EXECUTIVE SUMMARY

The U.S. Public Health Service has led the effort to control the human immunodeficiency virus (HIV) epidemic since the clinical disease, acquired immunodeficiency syndrome (AIDS), was first identified in 1981. Over the past 7 years, the severity and scope of the problem have become increasingly evident. Many research, prevention, and control activities have been initiated, in both the public and private sectors in the United States and throughout the world. Resources allocated to counter the epidemic, both public and private, have been increased continuously.

From June 1-3, 1988, PHS assembled its AIDS experts in Charlottesville, VA, to examine the current dimensions of the HIV problem, assess our progress to date, and plan for the future. This document is the result of that conference as well as subsequent planning and review efforts.

The full report of the 1988 Charlottesville meeting identifies more than 100 issues, 200 goals, and 500 objectives as priority areas for PHS efforts in controlling the HIV epidemic. The report is divided into 10 sections corresponding to the nine major areas of activity on AIDS and HIV within PHS and a section on the three cross-cutting issues, the HIV epidemic as it affects women, minorities, and children. While the cross-cutting issues are treated as separate reports, much of their content is drawn from the reports of the individual workgroups.

We believe that, as a whole, this PHS report represents a comprehensive, thoughtful, and realistic strategy for further progress in our Nation's response to this disease.

This summary contains the most important elements of the full report, but cannot be viewed as comprehensive. The many objectives in the full report are interdependent and complementary, and together constitute a comprehensive and feasible strategy for controlling the HIV epidemic.

Epidemiology and Surveillance

Our Nation is facing the most critical and devastating epidemic in recent history. HIV infection and the clinical complications that follow are already placing a heavy strain on medical and social services in both the public and private sectors. By late September 1988, more than 74,000 cases of AIDS had been reported in the United States, and almost 42,000 persons were known to have died. Nearly 40,000 AIDS cases are expected to be reported in the United States for 1988 alone, while the total number of infected individuals in the United States is currently estimated at 1 million to 1.5 million.

PHS projects that, by the end of 1992, the cumulative number of diagnosed AIDS cases will total 365,000, with 263,000 cumulative deaths. In 1992 alone, there are expected to be 80,000 newly diagnosed cases of AIDS, and 65,000 deaths--primarily persons diagnosed in previous years. During that same year, 172,000 AIDS patients will require medical care, at a cost expected to range from $5 billion to $13 billion.

To monitor the nature and scope of the HIV epidemic, and to implement strategies that will prevent further spread, PHS will:

- Continue to promote the confidential reporting of AIDS cases;
- Promote confidential reporting of HIV-positive individuals to State public health officials to facilitate local prevention and control efforts;
- Continue to work with States that currently require reporting of HIV-positive individuals to public health officials, in order to evaluate the effectiveness of reporting in reducing the spread of HIV;
- Promote expanded counseling and testing of persons at increased risk of infection;
- Support efforts to notify, counsel, and offer HIV testing to sexual and needle-sharing partners of persons with HIV infection; and,
- Use data from carefully conducted HIV serologic surveys to obtain a more complete picture of HIV infection in the U.S. population to better target prevention programs.

To enhance understanding of the spread of HIV infection in the United States, improve estimates of anticipated morbidity and mortality, and measure the effect of prevention programs, PHS will:

- Conduct and evaluate more than 420 different seroprevalence surveys in 30 Standard Metropolitan Statistical Areas, including surveys in sexually transmitted disease clinics, drug abuse treatment centers, tuberculosis clinics, women's health clinics, newborn infant screening programs, and selected ("sentinel") hospitals;

- Conduct a pilot study in one or more cities to determine the feasibility of a national random household seroprevalence survey to obtain demographic and HIV risk-factor information and a blood sample to test for HIV, in order to establish an estimate of the prevalence of HIV infection in the United States;

- Collect better data on the characteristics and distribution of behaviors associated with risks of HIV infection; and,

- Support the development of more effective mathematical models and promote expanded collaboration among modelers, epidemiologists, and behavioral and laboratory scientists.

Prevention: Information, Education, and Behavior Change

The only effective weapon available today for preventing direct person-to-person transmission of HIV infection is education that may result in behavior that reduces exposure to the virus. The public must be thoroughly informed regarding the modes of transmission, the behaviors that place individuals at risk, and the actions necessary to change and sustain behavior that eliminates risk.

Programs to promote behavior change have been successful in cities such as San Francisco where the HIV seroconversion rate among homosexual and bisexual men has declined dramatically. In addition, some programs to reach intravenous drug abusers have succeeded in reducing needle-sharing behaviors. Successful prevention programs need to be implemented for all persons who are at risk for HIV infection, with particular attention to minority populations with a disproportionate rate of infection.

In addition to education and interventions to change knowledge, attitudes and behavior, voluntary HIV counseling and testing of individuals who have practiced high-risk behaviors have been an important part of prevention activities since 1985, when the first test for HIV antibody became available. The PHS will continue to provide assistance to States and localities for expanded counseling, testing and partner notification services in accordance with PHS guidelines. These programs need to be evaluated to identify those counseling techniques that are most successful.

To further raise the consciousness of every American about the facts on AIDS and HIV infection, and to promote safe behavior, PHS will:

- Intensify activities during special media campaigns, such as the second annual AIDS Awareness and Prevention Month in October 1988;

- Continue the national public information campaign, "America Responds to AIDS," to increase knowledge about AIDS and HIV infection;

- Develop additional educational initiatives aimed at the general public, school and college-age youth, persons at increased risk and persons infected with HIV, minority populations, and health workers;

- Develop behavioral research initiatives to foster the design and evaluation of interventions that can be used to modify the behavior of individuals at risk for HIV infection; and,

- Promote measures to protect persons with HIV infection from discrimination and to strengthen the confidentiality of personal information about HIV infection status.

To focus special prevention efforts on populations that have been at greatest risk for HIV infection, PHS will:

- Expand development and dissemination of community-specific intervention programs, taking into consideration race, ethnicity, gender, drug use, sexual orientation, and socioeconomic status;

- Evaluate intervention programs so that the most effective can be widely disseminated for adaptation in individual communities;

- Evaluate and implement innovative methods to reach high-risk individuals, such as the use of indigenous outreach workers to reach intravenous drug abusers and their sexual or needle-sharing partners;

- Support a systematic program of behavioral research to obtain information necessary for the development of effective, culture-specific programs to prevent HIV infection; and,

- Continue to provide financial and technical assistance to State and local health departments, as well as to national and community-based organizations, to support the development, implementation and evaluation of effective HIV prevention programs for minorities who are at risk.

To capitalize upon the pivotal role that health professionals play in the enhancement of prevention programs, PHS will:

- Continue to support programs designed to educate and train health care providers in the knowledge, skills, and attitudes required to effectively counsel and care for individuals at risk or infected by HIV.

Clinical Manifestations and Pathogenesis

In the 7 years since the first cases of AIDS were reported, much has been learned about the virology, immunopathogenesis, epidemiology, and clinical manifestations of HIV infection. These advances have resulted in at least modest improvements in the quality and duration of life for some infected individuals, and hold great promise for the future. However, much remains to be understood about the full nature and impact of HIV infection, in order to more effectively prevent additional infections and treat those persons already infected.

To gain further knowledge about HIV, and the natural history of HIV infection and its sequelae, PHS will:

- Continue and expand studies on the natural history of HIV infection in all affected populations, with special recognition of the serious problems associated with HIV infection of women and children;

- Support studies to clarify subpopulation differences in the pathogenesis, epidemiology, and patterns of clinical expression/progression of HIV-associated infections and neoplasms;

- Extend basic research efforts in molecular biology and virology, especially studies of the structure and function of viral genome components, the immunopathogenesis of infection, the genetic variability of HIV, and the virologic and clinical consequences of this variation;

- Expand research efforts concerning the nature and course of HIV infection in the nervous system and other target organs;

- Undertake studies elucidating the relative roles of the direct effects of HIV on target tissues and organs and the effects caused by HIV-induced immunosuppression;

- Continue investigations into the basic biology, pathogenic mechanisms, and clinical manifestations of opportunistic infections and neoplasms associated with HIV infection;

- Extend basic research efforts to understand the nature and role of the entire host immune response to HIV infection;

- Conduct further research into the mechanisms of viral persistence and activation;

- Expand existing research on the role of potential co-factors in the transmission of HIV infection as well as in the expression and progression of disease, including concurrent viral infection, sexually transmitted diseases, and environmental and behavioral cofactors; and,

- Continue efforts to develop animal models for HIV infection.

Therapeutics

For persons infected with HIV, hope lies in the introduction of new therapies to slow and, eventually, arrest the progression of disease. A substantial national effort to discover, develop, and evaluate such new therapies is under way.

One drug, AZT, can significantly prolong life in persons with severe HIV infection, and is already in widespread use following its approval by the Food and Drug Administration in 1987. The rapid movement of this drug through the evaluation and approval process was the result of close cooperation between PHS and private industry. Additionally, as of late September 1988, about 85 drugs have been granted investigational new drug (IND) status.

To promote further cooperative efforts in drug development, PHS will:

- Explore ways to create incentives for and reduce barriers to the commitment of additional private industry resources to the development of drugs for AIDS and HIV infection.

To stimulate progress in basic and applied HIV-related research and product development and approval PHS will:

- Continue to support the AIDS/HIV drug development program, including all phases of drug discovery and development;

- Support independent research programs to find drugs to attack HIV at each of the steps in its life cycle;

- Expand drug development programs to foster multi-institutional and multidisciplinary research in the molecular biology and the biophysical properties of HIV;

- Continue to support a preclinical drug evaluation program with a capacity to screen approximately 400 new compounds per week for signs of antiviral effect; and,

- Ensure rapid review of investigational new drugs and applications for marketing by implementing, among other initiatives, the Vice President's directive on expedited approvals.

To find drugs that are effective and to eliminate from consideration those that are not, PHS will:

- Continue to support the AIDS Clinical Trials Group (ACTG), a cooperative group of 35 institutions that are evaluating therapies for HIV infection;

- Continue to test new drugs in scientifically controlled and evaluated clinical trials for the full range of diseases faced by HIV-infected patients, including opportunistic infections and HIV-related neoplasms;

- Validate and verify data collected in clinical trials to ensure that conclusions drawn are accurate;

- Identify barriers that reduce access of HIV-infected individuals to the clinical trials system and develop strategies to remove these barriers; and,

- Ensure that knowledge about clinical trial design and statistical methods is better communicated to the public and provide specific facts about clinical trials of new therapies and facts about existing available therapies.

To get new therapies to HIV-infected persons as rapidly as possible, PHS will:

- Encourage the use of the newly devised treatment IND mechanism to make new drugs widely available to patients once there is preliminary evidence of safety and efficacy;

- Explore additional proposals for expediting drug approvals; and,

- Encourage community care providers to participate in clinical trials.

Vaccines

The control of infectious diseases such as polio has relied heavily on the use of safe and effective vaccines. HIV, however, is unlike any of the viruses for which vaccines have been developed. There are many theoretical as well as practical reasons to suggest that the road to an acceptable AIDS vaccine is going to be difficult. Nevertheless, PHS places high priority on the accelerated development of vaccines for the prevention and control of HIV infection.

To expand our knowledge of the essential strategies needed to elicit immune responses that protect against HIV infection or HIV-related disease, PHS will:

- Move advances in basic vaccine research rapidly through the preclinical development process by continuing to support both the intramural efforts and the National Cooperative Vaccine Development Groups (NCVDGs), an interactive clinical and research network;

- Make standardized reagents accessible to all researchers through the newly established HIV Reagent Repository;

- Pursue research in animal model systems and expand efforts to develop new animal models; and,

- Continue to support the investigation of passive immunization, in part as an important clinical approach and in part to help establish whether antibodies or immune cells can be protective.

To expedite vaccine development, review, and approval PHS will:

- Continue to exercise "fast track" mechanisms for evaluation of vaccine candidates;

- Facilitate collaboration drawing on all available expertise by implementing the NIH Plan for AIDS Vaccine Development and Evaluation, which represents a multidisciplinary framework for government-industry-academic cooperation; and,

- Support research to establish the safety and efficacy of candidate vaccines in clinical trials.

To appraise potential legal and ethical consequences of vaccine development and testing, PHS will:

- Encourage discussion of legal and ethical issues, including issues related to product liability, through the support of workshops and conferences as well as through periodic internal assessments of these areas.

To address the special concerns related to conducting efficacy trials in developing countries, PHS will:

- Work with the World Health Organization to develop an acceptable framework for the evaluation and approval of such trials; and,

- Develop mechanisms for assuring bilateral agreements on the acceptability of HIV vaccine trials.

Blood and Blood Products

The risk of HIV transmission by blood and blood products has been greatly reduced by three specific actions taken cooperatively by PHS, blood and plasma collecting organizations, and industry: (1) rejecting donors whose behaviors put them at risk for HIV infection; (2) testing all blood and plasma donations for antibodies to HIV; and, (3) treating clotting factor concentrates. PHS, working with the blood-banking community, continues to strive for zero-risk in the safety of blood and blood products, and anticipates further reduction of HIV transmission.

To increase the safety of blood and blood products, PHS will:

- Expedite the review and approval of sensitive, cost-effective, and rapid screening tests for the earlier detection of infected donors; and,

- Increase regulatory oversight of blood-banking practices to encourage a reduction in the number of clerical and testing errors.

To evaluate the safety of blood and blood products, PHS will:

- Continue to assess the risk of HIV infection by maintaining support for surveillance programs.

To prevent donations from persons who practice high-risk behavior for HIV infection, PHS will:

- Develop targeted education and prevention programs aimed at increasing donor self-exclusion;

- Expand seroepidemiologic studies among blood donor populations to determine the prevalence and incidence of human retrovirus infections;

- Continue research efforts to determine why some at-risk persons continue to donate blood; and,

- Work with the blood-banking community to increase the effectiveness of donor deferral measures in excluding donations from all persons at risk for HIV infection.

To further reduce potential transmission through homologous transfusions, PHS will:

- Encourage autologous donation and blood salvage procedures through a variety of activities, including programs to broaden the understanding of transfusion practices among physicians and medical students.

To assess the clinical significance of HIV seropositivity in recipients of blood and blood products, PHS will:

- Continue to support clinical studies evaluating the outcomes of transfusions of seropositive units.

Intravenous Drug Abuse

Intravenous (IV) drug abuse is a major risk factor for HIV infection; more than a quarter of all reported persons with AIDS are IV drug abusers. Since there are an estimated 1.1 to 1.3 million IV drug abusers in the U.S. today, the potential toll is enormous. In addition, most heterosexual and perinatal HIV infections are at least indirectly related to people who abuse IV drugs.

Among IV drug abusers, HIV infection is spread primarily through needle sharing, but it is also spread through sexual contact. Inasmuch as the major factor underlying needle sharing is drug dependence, a chronic medical disorder, eliminating drug dependence is a major goal in eliminating the spread of HIV infection--and benefits not only the IV drug abusers themselves, but also their sexual partners and possibly their unborn children.

To reduce, to the greatest extent possible, HIV transmission through IV drug abuse, PHS will:

- Work to expand the number of IV drug treatment slots from the current 148,000 to a level

sufficient to treat the total accessible drug abusers at any one time;

- Expand efforts to improve the quality and effectiveness of drug treatment by increasing retention rates, decreasing relapse rates, developing quality of care guidelines, supporting research on new pharmacotherapies, and increasing flexibility of existing methadone regulations; and,

- Support the recruitment and training of enough drug treatment personnel to handle increased workloads.

To reduce the spread of HIV infection through alternatives to treatment, PHS will:

- Increase outreach and educational efforts for both IV drug abusers and their partners, and support research on more effective outreach measures; and,

- Increase efforts to provide effective information about the value of cleaning drug paraphernalia in reducing the risk of disease transmission.

To ensure that the primary health care needs of IV drug abusers, particularly those with HIV-related diseases, are addressed, PHS will:

- Support efforts to link drug abuse treatment services with primary health care services; and,

- Support research to identify models for integrated and cost-effective service delivery.

Finally, to expand basic knowledge regarding IV drug abuse and AIDS, PHS will:

- Support research to clarify the extent, nature, and natural history of IV drug abuse and needle sharing, with special attention paid to cultural differences; and,

- Support research on the role of drugs of abuse as cofactors in the spread of HIV infection, including the effect of drug use on risk-taking behavior.

Neuroscience and Behavior

HIV infection of the nervous system can lead to severe cognitive impairment in some persons. The early entry of HIV into the nervous system, the increasing risk of damage to the nervous system as the infection progresses, and the reversibility of some nervous system pathology with anti-HIV therapies, imply that HIV infection exerts a neurotoxic effect that may be independent of the immunosuppressive effects of the virus. The ability of the virus to enter the nervous system, and remain beyond the reach of most drugs, suggests that the search for methods to combat the virus specifically within the nervous system is particularly important.

Deteriorating nervous system function late in the course of HIV infection has been observed in some individuals, but existing data on impairment due to early HIV infection are insufficient to justify restricting employment or other activities solely on the basis of serologic status.

To expand our ability to understand and combat HIV infection of the nervous system, PHS will:

- Expand basic research in the pathogenesis, mechanisms, and course of HIV infection and impairment of the central and peripheral nervous systems;

- Support studies of the interactions among psychological, neurological, and immunological factors on the development and course of HIV infection;

- Support the investigation of nervous system and behavioral dysfunction in pediatric as well as adult patients;

- Encourage additional research on the neuropsychiatric and neurological aspects of other human retroviruses and of different strains of HIV;

- Advance the development and standardization of neuropsychological instruments and clinical examinations employed to determine the detrimental effects of HIV on the nervous system;

- Support studies exploring the relevance of HIV-related changes, as measured by neuropsychological instruments and clinical examinations, to the maintenance of job and independent living skills;

- Support the development of suitable animal models that mimic the central nervous system changes seen in human HIV infection;

- Support the development of drug and other treatments effective in the nervous system against the behavioral, sensory, cognitive, and motor changes associated with HIV infection;

- Continue research to identify HIV-related neurotoxicity and the development of treatments to combat the effects of these toxins;

- Identify specific health care services needed by an increasing population of patients with HIV-related cognitive impairment; and,

- Support research training for scientists working at the interface of psychiatry, psychology, neurology, and biology in order to increase the availability of trained investigators able to integrate research across these fields.

Patient Care/Health Care Needs

The responsibility of caring for AIDS patients and HIV-infected individuals will be a major concern to the Nation for some time to come. Health care delivery issues highlighted by AIDS and HIV infection need to be evaluated, whenever possible, within the context of the entire American health care delivery system.

Ideally, care for patients with AIDS and HIV infection should be delivered in the same manner as care for other patients with illnesses of similar severity. To this end, PHS is committed to encouraging the mainstreaming of health care delivery for AIDS and HIV-infected patients by building on existing services and systems.

This should continue to be done, although the care model will increasingly need to shift from one that addresses the needs of terminally ill patients to one that addresses the needs of the chronically ill.

PHS believes that integration of care, in the long run, will not only improve the quality of care and increase access to care, but also prove to be more economical. At the same time, PHS acknowledges that significant barriers impede both access to and integration of care. PHS initiatives are designed to support community efforts to overcome these barriers and, at the same time, help to fill unmet demands for health services.

To ensure that persons with AIDS and HIV infection have access to care that is effective, compassionate and comprehensive, PHS will:

- Support, through a variety of programs, community assessment of and planning for health services;

- Encourage efforts to protect HIV infected persons from discrimination, including active involvement of community-based organizations operating culturally sensitive programs;

- Promote innovative approaches to providing care, and the development of health care coalitions through existing demonstration programs;

- Enhance existing programs that provide primary and family-centered care for populations at risk of HIV infection, integrating that care into the total health care system for the target population;

- Continue supporting training programs for health care professionals and all health care workers in prevention, risk reduction, health education, and management of HIV infection;

- Work with the Health Care Financing Administration (HCFA) to evaluate the cost effectiveness of various care systems, assess the implications of a changing pattern of illness, and review the existing barriers to financing appropriate care in private and public programs;

- Encourage the development or modification of intermediate and long-term care facilities as well as other types of residential facilities appropriate for the needs of patients with HIV infection;

- Continue to support research on issues related to the utilization, cost, and financing of HIV-related care;

- Extend research programs to address access to care, barriers to care, quality of care, cost-effectiveness of alternative models for organizing services, and issues relating to health professionals involved with HIV-related care;

- Support the development of health measures and informational systems for HIV-related care that will assist in clinical decisionmaking and cost-effectiveness; and,

- Sponsor research initiatives on health systems analyses focusing on the interrelationships between HIV-related illnesses and other illnesses, and the effects of HIV-illnesses on the health care delivery system.