DOUBTS NEED FOR BARS

Heavy demand for phase one work may also be a factor in quality, Dr. Stetler added. But he said he was not sure the Government should restrict an investigator's work for high volume if the "end product" was satisfactory.

Each of the pharmaceutical companies that could be identified as having retained Dr. Stough was asked to comment on his drug testing, and each defended the validity of the data he submitted.

For example, Merck, Sharp & Dohme said in a prepared statement that Dr. Stough's "facilities, staff, volunteer group, and prior experience were particularly suited" for the studies it required.

The physician has conducted 14 projects for the concern since January, 1968, and, the company's statement concluded, "in our opinion the studies were properly conducted and the data provided have been sound."

Merck, Sharp & Dohme asserted that practically all of the studies carried out by Dr. Stough had been "extensively studied and clinically used" by others and that some of the drugs had already been approved for marketing.

LACK OF CRITICISM

A spokeman for Lederle Laboratories pointed out that Dr. Stough's testing operations at the Oklahoma State Penitentiary had not been criticized publicly by qualified medical observers.

Wyeth Laboratories said it had retained Dr. Stough for only a single study. The company said he was hired in 1964 to test an experimental drug that was never placed on the market and has not been used since.

One company official, who asked not to be identified, remarked: "How he [Dr. Stough] operated, how he had his machinery set up—they didn't even know at the prisons."

To ship blood products in interstate commerce requires a license from the Division of Biologics Standards, and when a manufacturer obtains one he must face and continue to face regular inspections.

DOCTOR NOT LICENSED

Dr. Stough does not have and never has had a license from the division. Under the so-called "short supply provision" of the agency's regulations, a licensed company can pick up the scarce plasma at Dr. Stough's door and ship it to its laboratories without violation.

Serious things can happen if the slightest thing goes wrong once the plasma reaches the hands of a licensed company. Nothing can happen, so far as the standards division is concerned, if everything goes wrong before that time.

Dr. Stough incurred no Federal disfavor for the hepatitis epidemic in three states because the disease apparently was routinely killed out in the manufacturing process that turned his plasma into gamma globulin.

"The conclusion that we came to was that the quality of the product was not affected," recalled Dr. Roderick Murray, the division's director, "and therefore we had no backing to tell them (the companies) not to use plasma that came from Stough."

INVITATION REJECTED

This is felt so keenly at the division that Dr. John Ashworth, then an agency official, refused an invitation from Dr. Johnson just to go and look at a plasmapheresis operation.

"He said that his appearance at the plasmapheresis center would not be consistent with the policy of D.B.S.," Dr. Johnson wrote, because the policy did not include "direct supervision or policing of the actual procedures."

"Any time that we've attempted to write into the regulations elements that are designed to protect the donor," Dr. Murray said, "this has been disallowed because there's no statutory authority."

What about the communicable disease center, which traced the hepatitis epidemic directly to Dr. Stough's programs? That agency, a spokesman said, is only a consultant to the states. Enforcement is up to the state authorities.

The question thus is put to the Alabama public health officer, Dr. Myers. He answers that the State Health Department has "no specific jurisdiction in the prisons."