

ALTERNATIVES

As the problem has been described, we are faced with the dilemma of "right" versus "right." It is certainly "right" that new drugs should be evaluated before release to the general public, it is "right" that this evaluation should be meaningful—that is, it should be done in a thorough, scientific manner by competent individuals. It is "right" that the individual who is to participate in the trial (whether he is a prisoner or not) should do it purely on voluntary basis with full knowledge of the hazards involved.

In this area we are to be guided by the principles outlined in the Nuremberg Code, the Declaration of Helsinki, and the American Medical Association's Ethical Guidelines for Clinical Investigation—see Appendix. It is "right" that the prisoner with few rights of any kind should receive at least the average medical care available to free citizens, and be protected from those who might abuse his position and sometimes his ignorance to the detriment of his health for experimental purposes. It is certainly good if not right that prisoners be given a chance to earn some money (especially considering the pittance they receive otherwise in the Alabama Prison System). It is also good that prisoners so motivated may enhance their self esteem by making a positive contribution to the general public welfare by participating in a medical research program. (Our interview with Dr. Clifton Meador, the Dean of the Medical School, shows that a well-run program by properly motivated people may have a definite rehabilitative benefit to the prisoners in their ability to relate to the free society).

If there is so much right and good about the program, then what is our problem? Just as it is good that a well-run private enterprise such as A.T. and T. runs a superb telephone service in most of the United States, it is also right that such a monopoly should be regulated for the benefit of the customer who has no choice. By the same reasoning the highly desirable drug testing program might be well run by reputable free enterprise (such as ethical drug firms presumably do in Michigan) or by nonprofit research organizations as long as the research is monitored adequately by the officially designated commission or regulatory board. There are, however, certain practical problems which make such a free competition system awkward. These stem from the necessity that a unit capable of conducting such research establish major facilities such as clinical laboratories, research laboratories and offices in the vicinity of the research site and maintain a staff of highly qualified, carefully selected personnel. This constitutes a highly specialized functional unit, the existence of which would be without purpose in the absence of contracts for research. It is doubtful that even an altruistic private organization would be willing to make such investment without assurance of continuing contracts. If there was such, a free competition system would seem impractical or would likely revert to a monopoly system which would be subject to criticism.

A foundation established by a state institution such as a major university would be a logical alternative. Such a foundation would serve as a functional unit with laboratories and other necessary fixed facilities and with clerical and administrative staff directed by a clinical pharmacologist qualified to conduct human drug research. This foundation would be under control of a board of appointees qualified in medico-legal aspects of human experimentation, with the foundation director serving as permanent chairman. The controlling board would be charged with the responsibility of reviewing all protocols from pharmaceutical firms, or others submitting clinical research projects, assessing hazards inherent in the projects and critically evaluating the safeguards to be provided. The controlling board would also be responsible for seeing that all research subjects were aware of hazards and entered the programs voluntarily.

To protect themselves from any possible imputation of a "conflict of interest," the controlling board of the responsible foundation might advantageously appoint a Prison Experimental Review Committee to advise them on any potential risk to the health of the prisoners. The members of this Committee should not be related to the research foundation and might include a competent practicing physician appointed by the Board of Censors, a lawyer nominated by the Attorney General, and a designee of the State Health Officer. Since our suggestion does not envisage a monopoly for the responsible foundation (though the bulk of research investigations would be channeled through them) the proposed Committee could also advise with regard to other groups which wish to conduct their own research in the Alabama prison system.