

and where he is conducting Department of Health and Human Services funded human subjects research" must report in writing to NIH's Office for Protection from Research Risks, documenting Gale's compliance with HHS policies for the protection of human subjects. Finally, "Until March 1, 1988, before Dr. Gale is appointed to any NIH committee whose functions include recommendations or decisions regarding research involving human subjects, appointing officials shall be provided with copies [of the NIH reports of its investigation and its decisions]."

Gale's 18 July trip to the Soviet Union was the culmination for him of nearly 3 months of frantic activity, sponsored and funded by Hammer. When the accident at Chernobyl occurred, the Soviets declined official offers of aid from the U.S. government but accepted Hammer's offer to send Gale and three other physicians to treat the most severely injured Soviets with bone marrow transplants (*Science*, 4 July, p. 19). Gale's team performed seven bone marrow transplants and three fetal liver transplants; seven of these patients are still alive.

While in the Soviet Union, on 6 June,

Gale signed a memorandum with Andrei Vorobiev, who is chief of the Central Institute for Advanced Medical Studies and a member of the U.S.S.R. Academy of Medical Sciences. In the memorandum, Gale and Vorobiev agreed to international cooperation in following the 100,000 to 200,000 Soviets who were exposed to potentially dangerous levels of radiation from the Chernobyl accident. Although U.S. government officials and the National Academy of Sciences also suggested to the Soviets that an international effort to follow Chernobyl victims be established, they received no reply (*Science*, 11 July, p. 147). The only signal the Soviets sent was the memorandum that Vorobiev signed with Gale.

In order to formulate a proposal to take to the Soviets, Gale organized a private meeting of 20 scientists from seven nations. Meeting on 8 July at Occidental Petroleum's Los Angeles headquarters, the scientists included Vincent DeVita, director of the National Cancer Institute; Edward Rall, deputy director of intramural research at the NIH; Itsuzo Shigematsu, chairman of the Radiation Effects Research Foundation in Japan; Edward Pochin of the National Ra-

diation Protection Board of England; and Bo Lindell of the National Institute for Radiation Protection in Sweden. The meeting participants, reports Occidental Petroleum, have expertise in a variety of disciplines, including radiation biology, nuclear physics, genetics, and oncology.

The proposal is that the new Armand Hammer foundation fund studies of cancers and birth defects that may arise in Soviet victims of Chernobyl and that the foundation sponsor basic research and exchanges between scientists from the Soviet Union and other countries.

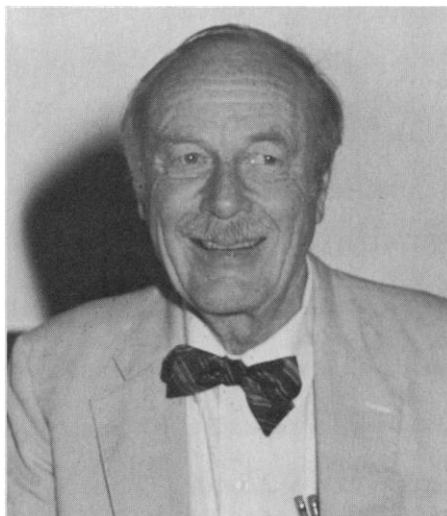
A press release put out by Occidental Petroleum on 18 July perhaps best expresses Gale and Hammer's views of their accomplishments. It says, "Obviously, there are far reaching implications to the Gale-Hammer initiative. Perhaps, occasionally, private citizens can accomplish what governments cannot. And as a result, if this effort succeeds, Messrs. Reagan and Gorbachev may include agreements on international cooperation in peaceful uses of atomic energy on a future summit agenda. Perhaps more good than was imagined will come from Chernobyl." ■ GINA KOLATA

Keeping the AIDS Virus Out of Blood Supply

More accurate blood tests are needed, according to an NIH consensus panel

SCIENTISTS and blood bank specialists have made great progress in freeing the nation's blood supply from contamination by the AIDS virus, but the system is not 100% perfect. Can the risk of getting AIDS through donated blood be reduced even further? "You know, there's a practical solution to that if someone would just announce it," said Ronald Reagan in a recent interview with the *Los Angeles Times*. "Why don't healthy and well people give blood for themselves?" the President asked. "And it can then be kept in case they ever need a transfusion. They can get a transfusion of their own blood and they don't have to gamble. . . ."

Participants in a recent National Institutes of Health consensus conference on the impact of testing donated blood for antibodies to the AIDS virus* concur with the Presi-



Thomas Chalmers, NIH consensus panel head.

dent if a person is facing elective surgery in the near future. "There is uniform agreement that autologous [your own] blood is the safest form of transfusion therapy. Blood banks and blood centers should make this option available to all qualified patients, simplify the donation process to the extent possible, and inform physicians and patients about the advantages and mechanics of this approach," according to the consensus statement.

In contrast to the benefits of autologous blood for immediate use, storage of your own blood for unanticipated future needs is "logistically impractical," says Amoz Chernoff of NIH, who spoke at the conference. Thus, the overall impact of autologous donations on transfusion medicine will be minor, leading conferees to assess other methods for improving the safety of the nation's blood supply.

AIDS was first diagnosed as a specific disease entity in 1981. By 1983, health officials realized that AIDS could be transmitted through infected blood, and in the spring of 1985, the first commercial kits to test blood for antibodies to the AIDS virus were available. Since that time, virtually all blood collecting agencies and blood banks

*NIH Consensus Development Conference on the "Impact of Routine HTLV-III Antibody Testing on Public Health," 7 to 9 July 1986.

have screened donated blood for antibodies to the AIDS virus.

James Allen of the Centers for Disease Control in Atlanta says that, as of 14 July, 422 people in the United States have developed AIDS because they received infected blood or blood products prior to the spring of 1985 when blood screening became routine. This number, which does not include hemophiliacs, represents less than 2% of all the people who have developed AIDS.

Major issues confronted by the recent NIH consensus panel include:

- Accuracy of antibody tests. When repeated tests indicate that donated blood contains antibodies to the AIDS virus, blood banks discard the blood and place the donor's name into a deferral registry to indicate that no blood from the individual should be used in the future. One problem with this approach has been that the widely used ELISA (enzyme-linked immunosorbent assay) test often gives false positive reactions, which incorrectly suggest that an uninfected person is infected with the AIDS virus.

Many of the inaccurate readings come from the first commercially available antibody test kits based on the HTLV-III virus that was isolated by Robert Gallo and his co-workers at the National Cancer Institute and grown in the H-9 cell line. Although these initial tests are sensitive and can detect low levels of antibody, up to 75% of the positive reactions from them are false. Newer ELISA tests are proving to be far more specific. One from Genetic Systems was recently licensed by the Food and Drug Administration and is based on the LAV virus isolated by Luc Montagnier and his colleagues at the Pasteur Institute and grown in the CEM cell line.

Blood banks perform a total of three ELISA tests on a blood sample before rejecting it as "repeatedly reactive." They then use the more specific Western blot test to confirm ELISA-positive reactions. A person who also tests positive on the Western blot is very likely to be antibody-positive due to infection by the AIDS virus.

But "antibody positivity is not synonymous with having AIDS," according to the consensus statement. Experts predict that 20% to 35% of the people who now carry antibodies to the AIDS virus will go on to develop the full disease within 6 to 8 years, estimates that will probably change as more is learned about the disease.

Although the most common problem with current ELISA tests for antibodies to the AIDS virus is that positive results are often false, a greater direct health problem arises when a test yields a "false negative" result. Fortunately, this is a "very rare occur-

rence," says Thomas Zuck of the Food and Drug Administration, and it is most likely to occur when an individual has been recently infected with the AIDS virus.

At very early stages of infection, blood may contain no detectable levels of antibodies to the virus, simply because the immune system has had too little time to produce them. This apparently occurred in a recent case in Colorado that received a great deal of media attention. It involved a newly infected man whose blood was ELISA-negative when he first donated it. His blood was used for transfusion in two patients, both of whom are now antibody-positive. One of the two could have also become infected through his homosexual contacts, and the other patient probably became infected solely because of the transfusion.

Zuck predicts a time window of about 6 to 12 weeks after an individual is infected with the AIDS virus, but before antibodies are detectable by existing ELISA tests. Potential solutions to this problem are more sensitive antibody tests, or tests that measure the virus or its proteins directly.

- Notification of recipients and donors. Blood banks encounter another problem

"Why don't healthy and well people give blood for themselves?"
President Reagan asks.

Long-term storage of your own blood is "logistically impractical."
Amoz Chernoff

when a regular suddenly tests positive. "When a blood bank discovers that a donor is positive for antibodies against the AIDS virus, they check back over their records to see if any of that person's blood was transfused," says Chalmers. If it was, the blood bank notifies the hospital. Then, it is the hospital's responsibility to notify the recipients that they may have been transfused with infected blood. "It's a big job, but is very important for health care and liability reasons," says Chalmers. This procedure, sometimes referred to as the "lookback" program, is highly recommended by members of the recent consensus conference.

Also at stake are the donor's rights. Blood banks and collecting agencies that identify donors who are antibody-positive by both

ELISA and Western blot tests notify them that they are probably infected with the AIDS virus. The consensus conference further recommends counseling programs for antibody-positive individuals and advice about protecting their sexual contacts from infection. They encourage infected persons and persons who think they may be infected not to donate blood.

For donors who test positive on three ELISA assays but are negative by the Western blot test (meaning they are probably not infected with the AIDS virus), the current procedure differs. Their names are placed into a deferral registry and, although they can still donate blood, no blood bank will use it. Many blood collecting centers do not tell them that their blood is being discarded. "This is an awkward situation that will probably change," says Harvey Alter of NIH. Alter thinks that noninfected donors who happen to test positive on the ELISA assay can be brought back into the system if they are later retested and found to be negative.

The consensus statement specifically recommends a change in the current notification procedure for donors who are ELISA-positive but Western blot-negative. The consensus document states, "We believe that it is inappropriate to enter a person's identity into such a registry without his knowledge and without giving him the personal advantage of sharing that knowledge and its meaning."

- Psychosocial implications. "Everyone involved in blood and plasma collecting is aware of the potential psychosocial ramifications of the knowledge of a positive test result," the consensus document states. It recommends "rigorous psychosocial research" on the problem, and stresses the need for confidentiality. It places the responsibility for "education and initial notification" on the agencies that collect plasma and blood, and says "... it is the responsibility of these centers to offer followup support and counseling through referral to the health care system."

The National Institute of Mental Health is currently reviewing contract proposals to develop training programs for health care personnel on mental health issues related to AIDS. These include the psychosocial impact on individuals infected with the AIDS virus and AIDS patients, as well as the neuropsychiatric problems associated with AIDS. The programs will be designed to educate nurses, doctors, and other health care professionals now in training, and will be available to those health professionals already in practice and to nonprofessional health care workers who counsel AIDS patients. ■ **DEBORAH M. BARNES**