

AIDS Vaccine Testing Begins at the Clinical Center

By Blair Gately

The first human clinical trial of an experimental AIDS vaccine has begun at the Clinical Center.

Dr. Anthony S. Fauci, director, National Institute of Allergy and Infectious Diseases, says researchers will study the vaccine in 75 homosexual males who have not been exposed to the human immunodeficiency virus, or HIV, the cause of AIDS. In addition, six persons with no history of risk behaviors will participate in the study.

"This is the first step in what will be a long process toward developing a vaccine to prevent AIDS," Fauci said. He predicts it will not be until the mid-1990s that an AIDS vaccine will be approved for general use.

So far, more than 40,000 persons in the United States have been diagnosed with AIDS, and almost 60 percent of them have died.

The vaccine being tested here at NIH is manufactured by MicroGeneSys, Inc. of West Haven, Conn. It consists of the envelope protein derived from the genetic material of HIV. The virus attacks and destroys cells of the immune system, allowing infectious agents to enter the body and cause life-threatening illnesses.

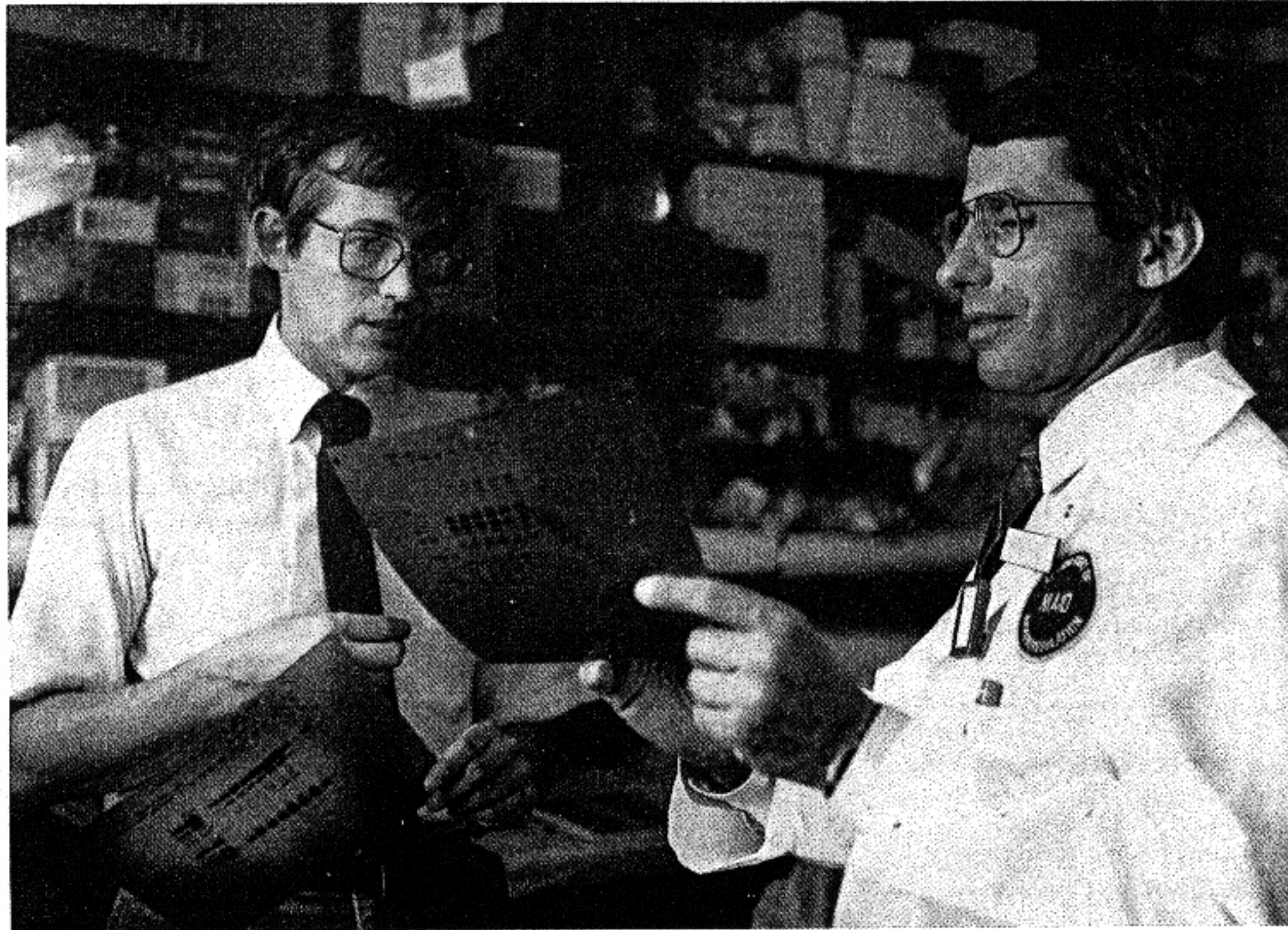
Dr. H. Clifford Lane, deputy clinical director, NIAID, and a senior investigator in the institute's Laboratory of Immunoregulation is carrying out the study. He says the majority of the volunteers are homosexual males since they are the most likely group in the United States to receive an AIDS vaccine.

The volunteers go through "an extensive pre-screening process" and are given three lab evaluations and a physical before the vaccine is administered, Lane says. In addition, they are tested twice to make sure they are free of HIV infection and they must agree to observe safe sexual practices while participating in the study.

In theory, the vaccine mechanism would work by taking a portion of the outer coat of the AIDS virus and injecting it into people, hoping their bodies will mistake the vaccine for the virus and causing their immune systems to mount antibody attacks. An antibody positive response would indicate a potentially effective vaccine.

"The vaccine consists of purified protein from HIV and not the virus itself," said Fauci. "Therefore, no one can get AIDS from the vaccine and we expect no adverse effects beyond those that sometimes occur from other immunizations, such as some redness and soreness at the site of the injection."

During the first phase of the testing, which is expected to last about 6 months, the toxicity



NIAID director and chief of the Laboratory of Immunoregulation, Dr. Anthony S. Fauci (r), and Dr. H. Clifford Lane discuss aspects of the first human AIDS vaccine trial. They are looking at X-ray film results of a Western blot antibody test for AIDS virus infection.

and side effects of the vaccine will be evaluated, Lane says.

If results are encouraging, the second phase, lasting about 1 year, would involve about 200 volunteers. It is designed not only to explore the safety of the vaccine, but also the immunological response to it and, in addition, to determine proper dosage.

After the success of the second phase is determined, the third phase, involving thousands of volunteers, could begin. It is only after the results of the third phase are analyzed that it can be established whether or not the vaccine has actually prevented AIDS infection.

"This study is a natural outgrowth of the overall goal of NIAID's Laboratory of Immunoregulation, which is to understand the immunopathogenesis of AIDS," Fauci said. "NIAID scientists have been working closely with scientists at MicroGeneSys in developing the vaccine and in assessing its results in animal studies."

To make the vaccine, scientists inserted the modified gene for the entire HIV envelope precursor protein, gp 160, into the genome of a baculovirus, a virus that infects such insects as moths and butterflies. The recombinant virus is grown in a cell tissue culture system, which

products the gp 160.

Several other biotechnology companies are working on developing AIDS vaccines, but so far MicroGeneSys is the only one to have received approval from the Food and Drug Administration for human testing. Research is also progressing on development of drugs to treat those already infected with AIDS. □

Milestones in Medicine

A symposium titled "NIH: Milestones in Medicine II" will be held Oct. 15 from 7:30 until 10 p.m. in the ACRF Amphitheater.

Speakers include Dr. Anthony Fauci, director, NIAID; Dr. Sheldon Wolff, Tufts University; Dr. Victoria Harden, curator of the DeWitt Stetten Museum of Medical Research; and Dr. Ramunas Kondratas, Smithsonian Institutions.

The symposium is sponsored by NLM, NIDDK and the Washington Society for the History of Medicine. □

... the welfare and prosperity of all countries and communities, and, ... individuals, depend upon their morals. ...—Abigail Adams (1778)