

"Mr. Emery stated that [Dr. Stough and an associate] . . . could not be trusted to carefully supervise such a plasmapheresis program.

"I then asked Mr. Emery why Cutter did not choose to operate such plasmapheresis programs by themselves without using Dr. Stough's group as an intermediate company . . .

"Mr. Emery replied that Dr. Stough had contacts at the prison and it was through him the permission was obtained from the prison officials to operate the program."

REMAINED BIG CUSTOMER

Cutter nevertheless remained one of Dr. Stough's biggest customers.

Alabama shut down the plasmapheresis centers in the middle of the epidemics and blocked Dr. Stough's efforts to start them up again. Oklahoma had taken over the plasma and drug-testing programs almost simultaneously just before the Federal investigation.

In Arkansas, where he had never tested drugs, Dr. Stough was permitted to continue his plasma operations for three years before a quasi-public foundation successfully replaced him.

And although the Alabama authorities had stopped the traffic in plasma, they permitted him to continue his drug tests without interruption. The enterprise was quickly stepped up.

A pharmaceutical manufacturer generally develops a new product in the laboratory, tests it on animals, and then notifies the Food and Drug Administration that a three-phase tryout on human beings is ready to begin.

Phase one is in many ways the most delicate step of the three because it is designed to establish basic factors such as toxicity, safe-dosage rates, metabolism, absorption, and elimination.

Because of their critical nature, the first-phase tests are usually carried out on healthy subjects. The drug is tried on people who suffer from the target disease only after the phase one hurdle is cleared.

Phase two involves limited administration of the drug to "carefully supervised patients," and phase three embraces "extensive clinical trials" that can include studies by doctors in private practice.

COMPANY JUDGES DOCTOR

The Food and Drug Administration is responsible for * * * the advance from phase to phase. The role of the individual manufacturer is substantial, however.

It is basically the company, for example, that judges a doctor's qualifications as a drug investigator, chooses him to do the job, directs the testing, assembles the results and pays the fee.

Healthy prisoners who by definition exist in closely controlled circumstances are perfect for phase one studies, and Dr. Stough remained in heavy demand by pharmaceutical concerns.

The Food and Drug Administration, citing regulations of the Department of Health, Education and Welfare, refused requests by The Times to examine its records on Dr. Stough.

A spokesman for the agency said, however, that since 1963 the physician has carried out some 130 investigational studies for 37 drug companies. Other types of tests and work by an associate involved 45 additional programs.

The F.D.A. declined to disclose the names of the drugs that Dr. Stough examined or the names of the companies for which he worked. Some of the information has been obtained from other sources, however.

BIG COMPANIES

The companies included the Wyeth Laboratories Division of American Home Products Corporation; the Lederle Laboratories Division of American Cyanamid Company; the Bristol-Myers Company; the E. R. Squibb & Sons Division of Squibb Beech-Nut Inc.; the Merck, Sharp & Dohme Division of Merck & Co. and the Upjohn Company. These concerns, according to the current directory published by Fortune Magazine, are among the 300 largest corporations in the United States.

An investigation of Dr. Stough's work for these and other concerns began earlier this year after Harold E. Martin, editor and publisher of The Montgomery Advertiser, wrote a series of highly critical stories about the drug studies.