

Administrators deny 'experiment' label Willowbrook seeks OK of questionable drugs

By SYDNEY FREEDBERG

Administrators at Willowbrook Developmental Center have endorsed a plan to use a variety of potent chemical substances on some mentally retarded residents in an effort to modify their behavior.

The use of such mood-changing drugs — including two so-called "psychoactive" chemicals not sanctioned for the purposes for which they would be given — is being spurred by the conviction that other methods of dealing with mentally retarded children who have behavioral problems have failed.

Willowbrook administrators deny the program would constitute an experiment or research project. Instead, they argue, it would be a form of "innovative treatment" or a series of "therapeutic trials."

The federal government, however, believes the use of the substances in question, which often produce undesirable physical side effects, may not be indicated to curb abusive or aggressive behavior, particularly in children, and would thus require federal approval.

Using the drugs in these cases, according to Dr. David Davis of the Food and Drug Administration, appears to be experimental, and intrusive chemical research is specifically forbidden at Willowbrook under a 1975 court order.

Under a plan advanced by a prominent child psychiatrist at Bellevue Medical Center, Dr. Magda Campbell, who is also a professor at the New York University School of Medicine, some of 540 adolescents at Willowbrook deemed to have psychiatric or emotional problems would be given a variety of behavior-control drugs, while scientists monitored their condition.

According to Dr. Philip Ziring, Willowbrook's deputy director of clinical services, the aim would be to see which drug, if any, helps the individual.

Scientists agree that the drugs in question — including the chemicals lithium carbonate and haloperidol — in

some cases may diminish agitation or lessen psychotic episodes, thus reducing symptoms rather than diseases.

They may enable a person to function satisfactorily in a supervised atmosphere, but they would never, in themselves, constitute cures, scientists say.

It is common knowledge that the use of psychoactive drugs at Willowbrook and other institutions for the retarded has been increasing in recent years, in spite of a growing mound of evidence that these chemical substances significantly inhibit learning ability and produce depression.

An estimated 50 per cent of Willowbrook's 2,400 residents are maintained on drugs, according to unofficial estimates given by staff members.

The chemicals most frequently administered for individuals deemed "problem cases" are chlorpromazine marketed as Thorazine, and thioridazine, marketed as Mellaril.

And although the use of Thorazine and Mellaril are controversial in themselves, the two new compounds proposed for use may be more risky, scientists say, because the effects they have, and the types of symptoms they help, remain unclear.

Lithium carbonate, marketed under the name Lithium, has been used since the late 1960s as a drug of choice in treating the manic phase of manic-depressive illness, a mental disorder generally confined to middle or later-adult life.

Although there is some evidence, according to psychiatrists, that the drug helps in cases of childhood schizophrenia, it is not yet recognized for such a use by the FDA.

But there is no conclusive evidence that lithium salts aid persons with aggressive, abusive or hyperactive behavior — mentally retarded or otherwise.

It is known that the drug is powerful. Side effects include weakness, slurred speech, hand tremor, nausea, vomiting, diarrhea, excessive thirst and urination.

Haloperidol, marketed as Haldol, is slightly less controversial. A psychoactive substance 50 times as potent as the more traditional Thorazine, it is recommended for no one under 16 years old, according to scientific reports.

It is a drug that helps order disordered thinking in schizophrenics, although its precise mechanism of action has never been established.

Proponents say that because of its potency, a smaller dose is required for the management of schizophrenia than other drugs. But critics argue the power of the drug merely intensifies the unpleasant and sometimes serious side effects, which include lethargy, excessive shaking, dehydration and the creation of a "zombie-like" condition.

Both of the drugs, Dr. Ziring himself admits, have "some risks." Others contend, however, that if the drugs are administered improperly, permanent impairment and even death can result.

Using the institutionalized retarded without gaining the informed consent of a qualified party — in which the risks and the experimental nature of the drug's use are outlined — is professionally unethical and may be illegal, critics of the proposed treatment are charging.

Dr. Ziring, a respected clinician on staff at Willowbrook since the spring, believes, on the other hand, that the drug treatment proposed for some mentally retarded adolescents at Willowbrook is for their own good.

"It is our desire to see if there may be a place here for Lithium" Haldol and other behavior-control drugs, Dr. Ziring said in an interview.

He stressed that if the plan is approved, presumably by a series of review boards, potential candidates for Lithium and the other drugs would be screened with precision and their intake levels monitored carefully.

"We are in no frame of mind to do chemically intrusive research," Dr. Ziring maintained, answering mounting criticism from parents. "The availability for other forms of treatment are just not there... We have to try to stop (some

Willowbrook children) from hurting themselves and there are no other alternatives than drugs."

Ziring said Willowbrook must enter a "new era," explaining there is a need to try "new, innovative approaches" to diminish the behavior problems of some of the institutionalized retarded, including mood-control chemicals.

But he refused to characterize the treatment as an "experiment," even though the drugs have not been recommended for the purposes Dr. Campbell intends to use them.

The international standard of medical experimentation on humans was set originally at the Nuremberg trials for Nazi war criminals. It was adopted by the United States government in 1953. It said that medical experiments should be for the good of mankind and that a person must give full and informed consent before being used as a subject.

But today, no two doctors or scientists give the same definition of experimentation.

Dr. Ziring, for example, argues that by one standard everything in medicine could be considered research because a therapeutic experiment takes place each time a new treatment is prescribed — since, he explained, that particular patient has never been treated at that particular time in that particular way.

But according to most scientists interviewed, the most distinguishing aspect of experimentation is uncertainty about the outcome. Most believe a doctor is engaged in an experiment when he or she departs from standard medical practice in treating a patient for the purpose of obtaining new knowledge or testing a hypothesis.

The traditional method of dealing with abusive or aggressive mentally retarded persons is said, at least publicly, to be psychotherapy.

The use of psychoactive drugs at institutions like Willowbrook is discouraged by parents as well as experts, since there is a fear that the rights of the residents, incapacitated and vulnerable, will be violated, with contraindicated chemicals administered merely to "straightjacket" them.

There has been a history of such abuse at Willowbrook.

What makes parents worry about the proposal under review, they say, is that Dr. Campbell's research protocol is a closely held secret. A reporter's efforts to gain a copy from Willowbrook administrators proved fruitless, and Dr. Campbell herself refused to discuss its provisions.

But from interviews with Willowbrook administrators and workers, state officials in Albany, parents and Willowbrook Review Panel members, information was developed about the institution's desire to use the drugs Lithium and Haldol, in addition to the more traditional mind-control substances.

The plan, first revealed in a recent report of the Willowbrook Review Panel, the court-appointed committee charged with overseeing conditions there, was harshly criticized as a "disturbing" program, a proposal "in lieu of a plan for provision of psychiatric services...a proposal for chemical research on children with Lithium, Haldol and Thorazine in plain violation of the prohibition against such experimentation...in the Consent Decree."

Dr. Ziring, a professor at the Columbia University College of Physicians and Surgeons, explained he asked Dr. Campbell, a consultant at Willowbrook and a pioneer in Lithium research on children, to develop an approach to aid mentally retarded persons under 21 years old who have behavior, emotional or psychiatric problems.

If her proposal were accepted, Ziring told her, she would be paid by the state on a contract basis.

There are approximately 1,200 Willowbrook residents under 21, and half of those live in the baby complex which, come September, no longer be operated by the state. It is unclear exactly how many of the remaining adolescents are considered to have psychotic diseases.

Early in 1977, apparently Dr. Campbell submitted her protocol outlining an experiment that called for the testing of 30 adolescents to be divided in two groups.

One group was to have been given the drug Thorazine or a placebo, while the other was to have been tested with Lithium and Haldol. The aim: To see which drug best controlled undesirable behavior.

When the review panel heard of the plan — in a March 31 letter from Dr. Levester Cannon, Willowbrook's director, to Michael Lottman, an attorney serving on the review panel — the reaction was "one of shock," a spokesman for the panel said.

But the idea was volleyed back and forth, with review panel members telling Willowbrook administrators, in essence, to "Forget it" and Willowbrook administrators responding "Why should we?" according to the panel spokesman.

Last week, however, the highly critical comment contained in the panel's "Report to the Court" on conditions at Willowbrook, prompted Dr. Ziring, Dr.

Campbell and review panel members to sit down at a high level meeting. The idea for a controlled experiment testing the psychoactives was scrapped.

But Dr. Ziring said last Friday, two days after the meeting, that Dr. Campbell intends to submit another proposal, which will carry the same emphasis as the first — on psychoactive drugs as the primary mode of psychiatric treatment.

The drugs to be used, according to Ziring, include Lithium, Haldol, Thorazine and "some others, too."

The leadership of Willowbrook's consumer and professional advisory boards charge this second plan is perhaps more morally reprehensible than the first since its effect is to cloak an experiment under the veil of treatment.

"This is their way of trying to circumvent the proper channels and not ask for approval from any official body," Katie McKaig, president of the consumer board, said.

Dr. Ziring denied any "secrecy," saying it is ludicrous to think that the Willowbrook administration "could slip (the plan) through" several advisory groups as well as the court.

But he admitted that if the plan to use the drugs is undertaken, there would be no need to gain informed consent from guardians because "we are providing treatment any doctor would give."

Lottman, the review panel member, said: "Nobody should worry about it, because there's no way in the world the review panel is going to allow the use of Lithium." He said the panel had not voted on Dr. Campbell's first proposal since there was "total agreement it was ludicrous."

Dr. Campbell and Dr. Ziring, Lottman added, are both highly qualified physicians, "but the proposal is just not viable for Willowbrook."

Lottman said Thomas Coughlin, deputy commissioner of the Department of Mental Hygiene, favors the proposal for a psychoactive drug project at the institution. Coughlin could not be reached for comment.

Finally, Lottman said, the 1975 Consent Decree prohibits experimentation at Willowbrook to guard against the traditionally abusive way the institutionalized retarded had been treated in the past.

The Consent Decree states: "This standard (barring experimentation), however, recognize the possibility that such research or experimentation under proper safeguards, may be appropriate for persons who are not members of the (Willowbrook) class, in other facilities or other programs."