

Doubts about the tests, conducted in a number of Southern prisons by one of the nation's most active evaluators of new pharmaceutical products, were apparently felt within the Food and Drug Administration as long as two years ago.

Despite the shortcomings, the agency made no move to regulate the tests or to disqualify the physician responsible for most of them, Austin R. Stough. Dr. Stough is now based in Montgomery, Ala.

Dr. John Jennings, acting director of the agency's Bureau of Medicine, argued that two inspections of the prison drug testing programs had turned up no violations of the agency's regulations.

But Dr. Jennings went on in a recent memorandum to declare that "obviously we should be concerned that such an operation [as Dr. Stough's] can exist under current regulations."

The memorandum went to Dr. Herbert L. Ley Jr., Commissioner of the Food and Drug Administration. It was dated last Tuesday and was made available today by a source outside the agency.

The document briefly recounted the history of Dr. Stough's activities, beginning with a 1964 hepatitis epidemic "subsequently proven to be caused by his poor technique in the conduct of a plasma-pheresis program."

In addition to drug testing in the Alabama and Oklahoma state penitentiaries, Dr. Stough took blood from the inmates and extracted the plasma for use in a large number of the nation's gamma globulin products.

Gamma globulin is widely used to improve a patient's immunity to various diseases. One Federal Government source has estimated that Dr. Stough's plasma could have produced a fourth of the national supply.

A study by the National Communicable Disease Center at Atlanta showed that the 1964 epidemic afflicted hundreds of prisoners in Oklahoma and Alabama and in Arkansas, where Dr. Stough also worked.

Dr. Jennings noted that Dr. Stough's plasma and drug testing operations had been stopped in Oklahoma "when unfavorable publicity and press criticism led to his expulsion" from the prison there.

The plasma program continued in Arkansas, however, until late in 1967. It was halted in the Alabama prisons in 1964, but Dr. Jennings noted that Dr. Stough "set up shop" there for drugs tests, and these continued.

Dr. Alan B. Lisook, the lone physician regularly employed by the Food and Drug Administration to make field investigations of drug testing activities, visited Dr. Stough only twice.

"The February, 1969, inspection of Southern Food and Drug Research [Dr. Stough's company] was not materially different from that of 1967," Dr. Jennings wrote in his memorandum.

"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.

ENDED AFTER PUBLICITY

"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."

The January publicity consisted of more highly critical articles in The Montgomery Advertiser and The Alabama Journal.

A committee of the Alabama Medical Association found that physical examinations were not only "somewhat cursory" but also occurred in some instances which no doctor on hand.

"Interviews for subjective complaints," said by Dr. Jennings to have been "excessively brief," are considered essential by clinical pharmacologists judging a new drug.

"Although Dr. Lisook's two investigations of Dr. Stough's operations disclosed no violations of our regulations," Dr. Jennings said, "obviously we should be concerned that such an operation can exist under current regulations of F.D.A. and D.B.S."