

# Medical News

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## Legislative Rule Of Human Tests Is Opposed

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Proposals to restrict medical investigation procedures utilizing volunteers came under attack by authorities participating

**Second of two articles**

in a MEDICAL NEWS survey of opinion on the ethical problems of medical investigations involving human beings.

Dr. Louis Lasagna, of the Johns Hopkins University School of Medicine, said such proposals would make "therapeutic orphans" of the pediatric population. Dr. Dorothy M. Horstmann, Professor of Epidemiology and Pediatrics, Yale University School of Medicine, said that "medical investigators much prefer to use laboratory animals or other experimental systems in their research, rather than volunteers. Unfortunately, it is impossible to obtain all of the necessary answers in this manner."

Dr. John R. Paul, Emeritus Professor of Epidemiology and Preventive Medicine, Yale University, one of the authorities invited to comment, said: "I subscribe fully to the report which Dr. Saul Krugman made on the Willowbrook State School and which appeared in MEDICAL NEWS February 27. I also agree with the statements made by Dr. A. B. Sabin—that experiments on human beings were justified when the questions being asked were of great



DR. PAUL

importance to the control or prevention of human disease and when the answers could not be gotten in any other way.

"Obviously, there has to be a first time that any new thing is tried—either in an individual or on a large scale—even a new food product, a drug or vaccine, or a new surgical procedure. How many people realize in this country that they owe their freedom from the fear of epidemic polio to just these kinds of trials? The inconceivable miracle wrought by the use of polio vaccines in the U.S. in the decade

between 1955 and 1966 in reducing the cases from some 20,000 or more to a little more than 100 or even less could have never been achieved had not the safety of these vaccines been tested in various human trials."

### Expected to Use Judgment

In decisions by physicians on questions of clinical investigation that actually entail experimentation on human subjects or even the suggestion of it, Dr. Paul said the responsible investigators are expected to exercise all the clinical judgment and other kinds of judgment they have at their command as to whether the step is justified; they are also obligated, or at least expected, to secure approval for their projects from an independent committee appointed by the institution with which the physician is connected. It also goes without saying, he said, that in any work of this type, supported by a Government agency, the responsible investigator should seek approval of the appropriate Government committee. Dr. Paul agreed with Dr. Sabin that all such projects should be reviewed by appropriate boards or committees regardless of whether the work is being supported by Federal grants.

Dr. Horstmann said:

"When studies have been carried as far as possible in animals, cautious and controlled trials in humans have been necessary to establish the safety and effectiveness of such now widely accepted products as the Salk vaccine, the Sabin oral poliovirus vaccine, and measles vaccine. The first tests with these products were often carried out among closed population in institutions, because in such settings one can control the possible spread of infection, an important point in the early