

Medical

Medical NEWS

Vol. 8, No. 17

©1967, Medical Tribune, Inc.

world news of medicine and its practice—fast, accurate, complete

Wednesday, February 15, 1967

Furor Over Research and Consent

Charges Focus on Ethics In Institutional Setting

Medical Tribune Staff Report

NEW YORK—A state legislator from this city started a front-page controversy in the lay press about the ethics of medical research and experiments on human beings with an hour-long speech on the floor of the State Senate in Albany in which he charged that indigent patients were being used as guinea pigs in some public hospitals here.

Within a week, some of the examples he cited were being flatly denied by medical spokesmen, others were acknowledged as partly true but "distorted," and a series of experiments that he had not initially mentioned was brought to light by hospital authorities who said the procedures were contrary to regulations.

First of two articles

The charges were made by State Sen. Seymour R. Thaler of Queens, who recently has leveled a string of accusations against a program of New York City hospital affiliations with voluntary hospitals and medical schools.

Principal among the charges, for which he said he would offer documentary proof later, were these:

- Alcoholics admitted to Bellevue Hospital were subjected to needle biopsies of the liver for "research" purposes, and the biopsies caused the death of five out of 1,000 such patients.
- Surgical instruction at Harlem Hospital has resulted in the amputation of children's congenitally deformed limbs, instead of the more usual rehabilitation procedures, and at least one hysterectomy on a 23-year-old woman without her consent.
- Five hundred or more mentally retarded children, aged three to nine, at Willowbrook State School were injected with live hepatitis virus in a research program.

The conflict spread within hours after the speech was delivered. In short order, one or another spokesman for all the accused institutions rejected the charges.

Some of the specific replies to the charges:

● Liver biopsies at Bellevue are "in no sense a research procedure, they're an essential part of good medical care," said Dr. Lewis Thomas, dean of the New York University School of Medicine. Dr. Thomas, former chief of N.Y.U. medical services at the hospital, said pathology records "for the last five years showed not one death caused by liver biopsy."

● Harlem Hospital records show "no pediatric limb amputations at all," according to Dr. James B. Parris, the institution's chief resident in surgery. As to the hysterectomy, he said it was "unthinkable" that such a procedure would be done without a patient's consent or medical necessity. "We have as many as 10 hysterectomies a

week in the routine surgical service," he said, "which is more instructional material than anybody needs."

● At Willowbrook State School on Staten Island a hepatitis immunization research program has been going on for the past

11 years under a U.S. Army contract. Dr. Alan D. Miller, commissioner of the state Department of Mental Hygiene, said it has resulted in an "80 to 85 per cent reduction of this disease at Willowbrook for both patients and employees." The number of children given hepatitis virus is about 250, not 500, he said.



DR. MILLER

given hepatitis virus is about 250, not 500, he said.

The Willowbrook administrator, Dr. Jack Hammond, added, "It may be sensational to say that retarded children are being injected with hepatitis virus, but it leaves out a lot of the story." Equally important, he indicated, are the facts that (1) no child enters the program without written consent by fully informed parents, (2) if a susceptible child is not injected with hepatitis virus he will get the disease anyway, because hepatitis is endemic at Willowbrook, and (3) hepatitis is a relatively mild disease in children, often "nearly impossible to detect for what it is."

In a more general rebuttal, the Committee of Interns and Residents, which represents house officers in the city's hospitals, said that Senator Thaler's "smear and scare tactics . . . not only falsely impugn the ability and integrity of the house staff physicians who service the city hospitals, but also frighten patients at these hospitals and thereby inevitably cause such patients to be fearful of and to forgo necessary treatment."

Charges by Bellevue Resident

Dr. Henry F. Ryan, chairman of the committee and a surgical pathology resident at Bellevue, challenged Senator Thaler to "produce some case numbers . . . anything . . . on those liver biopsies." He said that Bellevue pathology records showed no liver biopsy deaths for the past "five or even seven years" in spite of the fact that the procedure is done on the average of once a day.

In addition to the intimidation of patients that the charges are expected to produce, Dr. Ryan said, he foresees "a profound effect on resident recruitment" at the city's hospitals.

Senator Thaler, in a television interview, acknowledged that some effects of his speech were worrisome. "I think I may have done a slight disservice to the community at large," he was quoted as saying. "When I get calls at home from

people who say, 'My doctor wants to put me in a hospital and I'm afraid to go,' I begin to question whether this should be debated in public view."

But he also indicated he had not ceased to question whether "informed consent" was valid from the subjects of some medical research in city hospitals. And he alluded to studies in which "doctors didn't even think it appropriate to get written consent."

Written consent from research subjects is required by city hospital regulations, as is authorization for experiments by the city's Commissioner of Hospitals. But in a TV interview of his own, Hospital Commissioner Joseph V. Terenzio said that some unauthorized medical experiments had been conducted in city institutions. He did not elaborate.

Consent Not Obtained From 3,000

The following day, authorities at Kings County (Brooklyn) Psychiatric Hospital acknowledged that written consent had not been obtained from 3,000 patients given experimental drugs in the past 10 years, but the patients suffered no lasting harmful effects, a spokesman said. In many cases they were not the only ones who did not know what drugs they were getting, he added, since a number of the tests were conducted on a double-blind basis and even the physician administering the dosage could not tell whether it was drug or placebo.

The liver biopsy issue came up again a short while later in a talk by Commissioner Terenzio to a Bellevue auxiliary group.

Biopsies had been done on alcoholic derelicts without their permission, he said, but the procedure was primarily for diagnosis, not research. He also was quoted as saying there were instances in which more than one biopsy had been made on a patient "as a follow-up to see what effect the treatment had." He repeated the assertion by other Bellevue officials that there had been no liver biopsy deaths in recent years.

Meanwhile, Senator Thaler introduced legislation that would amend the State Civil Rights Law to prohibit the use of any person in medical research without his "voluntary, informed consent subscribed to in writing."

The measure also would declare "null and void" the consent given by a parent or guardian on behalf of a child participating in research, excepting in cases of emergency "in which immediate treatment is necessary for a physical or mental ail-