

Exclusive: The Willowbrook Hepatitis Project**Studies With Children Backed
On Medical, Ethical Grounds***Continued from page 1*

bill that would preclude the use of children in medical research except in an unspecified emergency situation. The measure also would demand "informed consent" in writing from any adult entering a research program.

With the Willowbrook project brought into public controversy as an example of a medical investigation whose mere description sounds damning, MEDICAL TRIBUNE essayed to find out more precisely what the program is doing and where it might stand in regard to the ethical tenets of human experimentation.

The Willowbrook study has been going on for 11 years. For two years before that, a survey was conducted at Willowbrook to establish definitely what had become a distinct clinical impression to some of the institution's medical staff — that infectious hepatitis was endemic there.

The director of the hepatitis project since its inception has been Dr. Saul Krugman, Professor of Pediatrics and department chairman at New York University School of Medicine. He describes Willowbrook, a sprawling facility at the edge of a woodland belt on Staten Island, as "probably unique" for an investigation of this kind.

"Willowbrook was not chosen because its population was mentally retarded," Dr. Krugman said, "but because it had endemic infectious hepatitis and a sufficiently open population so that the disease could never be quieted by exhausting the supply of susceptibles." The patient population is nearly 5,500, a total that Dr. Krugman believes is the biggest in any one facility for the mentally retarded in the U.S.

Most Patients Are Children

In addition, he said, Willowbrook's patients are predominantly children: a few years ago the median age was 12, today it is slightly lower because the only general admissions have been to the infant facilities—the only buildings not overcrowded.

"It was well recognized," Dr. Krugman said, "that infectious hepatitis was a mild and relatively benign disease in children as compared with adults. Experience at Willowbrook indicated that the disease observed there was especially mild. Consequently only the Willowbrook strains of infectious hepatitis would be used for the study."

With the preliminary survey pointing to Willowbrook as a feasible place to investigate hepatitis immunity, Dr. Krugman organized his study plans and presented them to the N.Y.U. Committee on Human Experimentation, to the state Department of Mental Hygiene (which operates Willowbrook), and to the Armed Forces Epidemiological Board (whose sanction was needed if the project was to get supporting funds from the military).

All three bodies approved the study, and financial support came in what would be the first of a series of contracts from the Army's Research and Development Command.

According to plan, a 16-bed isolation unit was set up at Willowbrook, complete with its own kitchen and ward attendants. The idea was to protect the study subjects from Willowbrook's other endemic diseases—such as shigellosis, measles, rubella, and respiratory and parasitic infections—while exposing them to hepatitis.

Aside from the obvious emotionally inflammatory aspects of the study, the principal ones being that the subjects are children and mentally retarded, the factor in the Willowbrook investigation that has drawn the most fire for a number of years



DR. KRUGMAN