

linked with the plasmapheresis program and a significant break in aseptic technique was found which accounted for this.) In 1963, however, the Food and Drug Administration set for the various drug houses much stricter standards for drug testing and these included a greatly increased demand for Phase I testing (Phase I testing is that done on healthy humans after completion of the animal experimental work). As a result, proficient investigators with adequate facilities were in considerable demand and Southern Food and Drug Research then concentrated its attention in this area.

Over the years since then, the drug houses seem to have been generally satisfied with what was done in Alabama and the Food and Drug Administration has had no specific complaints although they queried the number of investigations being done at any one time as being perhaps too many for adequate medical supervision by the limited medical staff of Southern Food and Drug Research. Internal control over the program by the Board of Corrections and its officers appears to have been limited in amount with the Medical member of the Board (Dr. McLaughlin) briefly reviewing the protocols for each new drug trial and occasionally mentioning them to members of the Board.

Membership on the Board of Corrections is not a full-time position. With their primary interest to attend to, it could not be expected that members of this Board be completely and constantly aware of every transaction affecting the prison system at a given time. A busy physician could not devote the time required to properly evaluate the protocols without neglecting his private patients.

The Commissioner and his wardens apparently gave Dr. Stough and his group ready cooperation with very few questions being openly asked. The prison physicians for the other two prisons involved in the drug testing program (Dr. Edwards at Tutwiler and Dr. Mracek at Draper) generally required that they be kept advised of new drug testing programs in their own prisons when these were initiated.

While most of the work done by Southern Food and Drug Research was for private drug companies, other programs were occasionally undertaken for agencies such as NASA and on a subcontracting basis for the Medical College of Albany, New York. Conversely, a very limited use has been made by the University of Alabama Medical Center of prisoners for drug trials and the Red Cross has, at infrequent intervals, taken blood from prisoners.

In January, 1969, the *Montgomery Advertiser-Journal*, over the byline of Mr. Harold E. Martin (Editor and Publisher) launched a series of attacks at the drug testing program being conducted in Alabama prisons. In addition to hinting at excessive profits being made, at the expense of the health of the prisoners by Southern Food and Drug Research, certain additional medically oriented accusations were made:

1. Although the inmates signed a waiver they were not told of the possible effects of tests while the prisoners' strong need for extra money largely invalidated the requirement of informed consent.
2. Physical examinations were not being performed before each program as required in some protocols.
3. A doctor was not present during many of the potentially critical periods of reaction.
4. Some of the experiments left the men too sick to perform their regular duties.
5. Prison inmates drew blood and performed other technical procedures.
6. The contrast between the facilities for the private concern's testing program and the extremely inadequate facilities available for treating sick prisoners was shocking.
7. A number of quite serious reactions had occurred among prisoners but these had received little attention.
8. The administration of the program with prisoners sometimes, giving false histories and not taking the medicine provided for them, made the results of the testing program somewhat unreliable.

The newspaper articles were not entirely negative and they did point out that needed research was carried out, inmates did receive money to buy cigarettes and other needs, and the Prison Welfare Fund received some monies which could be used for programs that the State did not provide. (At Kilby and Draper twenty percent of the money paid to the prisoners went to the Prison Welfare Fund). The newspaper suggested that the entire program be placed under the authority and supervision of the University of Alabama Medical School, that the participants be properly remunerated, that profits from the program should