

# Medical News

**Exclusive Opinion Roundup**

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## **Authorities View Problems in Ethics, Call Testings in Children Imperative**

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AUTHORITIES on ethical problems of medical investigation using human beings, especially patients in institutional settings, agree in a MEDICAL NEWS survey of their opinions that the use of volunteers under strict codes requiring informed

consent is imperative but express disquiet at suggestions that lay persons be given a voice on review committees.

The opinions were gathered following a furor caused in medical circles early this year by charges of unethical experimentation made by New York State Senator Seymour Thaler against several New York City hospitals and institutions, and his introduction in the State Legislature of a proposal to sharply restrict in-

### **First of two articles**

vestigational procedures utilizing volunteers. A report on the factual background was published in MEDICAL NEWS ("Studies With Children Backed on Medical, Ethical Grounds," an exclusive report on the Willowbrook Hepatitis Project, February 27).

All the authorities agreed that the use of volunteers is imperative; that, in the words of Dr. Dorothy M. Horstmann, Professor of Epidemiology and Pediatrics, Yale University, "to prohibit the use of volunteers in medical research would mean the end of progress in the control of many diseases which still cause much suffering throughout the world."

The physicians also agreed that tests on children are imperative if childhood diseases are to be conquered, but there was some uneasiness regarding not only the physical and mental but legal consequences, regardless of "informed consent" of parents or guardians.



DR. HORSTMANN

Most of the authorities who touched on the advisability of including lay persons on review committees agreed that intelligent, informed lay opinion could be valuable, though agreement was tinged in several cases with the feeling that it might be a reflection on the integrity of physicians.

Dr. Louis Lasagna, of the Johns Hopkins University School of Medicine, commented that "no investigator should be conducting research which he is ashamed to discuss with laymen."

Dr. Albert B. Sabin, Children's Hospital Research Foundation, Cincinnati, said, "The suggestion that nonmedical people such as clergy also be on committees considering proposals for human experimentation is in itself not objectionable, even though it is indicative of a lack of trust in the judgment and devotion to human welfare of honored members of the medical profession on whom the public relies for judgment affecting the individual and public health."

### Experiments Justified by Importance

In his statement to MEDICAL NEWS, Dr. Sabin said that "during the course of my investigative career I have carried out many experimental studies on human beings—medical students, young men in state prisons or Federal reformatories, and children, including my own. The adults were persons who volunteered after a full explanation of the various aspects of the study, and in the case of children, the parents gave permission. It has always seemed to me that experiments on human beings were justified when the questions asked were of great importance to the control or prevention of disease and when the answers could not be gotten in any other way.



DR. LASAGNA



DR. SABIN

"The polio and measles vaccines in current mass use could not have been developed without tests on children. Any legislation that would prohibit such tests even when their parents give written consent for such tests would be a tremendous hindrance to the ultimate development of other vaccines or drugs for the prevention or control of diseases that are still an important source of human misery. A vaccine for German measles, currently in the final stages of development, can never become available without the necessary tests on children."

### Role of Legal Maturity

Dr. Charles J. Frankel, of the University of Virginia Hospital, Charlottesville, went a step farther in his thinking to consider the rights of children when they reach the age of legal maturity, regardless of the consent of their parents when the children were minors.

"If you will analyze the statement made by Dr. Sabin," he said, "you will note that he states very clearly that he has carried out experimentation, but only after full explanation or consent was obtained from adults and from parents where children were involved. It must be remembered that, despite the fact that parents give permission for children to be used in an experimental program, should anything untoward happen the child can sue in his own right after he reaches maturity. There have been a number of cases where suits have become active 12 to 15 years after the onset of alleged negligence.

"I find the use of children at Willowbrook a little more fraught with difficulties. A parent who gives permission for a mentally retarded child to be used in an experimental project is frequently abdicating the rights of the child to some sort of unseen or covert pressures. Where children who will never be competent are involved, it is customary for the court to be considered as their coguardians, especially in cases where there is some doubt about the manner in which the parents are conducting themselves so far as the best interest of the child is concerned.

"I see no valid objection to having an informed court rely on the judgment of the medical experts who are not involved in a research project. The clergy and perhaps nonmedical people should certainly also have a voice in the use of children in experimental projects."



DR. FRANKEL

Dr. Frankel said it is his personal belief that investigation should be carried out only after the canons of medical ethics, as well as the local and state regulations, are met fully. If these regulations seem to hold up medical progress, he said, then certainly medical asso-

ciations have enough influence to support legislation to bring about the necessary changes.

### Answers Should Justify Discomfort

In Dr. Sabin's opinion, the issue is how to make certain that only truly important questions are asked in human experiments and that the answers justify the discomfort and possible risks to which the subjects are subjected. He said the requirements by the Research Grants Division of the National Institutes of Health—that applicants for grants including human experimentation first obtain approval for their project from an independent committee of physicians appointed by their institution—provide a valid safeguard and should be a requirement for all experiments on human beings supported by grants from the Government.

"Suggestions that the judgment of such committees of medical experts must be implemented by a court order when children with their parents' consent are involved seems to me an unnecessary measure, since the court would also require expert medical judgment on the issues involved in the proposed study," he said.