

of the drug and are not found in your files—the patient who does not report it because he wants to continue to get the money?

Dr. LEY. The basic problem here, Mr. Chairman, is that the remuneration to the prisoner was too much. This meant that the prisoner had a very strong pressure not to report and not to withdraw from the study. Therefore, he would decline to say that he felt any adverse reaction. This is bad for the prisoner in that it exposes him to unnecessary risk, it is bad for our records in that it does not provide us full information. If the stipend system had been set by the peer review group at a much lower level, there would have been no such insistence on the prisoner's not reporting because he wanted to stay in the study.

Senator NELSON. I am going to ask that the full report of the Alabama Medical Association study of the use of prisoners for drug trials in Alabama be printed in the record at this point.

(The study referred to follows:)

THE USE OF PRISONERS FOR DRUG TRIALS IN ALABAMA

INTRODUCTION

Statement of the Problem: It has been well said that while conflict between right and wrong is melodrama, conflict between right and right is tragedy.

It is right that the health of the public be protected by drug testing. Following extensive animal experimentation, such as that now being conducted by (or for) all of the ethical manufacturers of pharmaceutical products, there inevitably arrives the time when someone has to be the first human to receive the new drug. We strongly endorse the policy of the Food and Drug Administration which insists that in most instances the someone be, not an enfeebled, sick man, but a healthy human volunteer. Who should that volunteer be? We shall shortly return to that question.

It is also *right* that every precaution be taken to safeguard the health of the prison inmates. We believe that this has been done in principle and in policy but that under the existing circumstances, it has not been possible to do so in detail.

At first glance, it may seem that there is an inevitable conflict between these two "rights". The major effort of this committee has been directed toward this dilemma. In this effort, we have been aided by the complete support of the governing body of the Medical Association, and by the cooperative attitudes of the Food and Drug Administration, of the State Health Officer, the *Montgomery Advertiser*, the members of the Board of Corrections, the Commissioner and staff of the prison system, the representatives of a number of leading pharmaceutical manufacturers, and of a variety of consultants from inside and outside our State. We wish to thank these groups and individuals. Without such support and cooperation, it would probably have been impossible for us to arrive at any practical conclusions and recommendations.

BACKGROUND INFORMATION

It appears that the Southern Food and Drug Research, Inc. has been operating a research program in the Alabama Prison System since 1962 with the approval of Commissioner Frank Lee and the Alabama Board of Corrections. The president of Southern Food and Drug Research (known between 1963 and 1967 as JEMCO, Inc.) is Dr. Austin R. Stough who is a graduate of the University of Oklahoma and of the Medical College of the University of Tennessee. He conducted research programs in the Oklahoma prison system and the Arkansas prison system before coming to Alabama. Dr. Irl Long who was previously in general practice in Montgomery and who is still prison physician for Kilby Prison is associated with Dr. Stough in providing medical direction for Southern Food and Drug Research.

The original emphasis for Southern Food and Drug Research was on a plasmapheresis program but this was discontinued in 1964 following an outbreak of hepatitis which involved 376 prisoner participants with three deaths. (A Public Health Service investigation showed that the outbreak was definitely