phases of investigation of live virus vaccines. While adults are suitable objects for some tests, they have a high rate of immunity to many of the infectious diseases, and it is therefore necessary to go to children for the ultimate trial. In the case of polio and measles vaccines, after initial satisfactory tests in institutionalized children, vaccination was carried out in open communities, beginning with small numbers and proceeding to larger groups."

Dr. Horstmann noted that in all of the many trials with these products before they were licensed, the informed consent of volunteers or parents of children was obtained, and the recommendations of the World Medical Association Draft Code of Ethics on Human Experimentation (the Declaration of Helsinki) were strictly observed. "The favorable results of the trials and their ultimate benefit to the children of the world is now obvious to everyone," she concluded. "Similar progress in the control of rubella, hepatitis, and other diseases, both infectious and noninfectious, will depend upon continued careful studies in humans, following closely the guidelines of the Declaration of Helsinki, which are supported wholeheartedly by the dedicated physicians who undertake such work."

Research "Impossible"?

Commenting on the restrictions on investigational procedures utilizing volunteers proposed by New York State Senator Seymour Thaler, Dr. Lasagna said they "would render almost any kind of research on children impossible."

"At the same time," he said, "I sympathize with those who wish a fuller discussion of the difficult ethical and scientific issues involved in experimentation with children. It is, in my opinion, a mistake for medicine to exclude the lay public from discussion in this area. I would favor the increased utilization of review committees composed of scientists and nonscientists. . . . With responsible and intelligent representatives of the lay public, there need be no apprehension about either the inability of laymen to comprehend the scientific issues at stake or the danger that laymen will be unduly swayed by the persuasiveness of medical scientists. There is a need to share this kind of decision making with the nonscientific community."

All the authorities inevitably mentioned "informed consent," but Dr. Thomas C. Chalmers, Jr., Lemuel Shattuck Hospital and Tufts University School of Medicine, Boston, discussed its interpretation in some detail.

In an address, "The Science and Ethics of Human Drug Trials: Problems and Solutions," given as part of the Lowell Lecture series, he pointed out not only the elusiveness of the definition of the term but its possible unethical application due to faulty judgment. His comments are given here with permission of the Macmillan Company, which will publish the lectures in their entirety.

"It should be emphasized, as Modell has eloquently stated," said Dr. Chalmers, "that the trial of a new drug should not be considered as something ethically apart from the routine practice of medicine. Doctors frequently use medicines on the market that may be toxic and have never been established as efficacious. They don't obtain written permission to do so. As an example of the potential seriousness of this problem, a series of committees of specialists appointed by the National Research Council are currently reviewing the efficacy data on all drugs approved for marketing before 1962. They will hand their report to the Food and Drug Administration some time next year. One can predict that few will have been found to be *not* effective, more to be effective as claimed, and most will be placed in a category requiring more information—i.e., the definitive trials have never been done. I suspect that it is not known whether the majority of drugs used today are more or less effective or harmful than other drugs in the same category or no drug therapy. Does this mean that it is less ethical to use, or to withhold, such a previously approved drug?

"A second point has to do with the rather difficult-to-define requirement of informed consent. This is a legal term that doctors have begun to use widely, while at the same time admitting that they are unclear about its exact definition. Does a patient need to know *everything* about his disease and the new therapy before he allows the physician to treat him as part of a new-drug trial? There is an important distinction here between the volunteer who is given a drug primarily for research purposes and only secondarily for his own benefit, and the patient who receives a drug primarily to treat his disease and secondly for research purposes. Consent should be explicit in the first instance; it should, in the judgment of the physician, be qualified in the second instance. The art of medicine requires that the good physician tell the patient what it seems best for him to know, frankly and honestly discussing the disease and its treatment, old or experimental. The physician should not be required to be brutal in his frankness if it seems in the best interests of the patient to receive a new drug, simply because regulations or fear of a lawsuit require bru-