

JOHN JENNINGS, M.D.