MEDICINE

Are Human Tests Ethical?

The moral and ethical basis for research involving humans is being investigated with stress on the importance of patients' consent—By Faye Marley

➤ THE ETHICS of experimenting on humans has been getting almost as much attention as the right and wrong of animal research.

The U.S. Public Health Association has awarded a grant of approximately $100,000 to the American Academy of Arts and Sciences in Boston to support an inquiry into the moral and ethical basis for research involving human subjects.

Eight medical organizations have now endorsed the ethical principles approved in 1964 in the Declaration of Helsinki by the World Medical Association concerning human experimentation.

Dr. Henry K. Beecher of the Harvard Medical School has charged in the New England Journal of Medicine that 22 cases of human experimentation had been either unethical or questionable; that is, performed without the patients' full knowledge and consent and without promise of benefit.

Dr. William H. Stewart, Public Health Service Surgeon General, told the American Federation for Clinical Research last April that one of the "pivotal clinical research problems of the day" is related to the use of human beings as research subjects.

"The decision to become a subject for research must be made by the subject," said Dr. Stewart. "We may like it or not, but the individual subject and only he, with all his personal whims and superstitions and foibles, can make the important choice. Being as fully informed as possible, he can make the choice for any reason, or for no reason at all. The principle involved is the same one that condemns slavery and underlay the judgments at Nuremberg."

Prior to the Helsinki Declaration, guidelines for doctors in clinical research were provided chiefly by the ethical tenet to "do no harm" as stated in the Hippocratic Oath, and in the Nuremberg Code adopted by the Nuremberg Tribunal in the Nazi war-crimes trials. The Helsinki statement emphasizes benefit to the patient who is ill.

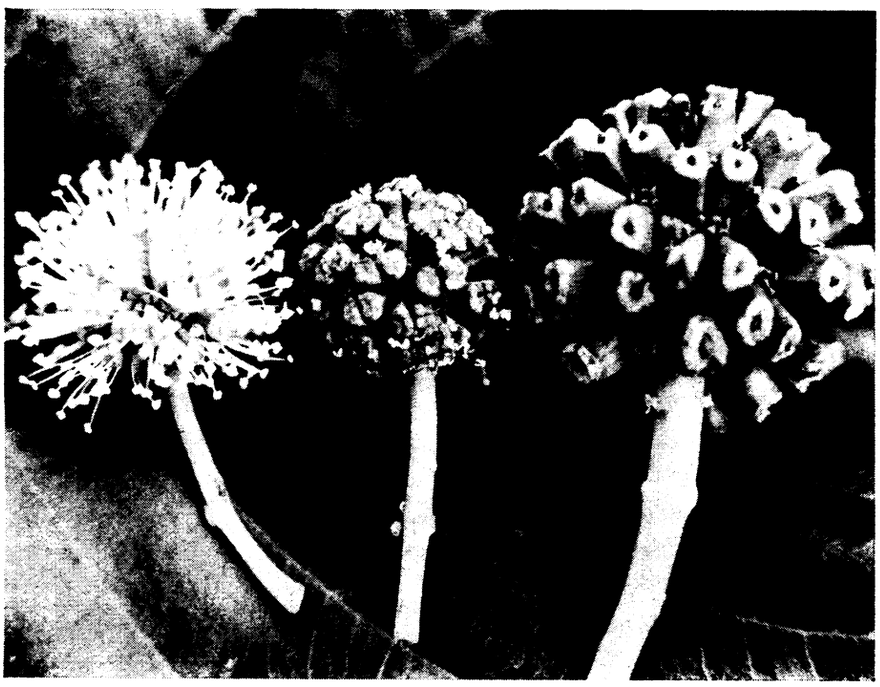
The Declaration of Helsinki states that if a patient is legally incompetent, the consent of the legal guardian should be obtained by the researcher. At any time during the course of clinical research, the subject or his guardian should be free to withdraw permission for research to be continued.

The Helsinki Declaration supplements the Nuremberg Code in that it applies more specifically than the Code to patients under medical care as well as to healthy persons. The Nuremberg Code is applicable to human experiments in which healthy persons are submitted to medical risk.

The eight organizations endorsing the Declaration of Helsinki are: the American Federation for Clinical Research, American Society for Clinical Investigation, Central Society for Clinical Research, American College of Physicians, American College of Surgeons, Society for Pediatric Research, American Academy of Pediatrics and the American Medical Association.

Co-chairmen of the American Academy of Arts and Sciences study are Dr. Stephen R. Graubard, editor of the Academy journal, Daedalus, in which conclusions will be published, and Prof. Paul A. Freund of the Harvard Law School, Cambridge. Dr. Graubard is currently in Paris and no meetings of the group studying the problem have yet been held.

Lawyers, sociologists and other professional groups will take part as well as physicians and medical scientists.



USDA

CANCER FIGHTER—The Camptotheca tree is being grown by botanists of the Agricultural Research Service for use in cancer studies. Shown here are one of its delicate flowers (left) and developing fruit (center and right).

MEDICINE

Rare Chinese Tree May Help Fight Leukemia

➤ LEUKEMIA victims may one day be helped by a substance drawn from an obscure Chinese tree.

Tests on laboratory animals with a type of experimental leukemia (lymphoid leukemia L-1210) have shown that the extract, known as camptothecin, has high antitumor properties. However, no tests on humans have yet taken place.

Chemists are trying now to synthesize the substance, whose only known natural source is the rare *Camptotheca acuminata* tree. More than 30 years ago seeds from China were planted as part of a long-term program to introduce new plants to the United States.

Today two 25-foot trees survive in Chico, Calif.

An intensive search of the West Coast revealed only a few fairly small specimens scattered from central to southern California. Some 1,300 seedlings planted at Chico this spring are expected to yield good quantities of raw material for continued testing within two years.

Camptothecin was isolated and identified by M. E. Wall of the Research Triangle Institute, Durham, N.C.

The project was reported in Agricultural Research, 15:3, 1966.