AIDS CONFERENCE

MOBILIZING AGAINST A GLOBAL EPIDEMIC

WASHINGTON, D.C.—All during June's week-long Third International Conference on AIDS, political and emotional reactions to the crisis surrounding acquired immunodeficiency syndrome (AIDS) ran high. A major effort to consolidate research findings from across the world, the conference also provided a forum for public health officials, health policy makers, and political figures to describe their recommendations on AIDS. Prominent scientists contend that, without the technical skills assembled over the past two decades—many in the arena of molecular biology—they would not know where to begin the battle against the several forms of human immunodeficiency virus (HIV) discovered so far.

Although conference organizers cautioned that sessions were not to be disrupted, hecklers did interrupt the keynote speaker, U.S. Vice President George Bush. Another demonstration was staged during the concluding address of Otis Bowen, the U.S. Secretary of Health and Human Services: virtually half the audience stood up silently, and then jeering broke out. Yet, despite such drama, the meeting also conveyed the seriousness of this growing global epidemic. Jonathan Mann, the World Health Organization (WHO) official who oversees the AIDS global task force, noted that some 51,535 AIDS cases now have been reported to WHO—and this figure is believed to underestimate the actual world case load by at least half. The U.S. has reported the majority of infections; by contrast, a total of just 160 cases have been reported from all of Asia, Mann noted, and the Eastern Bloc countries and the U.S.S.R. report a total of 60.

One seeming bright spot in the AIDS epidemic is the rapid and efficient way in which the research community and the blood and blood-products industry have mobilized to ensure that the use of such products—at least in the industrialized nations—would be protected from contamination. Mandatory screening of donated blood for HIV has significantly lowered the risk of becoming infected through blood transfusion in the United States; even so, imperfect screening and infected donors require health care officials to remain vigilant. Because of the "narrow window" (early after a potential blood donor becomes infected with HIV but before signs are measurable), better assays for the virus are needed as are improved means for treating blood and blood products to ensure that any virus present is fully inactivated, says Harvey J. Alter of the National Institutes of Health.

Routine screening of donated blood for antibody against the AIDS virus began in the United States during March 1985, and enzyme-based immunoassays remain the most commonly used tests. A French group recently evaluated 10 such methods, paying particular attention to their relative ability to detect HIV-2 in addition to HIV-1. According to F. A. Denis of the Institut Pasteur (Paris), only the method developed at Pasteur specifically for testing HIV-2 proved at all reliable. Other commercial tests varied over a 30 to 90 percent range in detecting HIV-2, probably via cross reactivity with HIV-1, he says.

Another kind of test, based on DNA probe amplification and analysis, soon may provide an alternative approach, according to John Sninsky of Cetus Corp. (Emeryville, CA). The system depends on the exponential amplification of DNA segments, with 20 cycles of an enzyme-based system providing a million-fold amplification of a specific DNA segment. Improvements, Sninsky says, including use of a hardy microbial enzyme that operates at high temperatures, will enable researchers to detect a single copy of an HIV gene segment in one million cells. Currently the procedure is being tested on clinical samples, where it is about 70 percent as effective as other methods for detecting HIV. In some cases, however, the DNA probe-based test picks up asymptomatic cases of HIV infections where other methods, including HIV antibody and Western Blot analysis, fail. Although reagents for applying this method in a research laboratory setting soon will be commercially available, a clinical test kit is not expected until mid-1988.

In other developments, the U.S. Food and Drug Administration (FDA) recently approved a Western Blot confirmatory test kit from DuPont (Wilmington, DE) for detecting antibodies to HIV. Moreover, a rapid latex agglutination test as well as a dot enzyme immunoassay for measuring HIV were described during the meeting. The latex test is being developed commercially by Cambridge BioScience (Worcester, MA), and the dot assay by Bio-Medican Corp. (Huntington Beach, CA) and Virotechnology Corp. (Stockton, CA). Also, microplate enzyme immunoassay kits for detecting HTLV-I and HIV-2 antibodies are being advanced by Olympus Corp. (Lake Success, NY) in collaboration with United Biomedical. And Abbott Laboratories (North Chicago, IL) has applied to FDA for approval of an enzyme immunoassay that detects HIV antigens directly in blood samples from patients, rather than antibodies formed there in response to the virus. **—Jeffrey L. Fox**

ASTM

EVOLVING CONSENSUS STANDARDS

CINCINNATI—While overall membership in the American Society for Testing and Materials' (ASTM) Committee E-48 on Biotechnology continues to increase, the *active* membership—those who attended this May's semi-annual meeting—is declining. Thus, only a handful of people have become responsible for discussing, drafting, and finalizing standards that are intended to provide guidelines to the entire biotechnology industry. Although ASTM's rather formal procedures move slowly, the first standards are now coming to the point of balloting.

E-48's subcommittee on materials for biotechnology now has developed a preliminary draft on standards for purity, impurities, and contaminants of recombinant DNA-derived biological drug products. The proposal includes working definitions.

The subcommittee on characterization and identification of biological systems has a draft document on standards for low-temperature preservation and freeze-drying of bacteria, fungi, other microorganisms, genetic elements, viruses, and plant and animal cells.

And E-48's subcommittee on processes and their controls has a working draft on standards for ultrafiltration membranes and another, more specific one, on a standard test method for molecular weight cut-off evaluation of ultrafiltration membranes. This subcommittee is also developing standards for *in situ* measurement of biochemical processes and for aseptic sampling procedures in biological systems. **—Jennifer Van Brunt**