

limited training in basic pharmacology of both clinical investigators (Drs. Stough and Long) is considered.

That the drug manufacturers are interested in conducting and supporting research programs of quality is confirmed by a consideration of two clinical programs established and operated by two of the major firms, the Upjohn Company and Parke-Davis at the Southern Michigan State Prison. These programs involved an initial expenditure of perhaps one half million dollars for facilities and are generally believed to be first class, both in providing for optimum safety and welfare of the human subjects and in providing dependable clinical data.

There is no reason to doubt that excellent programs are desired by the drug manufacturers or that they would support such programs. Despite this, both the drug firms and FDA have given tacit approval to the research in Alabama prisons, an approval based on their confidence in the reliability of data so obtained.

It should be noted, however, that neither is primarily concerned with the rights and welfare of the institutionalized research subject. There is within the body of the law some provision for protecting the welfare and rights of prisoners used as research subjects, but in the absence of sufficient funds and some watchdog mechanism, these rights may be abused. There is the justifiable view that the drug manufacturer is not abandoning any moral or ethical responsibility in assuming that the welfare of institutionalized human subjects used in testing its products will be adequately underwritten by the administrators of the institutions or by other state agencies, boards, or commissions charged with that responsibility. The states in which prison inmates are used as experimental subjects provide examples of very adequate provision for welfare of the human subjects through "human use" committees and "human experiment review boards" which are concerned primarily with protection of the human subjects. That, except at the Medical Center, there is no such firmly structured monitoring group in Alabama should not be considered to extend the responsibility of the drug manufacturer to assume this neglected duty. There is good reason to believe, however, that the pharmaceutical manufacturers would much prefer to have their clinical programs conducted under an officially supervised system in which the welfare of the human subject is assured.

The committee is of the opinion that drug companies would also prefer a system which would provide for on going "quality control" during a drug testing program and a certainty that all possible toxic reactions, whether real or only apparent were being fully reported. An agency which would establish clinical research standards and policies and critically assess the safety and propriety of all procedures and the conducting of these would serve the cause of drug research and the principle of individual rights.

In summary it may be concluded that the pharmaceutical firms are generally not subject to criticism for the present state of the clinical research program under investigation. They have contracted with approved clinical investigators to do approved research on compounds which they have developed and for which they have provided very thorough preclinical testing. That they may have been unwise in their selection of a clinical investigator is a point for criticism but is understandable. That they have not shown greater interest in the welfare of the subject used in the clinical investigations is explicable since they would understandably assume that such an obligation would be underwritten by alert state agencies. There is evidence that the pharmaceutical firms would prefer to have their clinical research program conducted under a system by which adequate state provision for prison inmate welfare would be assured.

4. The Situation in Other States

During the course of this committee's work, a survey was made on the use of inmates for drug testing in the prison systems, of other states. This survey was made by written inquiry to the commissioners or their counterparts of the 49 other prison systems. At the time of this writing 35 responses have been received.

Twenty states do permit drug testing within their prison systems. Fifteen states do not permit testing; however, the State of Tennessee has proposed legislation which would permit testing within the system there.

In those states where testing is permitted, their programs appear to be well structured along two main lines, in order to insure (1) ultimate protection of the health and safety of the human subjects and (2) minimum interference with the operational aspects of the prison itself.

The protective mechanism in most instances is centered around a professional committee which passes judgment on each testing program that is proposed. Such