

Willowbrook Rebutts Critic On Research

By SANDRA FREED

Willowbrook Officials Reject New Charge on Research

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A new accusation by State Sen. Seymour R. Thaler about hepatitis research at Willowbrook State School has been heatedly challenged by its director, Dr. Jack Hammond.

Thaler, a Queens Democrat, told the Advance a search conducted for him by State Department of Health personnel failed to turn up a required protocol, or detailed proposal, of the institution's 11-year-old hepatitis research program.

But Dr. Hammond produced correspondence from 1956 which approved the project "as submitted" to the State Department of Mental Hygiene. The letter, dated Feb. 1, 1956, was signed by Dr. Henry Brill, then assistant commissioner of the department. The Department of Mental Hygiene operates the school for the mentally retarded.

Dr. Hammond explained the outline of the project was sent to the Department of Health for approval before being approved by the Department of Mental Hygiene.

The correspondence was produced during an interview by an Advance reporter with Dr. Hammond.

Hammond and Hepatitis Research Program director Dr. Saul Krugman and Dr. Joan P. Giles, Dr. Krugman's assistant.

Dr. Krugman commented, "If the senator had called Dr. Hammond or had come to see him, he would have seen the correspondence and all this would have been avoided."

The hepatitis research program made headlines in January, when the Queens senator charged that in the 1950s, 500 or more mentally retarded children at the institution, aged 3 to 9, received injections of live hepatitis virus.

He implied the injections were given without the "signed, informed consent" of the parents. He later stated parents had no right to sign their children into a medical research project and physicians have no right to give a disease to a child in order to study the disease.

Still later, Thaler introduced a bill to 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.

Dr. Hammond recalled angrily he has been "bothered day and night" for the past month by newspaper and television reporters. But few phone calls or letters have come from the parents of children at the institution.

Dr. Alan D. Miller, state commissioner of mental hygiene, defended and supported

the program after Sen. Thaler's charges.

Neither the U.S. Army's Research and Development Command nor the New York City Health Research Program, which finance the project, have been heard from.

Dr. Hammond angrily denied the senator's charges that injections were given without parents' signed and informed consent.

"Our records containing the parents' signed consent are always available to any state investigator of legislative committee," he said.

To date, neither the senator nor anyone from his staff has been to the institution or talked to its director.

Dr. Hammond and the research unit's doctors acknowledge only one statement made by the Queens senator—that research unit patients are injected with live hepatitis virus. Serum used in the study has been taken from Willowbrook patients early in their hepatitis episode. It is inoculated into suckling mice and four different tissue cultures to rule out the possibility of other infections.

Three times previously the research program has been the subject of criticism. The criticism was undeserved, its director said.

In 1965, Dr. Henry K. Beecher of Harvard used the research study as one of many examples of "questionable ethical studies."

The question was mainly the matter of "experimentation on a patient not for his benefit but for that, in theory, of patients in general."

In 1966, in an article in a medical journal, Dr. Beecher questioned whether parents were fully informed of the hazards involved in the study.

Again on the matter of obtaining consent, Dr. Hammond said the "biggest fuss" arose more than a year ago over a "complete misinterpretation... of an unfortunate coincidence."

The circumstances were set up by the closing of Willowbrook in late 1964 to all new admissions because of overcrowding. Parents who applied for admission for their children were sent a form letter over Dr. Hammond's signature saying that there was no space for new admissions and that their name was being put on a waiting list.

But the hepatitis program, occupying its own space at the institution, continued to admit new patients as each new study group began.

To recruit patients, for the program, a new batch of form letters went out to parents who had already applied, stating a few vacancies existed in the research unit.

In some instances the second form letter closely followed the first, apparently causing some parents to believe they were being pressured into volunteering their children for the research.

Canvassing the parents by letter "obviously was open to misinterpretation, so we stopped it more than a year ago," Dr. Hammond said.

Hepatitis is quite common wherever there are large groups of people living in close quarters. It plagues military

and Peace Corps personnel.

No child coming into Willowbrook can escape natural exposure to hepatitis, according to Dr. Giles. Some are even admitted with it. Children who have not had hepatitis will develop it sooner or later—usually within a year after admission to the institution.

For these reasons Dr. Krugman, professor of pediatrics and department chairman at New York University School of Medicine, undertook the project 11 years ago.

Willowbrook "had endemic infectious hepatitis and a sufficiently open population" to continually provide new subjects for the research, according to Dr. Krugman. In addition, Willowbrook's patients are predominantly children. Hepatitis is a mild disease in children.

The research unit is located in a former penthouse of a former doctor's residence building. There is a 16-bed isolation unit, kitchen and recreation room, and special ward attendants.

An average of 12 patients are admitted four times a year. They remain in the isolation unit an average of two months and in a special observation unit for about one month.

In a prepared statement, Dr. Giles noted the children in the research unit experience the mildest hepatitis cases in all of Willowbrook.

In stressing the importance of the research, she stated "Willowbrook has been, and still is, one of the areas actively working against the next epidemic (of hepatitis) which may occur in New York in 1969 or 1970."

As a result of the research program, infectious hepatitis in patients has been reduced from 5 per cent to 0.3 per cent; and in employees, from 5 per cent to 0.5 per cent.

Among other information, the research has shown that gamma globulin provides some immunity to the disease. As of last September, every new patient receives a series of gamma globulin injections. Employees also receive injections.

The Willowbrook results have paid off for the armed forces, according to Dr. Krugman. Troops going to areas of existing hepatitis, such as Vietnam, routinely receive a similar series of injections. The same treatment has been applied to Peace Corpsmen.

Since its inception, 651 patients have been admitted to the research unit. This represents about 8.4 per cent of the total admissions. None have died or become seriously ill as a result of the research, said Dr. Hammond.