

PHYSICIAN OPPOSES CURB ON RESEARCH

Thaler Proposal on Minors Is Called 'a Disaster'

By JANE E. BRODY

A leading New York pediatrician said yesterday that a bill introduced this week in the Legislature to severely limit medical research on children would, if passed, be "a disaster—a real disaster."

Dr. Saul Krugman, chairman of pediatrics at New York University, said in an interview that if such a law had existed in the early 1950's, polio would still be running rampant, hundreds of children would be dying of measles every year and medicine would not be on the verge of eliminating the pregnancy hazards of German measles.

The doctor explained that the vaccines for polio, measles and German measles had been tested on children and "could not have been tested any other way."

Court Sanction Required

The bill, introduced Tuesday by Senator Seymour R. Thaler of Queens, would require written "voluntary informed consent" before any patient is entered into a medical research program, and would prohibit research on children unless authorized by a "court of competent jurisdiction."

"The court may authorize a medical experiment or other medical research upon a minor," the bill states, "when such experiment or research is related to the minor's physical or mental ailment and upon a finding by the court that the best interests of the minor would thereby be served."

According to Senator Thaler's interpretation of his bill, it would not stand in the way of good, ethical, justifiable research, including vaccine development.

But to perform such research, Mr. Thaler said yesterday, the doctor would first have to take his research proposal to court.

"Somebody other than the medical profession would decide whether children could be used in pure research," he said.

Question of Competence

"Who will appoint this court?" Dr. Krugman asked. "What will give it the competence to make medical decisions?"

"If one had to present a protocol of every research project involving children to a court for approval, it would certainly, as I read it, seriously hamper research," the doctor asserted.

As an example of research that a judge probably would not have permitted, Dr. Krugman cited a daring study to eliminate blindness in premature infants.

He said that doctors had begun to suspect that excess oxygen was causing the blindness and that they then suggested reducing the amount of this life-saving substance given to the infants.

"If we had gone to a judge and said that 'we may prevent blindness but, on the other hand, the babies might die from insufficient oxygen,' could he have permitted us to proceed?" Dr. Krugman challenged.

"Decisions such as this have to be made by responsible investigators, not judges," he said.

According to the code of ethics of the World Medical Association, he continued, when children are to be the subjects of experiments, the nature, reason and risks should be fully explained to the parents or guardians who should have complete freedom to make a decision on behalf of the children.

Pressure on Parents

Senator Thaler said, however, that sometimes the parents or guardians "may be under pressure or illiterate or otherwise unable to make a free, informed decision."

Dr. Krugman said there were safeguards to assure the ethical nature of medical research. He went on:

"There isn't an investigator in the country who can get a Federal research grant if his protocol is not first approved by the research committee on experimentation within his institution." About 80 per cent of medical research is supported by Federal funds.

In addition to the research committee, a Government committee reviews the research proposal and will not approve the requested funds if the protocol appears unethical.

Mr. Thaler acknowledged that his bill "probably is not perfect and probably will be dramatically amended, but it is a start to make the community and the legislator consider what is a great medical problem."