THE PRESIDENTIAL COMMISSION on the HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

Interim Report to the President

March 15, 1988

PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

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MAR 15 1988

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the Presidential Commission on the Human Immunodeficiency Virus (HIV) Epidemic, I am submitting this interim report. It represents the Commission's recommendations in three important areas affecting the HIV epidemic: intravenous drug abuse; patient care; and research and drug development.

As noted in the report's introduction, these recommendations represent the first three of a number of key elements which will eventuate in the comprehensive national strategy needed to respond to the epidemic. The Commission will integrate these with all remaining key elements over the next several months and then present the comprehensive plan to you in our final report due June 24, 1988.

While further modification may be required as our continuing deliberations unfold, we believe these interim recommendations are sufficiently complete to warrant their use now in decision-making. Their implementation will help to commence a national healing process by curbing the spread of HIV infection through intravenous drug abuse; expediting development of therapies that will deter progress of the disease in those already infected; and providing compassionate and cost-effective health care to those in need.

Sincerely,

James D. Watkins
Admiral, U.S. Navy (Retired)

Enclosure

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INTERIM REPORT

PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

SUBMITTED MARCH 15, 1988

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Introduction to the Interim Report

As noted in the December 2, 1987 preliminary report to the President, the Commission felt it was unnecessary to wait until June 1988 (the date contained in the Commission's charter for a final report), to make recommendations on all aspects of the HIV epidemic. The following four discrete areas were identified as potentially suitable for immediate examination: intravenous drug abuse, patient care, basic research and drug development, and incidence and prevalence. This interim report makes recommendations only in the first three of these four areas.

The recommendations on intravenous drug abuse, patient care, and basic research and drug development which are included in this report are for the most part complete, and represent the beginning of the Commission's efforts to build for the President an integrated national strategy which responds to the HIV epidemic.

After an initial review of obtaining an estimate of the number of currently infected individuals (prevalence) and the rate at which new HIV infections occur over time (incidence), the Commission has determined that recommendations at this juncture would be premature. Issues of testing, confidentiality, discrimination, and other legal matters are closely intertwined with collecting such data. Furthermore, a thorough review of the nation's public health system is necessary in order to make recommendations in this area. For these reasons, the Commission has decided to address the area of incidence and prevalence in the final report, and in the context of an overall integrated national strategy.

The Commission notes that available data do not provide a basis for comfort or complacency to any segment of our society. Heterosexual transmission has been conclusively documented through extensive research. We express our concern that inaccurate and misleading statements suggesting that HIV cannot be spread through heterosexual activity could stimulate transmission among those who would see such reports as bases for ignoring the danger that does, in fact, exist. Heterosexuals should not be misled into a false sense of security, unwarranted under the present circumstances.

The recommendations in this report were developed after hearings on each of the topics, in which hundreds of witnesses presented their views. Individuals from a range of perspectives have shared their thoughts with the Commission, including persons with AIDS and HIV infection, Federal officials, business leaders, representatives of community-based organizations, local and State government leaders, members of Congress, and experts in the field. It is from this input that the Commission has developed recommendations in these three areas.

Summary of Recommendations

Intravenous Drug Abuse

The Commission's recommendations propose elements that need to be incorporated into a comprehensive strategy, sustained over time, to address intravenous (IV) drug abuse. They include suggestions for increasing treatment capacity and treatment research, improving treatment quality, strengthening primary prevention and early intervention drug abuse programming, and conducting aggressive outreach and education. The recommendations are geared toward the establishment of a "treatment on demand" system for IV drug abusers, whereby treatment would be immediately available for any IV drug abuser who sought it.

Patient Care

The Commission's recommendations are targeted to expand and strengthen health care and related services for persons infected with HIV. The recommendations address health care provider education, health care systems, psychosocial needs, nursing care, minority and underserved populations, and information coordination and exchange. The recommendations are intended to promote a continuum of comprehensive, accessible, cost-effective, high quality care for persons infected with HIV.

Basic Research and Drug Development

The Commission's recommendations include suggestions for enhancing basic biomedical research such as expansion of investigator initiated grants, an expansion of training programs to encourage students to become biomedical scientists, and changes in the management of NIH research funds. The Commission also makes recommendations intended to enhance behavioral research efforts.

In the area of drug development, the Commission recommends expanding resources for the Food and Drug Administration; expanding community-based clinical trials; expediting clinical trials; removing placebos in clinical trials whenever possible; immediately increasing access to clinical trials for women, hemophiliacs, transfusion-exposed persons, minorities, and IV drug abusers; resolving problems encountered in implementing the treatment IND (investigational new drug application) program; and centralizing and expanding information on drug trials and potential new drugs for both consumers and health care providers.

Future Work of the Commission

Issues which remain to be addressed by the Commission in the final report (due June 24, 1988) include: incidence and prevalence, prevention and education, discrimination, ethics, testing, confidentiality, safety in the workplace, legal concerns, financing of health care, and international concerns. The Commission will complete hearings on each of these issues prior to the development of final recommendations. In addition, the Commission may further address the three topics of this report as a comprehensive national strategy is developed.

A hearing schedule appears at the end of this report.

DRUG ABUSE RECOMMENDATIONS

The future course of the HIV epidemic depends greatly on the effectiveness of our nation's ability to address IV drug abuse. IV drug abusers constitute 25% of the AIDS cases in the United States. They are a substantial vector for HIV infection, spreading it through sharing of needles and other drug paraphernalia and through sexual contact, as well as perinatally to their children. In addition to direct transmission, the use of drugs that impair judgment can contribute to sexual transmission. Approximately 70% of U.S. native citizens reporting heterosexually transmitted AIDS have had sex with an IV drug abuser, some of whom support their habits through prostitution. Seventy percent of the perinatally transmitted pediatric AIDS patients are children of IV drug abusing women or of women whose sex partners are IV drug abusers. The number of AIDS cases among infants and children is rapidly increasing and expected to total between 10,000 and 20,000 by 1991.

These estimates represent only the beginning of the tragedy if this nation does not act to address its drug abuse problems. The United States continues to have the highest rate of illicit drug use among young people of any country in the industrialized world. With 57% of last year's high school seniors having tried an illicit drug and over one third of all high school seniors reporting experimentation with drugs other than marijuana, drug abuse remains a significant problem that demands a dedicated and determined long-term response. America's drug problem pervades all elements of our society. A recent Rand Corporation study of drug abuse in the Washington D.C. area made evident that drug abuse remains a problem for suburbs and inner cities, among all races, and at all income levels. Without a coordinated long-term response, America's youth remain vulnerable to a bleak future.

Among the most tragic manifestations of the HIV epidemic are the infected infants of IV drug abusers. Often with drug abusing parents whose resources are limited, these infants are frequently without the support and care they need. Most of these children die in the first few years of life. With foster care and group home placement limited, many never leave the hospital. Their time on this earth begins with a few months of drug withdrawal in an isolation unit in a hospital and ends after a series of painful illnesses. Few have relatives to visit them while in the hospital. The hard working nurses, doctors, social workers, and volunteers who staff our acute pediatric care units are father, mother, friend, and teacher to these children.

In addition to the devastation that drug abuse represents for our families and communities, the cost of drug abuse is an estimated 60 billion dollars annually in health care, reduced productivity,

law enforcement, theft and destruction of property. This figure does not account for the addition of the staggering costs of providing health care for drug abusers with AIDS. Crime is also intimately related to drug abuse with studies of male arrestees in major cities finding that 66% test positive for drugs.

A number of efforts have been initiated to curb drug abuse, including First Lady Nancy Reagan's highly visible "Just Say 'No'" campaign. The First Lady's efforts have been successful in drawing our nation's attention to the devastation of drug abuse and calling on our nation's young people to reject it. The Commission's recommendations in the area of IV drug abuse are intended to build upon previous strategies and establish a long-term comprehensive plan for the systematic provision of both prevention and treatment services.

The Commission's recommendations propose elements that need to be incorporated into a ten-year comprehensive strategy to address IV and other forms of drug abuse. The recommendations are geared to providing a treatment system which can accommodate a "treatment on demand" response for IV drug abusers. Of course, no treatment system can be effective in the absence of commitment by individual drug abusers to take responsibility for their well being. People have to be helped to develop values that are not self-destructive.

Curbing IV and other forms of drug abuse is a multifaceted challenge requiring a major commitment of the Federal, state and local governments, parents, educators, and community leaders working together to initiate new prevention and education programs, expand treatment programs, and build community support to eliminate drug abuse and trafficking.

In addition to focusing on the demand side of the drug abuse equation, we must not slacken in our efforts to address the supply side by addressing illicit domestic and international drug trafficking in our policy decisions. Although the recommendations made in this interim report deal solely with the demand side of drug abuse, we expect that the international section of our final report will include a discussion of the supply side, drug trafficking.

The Commission recognizes that drug abuse in all its manifestations represents a threat for the spread of HIV infection. Our recommendations are designed to develop comprehensive programs to deal with the nation's drug abuse problems through increasing treatment capacity and treatment research, improving treatment quality, strengthening primary prevention and early intervention drug abuse programming, and conducting aggressive outreach, education and AIDS prevention for drug abusers.

SECTION 1: PROVISION OF TREATMENT SERVICES

The Commission believes that curbing drug abuse, especially IV drug abuse, through treatment is imperative to deter the progression of the HIV epidemic. What is needed is a clear Federal, state, and local government policy, in other words a national comprehensive policy, unequivocally committed to providing "treatment on demand" for intravenous drug abusers, with a coherent funding structure that provides for an ongoing, stable ten year commitment to providing drug treatment services and treatment research.

We estimate that a ten year funding commitment for a treatment program as outlined would be approximately 15:1 billion dollars above current funding levels (approximately 1.5 billion dollars per year). The funding should be accomplished through a 50% federal and 50% state and local matching program. This spending should be accompanied by a commitment to the institution of a national campaign to promote community acceptance of treatment programs.

In a purely financial evaluation, given the fact that temporarily ameliorating the health effects of AIDS can cost as much as $100,000 per person, and imprisonment has an average annual cost of $14,500 per person, and even without considering the previously cited astronomical costs of drug abuse to the nation, the investment necessary to provide for IV drug abuse "treatment on demand" is sound public policy.

The major treatment modalities for dealing with IV drug abusers, including methadone maintenance and drug-free residential therapeutic communities, have demonstrated their effectiveness in reducing illicit drug use, improving employment among addicts, reducing criminality, and improving social functioning. However, rates of effectiveness of treatment are directly related to retention in treatment. Therefore, attention must be paid to improving the quality of treatment to retain clients until they are rehabilitated. Rehabilitation is a long-term process which focuses on maintaining productive behavior and minimizing relapse to chemical dependency.

The Commission has identified the following obstacles to progress in the provision of treatment services nationwide:

- The National Institute on Drug Abuse estimates that there are 6.5 million people who are using drugs in a manner which significantly impairs their health and their functioning, 1.1 to 1.3 million of whom are IV drug abusers. At any given time there probably are not more than 250,000 drug abusers in treatment, of whom 148,000 are intravenous drug abusers. This lack of treatment capacity has resulted in three out of four cities in the U.S. reporting long waiting

lists for treatment, in some cases as long as six months, during which time IV drug abusers continue to use drugs intravenously several times each day, increasing their risk of contracting and spreading AIDS.

o Current treatment capacity in most parts of the country can be increased by approximately 20% with the addition of treatment funds. Further expansion could go beyond the capacity of the nation's existing infrastructure and may require an increase in "bricks and mortar" and a concerted effort to recruit and train new treatment personnel.

o The treatment system will require a substantial commitment of funds by the Federal, state, and local governments and private care providers to expand capacity and improve the quality of treatment. Expansion must be accomplished expeditiously, and collaboration among Federal, state, local, and community officials and treatment providers is needed to design innovative plans for reducing barriers to expansion. This expansion should incorporate effective treatment models which have already been demonstrated to be cost effective. As an interim emergency measure we may need to establish minimal service or holding clinics, but as soon as possible patients must be admitted to programs with full services, including psychological counseling and medical care.

o The presence of HIV infection in the drug abusing population has generated a decline in the overall health of this population, with dramatic increases in deaths from bacterial pneumonia, tuberculosis, endocarditis, nephritis, and a wide variety of other infections.

o Establishing community-based treatment programs has been hampered by the "not in my neighborhood" syndrome.

o Many community services which could provide much needed support to clients in drug treatment programs are not being well coordinated in local communities.

o Additional trained staff and in-service staff training are needed in the treatment field. The advent of AIDS has increased the already heavy burdens on treatment staff. In addition to their regular duties they are now faced with the need to educate their clients on HIV-related issues, risk reduction activities, and, in many cases, the psychosocial needs of dying clients.

o The special needs of women of childbearing age have become more pronounced, pointing out the need for special programs to deal with addicted women, addicted pregnant women, and their children.

In response to these obstacles, the Commission recommends the following improvements in the treatment of drug abuse, with emphasis in every instance on appropriate AIDS education and prevention:

(TRE-1) In the near term, the National Institute on Drug Abuse, in conjunction with single state agencies, local drug abuse officials, and drug treatment provider representatives, should develop a strategic plan for increasing the capacity of the drug treatment system so that the goal of treatment on demand can be met. The plan should include the designation of an implementing office with the staff and technical capacity to guide the implementation of the plan and the provision for matching federal funding with state and local entities on a 50% federal and 50% state/local basis. The plan should also include elements to insure the quality of care. The planning process should include mechanisms for a phased, targeted increase in programs with an evaluative component to review progress and make appropriate adjustments.

(TRE-2) Unless subject to undue delay, the Alcohol, Drug Abuse, and Mental Health Block Grant should continue to be the mechanism for the disbursal of treatment funds. However, provisions must be made for expediting disbursements, targeting the money to the areas with the largest IV drug abusing populations. If using the block grant mechanism initially would cause undue delay, methods such as state and citywide contracts which could later be folded into the block grant should be considered.

(TRE-3) Alcohol, Drug Abuse, and Mental Health Block Grant funds should be directed to activities that stimulate and facilitate entry into the treatment system. These activities should include, but not be limited to: aggressive outreach services to drug abusers; telephone hotlines that provide treatment information and initial access to treatment programs; centralized assessment, referral, or intake units; linkages between drug abuse programs and community service agencies, criminal justice and corrections systems, employers, schools, churches, clinics for treatment of sexually transmitted diseases, prenatal clinics, mental health professionals, marriage, family, and sexual counselors and therapists, hospice care, AIDS crisis networks and coalitions; and mechanisms for identifying, developing, and cataloguing treatment resources within the community.

(TRE-4) Federal constraints on the use of funds to construct, expand, and renovate facilities for IV drug treatment should be made more flexible in order to respond to increased treatment needs. In addition, a wide range of

Federal and local financing arrangements for community-based treatment programs should be carefully considered.

(TRE-5) An estimated 1,200,000 IV drug abusers reside in 24 U.S. cities. Treatment should be expanded in those cities on an expedited basis by involvement of state, city, local, and community officials in identifying facilities which could be used for drug treatment, including hospitals, clinics, and other buildings which can be adapted to provide drug abuse treatment. Approximately 3,300 new facilities may need to be developed.

(TRE-6) As an interim step until new treatment facilities can be developed, state drug abuse agencies should give consideration to contracting with human service professionals or organizations to serve as case managers for drug abuse clients. Case managers, who need not be affiliated with traditional drug abuse facilities, could procure medical, educational, job training and social services, and other necessary services, from existing community resources. They could assess client needs, develop individualized treatment plans, procure services, and monitor service delivery. The federal government should provide demonstration funds for projects that integrate the case management approach with the use of external community resources as service providers.

(TRE-7) Special model demonstration programs for community-based recipients should be developed by the National Institute on Drug Abuse focusing on ethnic minority populations which have been disproportionately impacted by the HIV epidemic. In addition, grants should be made available to local communities which are designing and implementing community-based treatment programs which are integrated with community services and supported by community leadership. Specially designed demonstration programs should be developed to serve the treatment needs of teenage IV drug abusing populations.

(TRE-8) Drug abuse is a disease of the whole person involving multiple areas of functioning. For treatment approaches to be effective, they must ultimately address many dimensions of the client. Those funding and administering drug treatment programs should become more flexible, focusing not only on drug abuse behaviors but also on other dimensions of the client's life (e.g. educational and vocational deficiencies and family dysfunction) that may contribute to drug abuse. More emphasis needs to be placed on matching treatment with client needs. Programs should increase their range of services in the context of individualized treatment plans. Services should not be limited to those that can be provided within a program's own

facilities or by its own staff. There should be more extensive use of generic services available in local communities which can aid in the rehabilitation of the drug abuser. This will require a focus on continuity of care, whether services are provided in one facility or in a number of community facilities. Publicly funded community-based care facilities should be required to cooperate in the effort to coordinate services and monitored by appropriate authorities.

(TRE-9) Treatment programs should experiment with a variety of strategies to encourage participation including extended hours of operation, operation during unusual hours, provision of mobile treatment units, satellite clinics in medical facilities open 24 hours, and storefronts in local communities immediately available to respond when addicts are ready to enter treatment. Results of these efforts should be carefully evaluated.

(TRE-10) Effective treatment, especially in this era of AIDS, includes dealing with the health care needs not only of patients but also of their families. Treatment should involve on-site provision of primary services or referrals to community health centers, mental health centers, and other accessible community-based health care resources.

(TRE-11) Special programs should be available to serve IV drug abusers who are women of childbearing age, pregnant, or mothers. These programs need to be comprehensive, providing for treatment as well as such services as prenatal and postnatal care, day care facilities, family planning, HIV testing, counseling, and specialized child welfare services. Extended hours for the provision of services are essential.

(TRE-12) Drug treatment programs must aggressively provide AIDS prevention and risk reduction education for clients and their sexual partners. Information must be provided on the dangers of needle and paraphernalia sharing, the immunosuppressive effect of drugs including non-IV drugs, sexual transmission, and risks to the unborn. Voluntary HIV testing should be strongly encouraged for clients, their sexual partners, and children of IV drug abusing mothers and of sexual partners of IV drug abusers in conjunction with an organized test-linked counseling program.

(TRE-13) Political and community leadership should be exerted to reduce barriers to establishing community-based treatment facilities in appropriate locations. In communities where there is a high incidence and prevalence of drug abuse and a proven need for drug abuse rehabilitation programs but continued resistance to their establishment, Health Commissioners should review the

possibility of invoking emergency health measures to overcome this inertia and resistance.

(TRE-14) Quality assurance needs to be reexamined. The drug abuse treatment field needs better to define quality of care, and establish and refine standards for its programs and practitioners. States should reexamine their licensing procedures for drug abuse treatment programs. The Federal government should support treatment outcome studies and the development of scientifically based quality assurance mechanisms.

(TRE-15) A significant increase in trained personnel will be necessary in order to implement new programs. (Approximately 32,000 individuals will be needed to join the ranks of drug abuse workers.) Staff training should be enhanced through developing new programs at community colleges, universities, vocational and technical schools, through offering internships in existing drug programs, and through training of ex-addicts. Curricula should be developed and instituted throughout the medical, nursing, and social service provider educational systems dealing with education in and prevention and treatment of substance abuse as well as AIDS. Federal leadership is needed in the fostering and identification of model curricula for training programs as well as establishing drug abuse prevention, treatment, and research as viable and rewarding professions.

(TRE-16) Ongoing staff development activities and training for drug abuse treatment providers must include in-service education and skill development related to AIDS such as education in the modes of HIV transmission and the prevention of HIV transmission.

(TRE-17) Consideration should be given by state judicial and correctional systems to assigning individuals to drug treatment programs as a sentence or in connection with sentencing. For persons convicted of drug-related offenses or convicted on non-drug related offenses but found to be drug abusers, in instances where probation authorities recommend alternative programs to prison confinement, the convicted persons should be placed in an appropriate drug treatment program. To assure program compliance, the convicted person should serve his or her prison sentence for violation of the terms of the drug treatment program.

The Commission will further review incentives to promote user responsibility in its hearings on societal and legal issues.

SECTION 2: TREATMENT RESEARCH

Commission research among experts in the field has led us to the conclusion that improved and expanded research efforts focusing on IV and other forms of drug abuse and HIV will require a commitment of 18 million dollars per year above current funding over the next ten years. Funding priorities should follow guidelines set forth below.

The Commission has identified the following obstacles to progress in treatment research:

- o IV cocaine use has been increasing in the U.S. and, while there are pharmacological treatments for IV heroin use, there are no such proven pharmacological agents for IV cocaine use.

- o Efforts to be innovative in the treatment field have not been aggressive. There has been insufficient experimental work with new procedures and model treatment program development that can be distributed to the field.

- o Due to inconsistent levels of funding, treatment researchers have often sought other, more stable fields in which to work.

- o Grant and contract cycles are often too protracted to meet the urgency of the HIV epidemic.

- o Data are not being collected on the drug abusing community in a uniform way to provide the basis for responsive policy decisions.

In response to these obstacles in treatment research the Commission recommends the following:

(RES-1) The National Institute on Drug Abuse (NIDA) should expand their comprehensive research program giving particular emphasis to developing strategies for the treatment of IV cocaine use.

(RES-2) NIDA should sponsor additional research to determine characteristics of clients whose success in a particular treatment modality could be predicted.

(RES-3) NIDA should sponsor additional research in the following areas: improved pharmacological agents for drug abuse treatment, including narcotic antagonists, mixed agonist-antagonists, non-pharmacological strategies and more effective delivery systems.

(RES-4) NIDA should fund research to develop improved service delivery and treatment methodologies and innovative types of treatment. Results should be disseminated to the field.

(RES-5) Federally sponsored research should be conducted on the effects of drug abuse on the immune system in order to determine the effectiveness of HIV transmission to and from drug abusers and to prevent HIV-infected individuals from progressing to AIDS.

(RES-6) The grant processing cycle must be shortened throughout the government to provide expedited procedures for review and approval of applications for grants related to AIDS research in general and as it relates to drug abuse research in data collection, demonstration programs, prevention and treatment research.

(RES-7) NIDA-funded studies should be undertaken expeditiously to provide adequate data on the number of drug abusers, the number in treatment, the HIV rates among drug abusers, and baseline research into the sexual patterns of drug abusers. The data can be used to promote detailed planning by the Federal government, states, cities, and communities. Also needed is research examining characteristics of addicts which lead them to respond to various types of social and environmental pressures. Since success rates in treatment are related to length of stay in treatment, research to determine methods of enhancing retention in treatment should continue.

SECTION 3. DRUG ABUSE PREVENTION

Primary or overall drug abuse prevention requires the sustained efforts of parents, educators, community leaders, and all levels of government, collaborating to develop effective new prevention approaches and expand existing prevention programming. Community organizations, religious institutions, and schools should be encouraged to design "value oriented" educational programs to discourage drug abuse and to encourage rehabilitation. We estimate the prevention effort will cost 30 million dollars per year over current funding.

The Commission has identified the following obstacles to progress in implementing drug abuse prevention:

- o Prevention strategies need to be evaluated over long periods of time; such a process is complicated by the multitude of factors that influence human behavior, slowing determinations of effectiveness of various strategies and even further slowing dissemination of model programs.

- o Funding for prevention research has not always been consistent, leading to the migration of researchers in and out of the prevention research field and unevenness in the productivity of the research effort.

- o Coordination of efforts linking school to community to religious institutions to family to individual, presenting a consistent message, is fundamental to eliminating confusion about drug abuse among children, yet such coordination is sporadic at best.

- o Not enough attention is being paid to providing effective model programs and training community groups in effective prevention programming.

In response to these obstacles the Commission recommends the following:

(PRE-1) The Office of Substance Abuse Prevention should sponsor more research regarding the etiology of drug abuse, who is at greatest risk, and the most effective means of preventing drug abuse.

(PRE-2) The Federal effort should emphasize the development, implementation, and evaluation of model prevention programs with aggressive dissemination of effective models. The current knowledge base of effective prevention and intervention strategies, such as those based on the significant influence of family and peers, should be utilized in developing additional prevention programs.

(PRE-3) To the extent that current research provides the tools to identify young people at risk for drug abuse through their behaviors, the Office of Substance Abuse Prevention should make this information, as well as proven intervention techniques, widely available through publications, conferences, training sessions, and a national clearinghouse.

(PRE-4) Educators should design and offer training courses on drug abuse prevention and intervention at both the undergraduate and graduate levels as well as programs to train specialists with the expertise needed to develop and implement drug abuse and AIDS prevention efforts in ethnic minority communities. Special training should be designed for health professionals and alcohol and drug counselors which should include the latest information on prevention of high risk behaviors.

(PRE-5) Local community plans for developing human resources within minority communities for the drug abuse and AIDS effort should be developed and implemented on an urgent basis.

(PRE-6) The Federal government should provide support for regional workshops designed and implemented to provide educators, parent groups, voluntary organizations, and community leaders with the skills to conduct effective prevention programming to meet local needs.

(PRE-7) Community and parental involvement should be sought in community-wide drug abuse programming. Developing public commitment to the elimination of drug trafficking should be an integral part of this effort.

(PRE-8) Innovative community-based prevention programs should be implemented, such as culturally significant and current modes of communication, like "Rap" contests on preventing drug abuse and AIDS, and peer youth training aimed at preventing initiation into the drug culture.

(PRE-9) Current information and prevention strategies should be utilized widely within our education systems and communities in order to create an atmosphere which promotes drug-free lifestyles. Educational materials and prevention strategies must be age-appropriate and culturally relevant.

(PRE-10) Media should be urged to increase their involvement in providing public service time for appropriate messages on drug abuse and AIDS. Additionally, programming should include accurate messages on the consequences of drug abuse.

(PRE-11) HUD, in conjunction with state drug abuse agencies, should give special attention to public and other low income housing to assist in creating a drug-free environment for our youth. Communities in public housing seeking to establish drug abuse prevention programs should be offered the organizational support of drug abuse prevention specialists and the funding to support drug abuse education and prevention campaigns.

(PRE-12) Schools, churches, and religious institutions should be encouraged to design appropriate value-oriented educational programs to discourage drug abuse and to encourage rehabilitation.

SECTION 4: OUTREACH EDUCATION

Although education is one component of an outreach effort which should be an ongoing and persistent process, it alone cannot necessarily change behavior. Targeted information, coupled with intervention and treatment, is more likely to produce the desired behavior change. The outreach effort will cost 126.5 million dollars per year in addition to current funding.

The Commission has identified the following obstacles to progress in the provision of outreach education:

o Because they are engaged in illegal activity, drug abusers are frequently alienated from society and thus more difficult to reach through the usual education mechanisms. However, contrary to common belief that IV and other types of drug users do not care about their health, outreach efforts thus far have identified concern among drug users about AIDS and a willingness to change behavior in order to reduce the risk of developing it.

o Currently, much needed outreach is being conducted in high incidence areas; as that work continues and is expanded, low incidence communities must not feel any sense of complacency. The time is short from introduction of HIV into a drug abusing population to the increase of the prevalence of the infection in that community. Action must be taken in advance to prevent the spread of the virus.

o In reaching drug users, the most effective technique demonstrated so far has been the use of indigenous street outreach workers, often ex-addicts, who are recruited and given intensive training on HIV and its spread. Many more of these trained outreach workers are needed, and they should be provided with written material to distribute and

should initiate conversations with drug users near shooting galleries and other places frequented by drug users, engaging in one-on-one communication and education.

o Outreach workers have noted that when they meet with drug abusers and discuss risk reduction, they are asked for treatment. Unfortunately with nationwide waiting lists for treatment, outreach workers too often do not have treatment to offer. This leaves addicts otherwise ready to receive help with virtually no options.

o With 70% of the perinatally transmitted pediatric AIDS patients being the children of IV drug abusing women or women whose sex partners are IV drug abusers, these women are at increased risk and need many specialized services, which today are in extremely limited supply.

o Many minority communities are facing disproportionate rates of HIV infection; too few targeted outreach programs are currently being designed and implemented for these communities.

o Verbal one-on-one communication within this group appears to be the most effective means of communicating health messages. We do not hesitate to solicit the help of religious institutions to reach this population. Television and radio can also be effective if appropriate assessments are made of peak viewing and listening times. More needs to be done in this area.

In response to these obstacles in outreach education the Commission recommends the following:

(OED-1) Additional research should be sponsored by NIDA to determine which techniques are effective in producing behavior change among IV drug abusers. Particularly needed is research examining the most effective ways of educating ethnically and culturally diverse groups. Since time is critical, research must take place in conjunction with the institution of programs.

(OED-2) While drug using populations in high HIV prevalence regions are targeted, local communities in low incidence areas should recognize the threat of HIV spread and act expeditiously to encourage drug users to seek treatment to prevent further spread of the infection. While treatment has proven an effective means of reducing the rate of spread of the HIV, without intervention in both low and high incidence communities, the spread of the epidemic will not be stemmed. Outreach programs to the drug abusing population should therefore be expanded in both high and low incidence areas. In addition, communities with low

seroprevalence rates currently in their IV drug using population should engage in prevention and education campaigns to keep those rates low.

(OED-3) Expansion of the treatment system and expansion of outreach efforts should be carried out in conjunction with one another. Outreach workers must have treatment programs available to offer drug users who are willing to take action. Education without treatment is not enough.

(OED-4) Programs aimed at prevention, intervention, and rehabilitation among intravenous drug users should include outreach to their sexual partners. All providers of care in substance abuse programs should be enlisted in efforts to prevent sexual transmission of HIV.

(OED-5) Creative outreach programs should be designed and implemented to reach drug users and adolescent runaways in homeless shelters, shooting galleries, hospitals, and other places where addicts congregate. Innovative outreach techniques should be utilized, including such ideas as the distribution of coupons to be redeemed for drug treatment and the use of mobile vans. One-on-one communication should be supplemented by the use of flyers, posters, and other creative means of supplying information.

(OED-6) Outreach should have an AIDS prevention and risk reduction emphasis, focusing on the risks associated with needle and paraphernalia sharing as well as sexual and perinatal transmission.

(OED-7) Training of street outreach workers and staff should be continued and expanded. Ex-addict street educators should be integrated with community-based treatment staffs familiar with the communities within which they work and reflecting the ethnic composition of the communities.

(OED-8) Prevention programs for minorities should be established at the grassroots level, and on a one-to-one basis with peer contact, in shooting galleries and neighborhoods. Information transmitted must be understandable, culturally sensitive, and direct. Ethnic minorities should be included in the process of planning, developing, and implementing such efforts.

(OED-9) Special outreach should be targeted at female IV drug users and female sexual partners of IV drug users, of childbearing age. All providers of women's health care should be enlisted in efforts to prevent sexual transmission of HIV. Most women who visit a women's health care provider, whether it be for family planning or a routine checkup, have no other health contact annually.

(OED-10) Maximal efforts should be made during prenatal care and delivery to avoid increasing the risk of infection of neonates by infected pregnant women.

CARE RECOMMENDATIONS

The health care needs of persons infected with HIV are varied and complex and present new difficulties for the current health care delivery system. The health care community is responding to meet this unique challenge as best they can, but much more needs to be done.

Further, the Commission's examination of health care for persons with AIDS has revealed several areas in urgent need of attention which, if given, will not only benefit HIV-infected persons, but also promote better delivery of care to persons with other chronic illnesses. As these many issues are addressed, the result will be improved care both for persons infected with HIV and for persons with other major illness.

The extensive topic of health care is discussed in this report in six subsections, each related but discrete. These areas include health care provider education, health care systems, psychosocial needs, nursing care, minorities and underserved populations, and information coordination and exchange.

This portion of the report provides, for each of the above segments, background information on the issues studied, identification of obstacles to progress, and specific recommended solutions.

SECTION 1. HEALTH CARE PROVIDER EDUCATION

A well educated, skilled, and concerned health care community is not only vital to the task of caring for those who are ill, but during this critical time when great fear and misunderstanding about the HIV epidemic exist within our population, the leadership established by providers of health care to persons with AIDS is crucial to fostering a sense of compassion and rationality among all our citizens. When health care professionals care for all patients who need their help, regardless of HIV infection status, and do so without reservation or trepidation using time-tested infection control methods, they communicate to all people that calmness and reason can prevail over panic and anxiety as we confront this epidemic.

There is clearly a need for more knowledge about HIV among many health care providers, an issue which was repeatedly raised by expert witnesses at the hearings on care. There is also a need for an effective, coordinated response within the health care community to promote adequate education for every provider about modes of transmission, prevention, recognition, and management of HIV infection.

The Commission has identified the following obstacles to progress in health care provider education:

- The professional education system has not moved synchronously with the HIV epidemic, and as a result there are significant gaps in knowledge among many providers about management of this illness. There are currently no comprehensive data, within medical college accreditation bodies or elsewhere, on how medical schools have adapted their curricula to assure that medical students are being prepared to treat or prevent HIV-related illness, and there is no existing coordinated plan on how to meet future needs.

- Education for graduate physicians in specialty training, and continuing education for practicing physicians, may or may not address HIV prevention and treatment, and as a result many physicians are severely lacking in knowledge about AIDS.

- Dental professional education, according to dentists themselves, has been especially lacking in providing education about management of persons infected with HIV. This has resulted in limited access to dental care for persons with AIDS.

- The nursing profession also has need for more education about HIV. While nursing has formally studied AIDS educational programs at American colleges of nursing to consider proposals for curriculum changes, and while there have been several initiatives to educate practicing nurses, this response is still inadequate to meet current and projected needs for more education.

- Pre-hospital emergency care providers (paramedics, firefighters, and police) have an immediate and continuing need for more education about infection control, because their frequent exposure to blood and body fluids, in handling all types of patients in uncontrolled settings, places them at increased risk of exposure to the virus.

- Providers of allied health care (including social workers, therapists, aides, laboratory personnel, and many others) are also in need of more complete education about HIV, because their educational background may not have provided sufficient information about infection control and other aspects of providing care to persons with HIV infection.

In addressing these obstacles to progress in health care provider education, the Commission recommends the following: (N.B. Cost estimates are in addition to current federal allocations.)

(EDU-1) The Liaison Committee on Medical Education (of the Association of American Medical Colleges and the American Medical Association), which accredits medical colleges, should immediately determine how medical colleges are modifying curricula to assure adequate education about prevention and treatment of HIV infection. A model plan for curriculum structure, by which medical schools can develop individualized programs to best meet local needs and circumstances, should be developed and made available to member institutions of the American Association of Medical Colleges. The Health Resources and Services Administration's Multidisciplinary Curriculum Development Conference on HIV Infection, in November 1987, produced consensus recommendations useful for this purpose.

(EDU-2) The State regulatory agencies which issue licenses for health care providers should encourage completion of comprehensive continuing education programs about HIV, with particular attention to prevention and infection control. Professional societies should assume the responsibility for seeing that every health professional is educated concerning the disease of AIDS.

(EDU-3) Health professions' educational institutions should provide faculty development programs so as to assure that faculty are adequately prepared to educate students about aspects of HIV. Faculty development grants should be provided by the Federal government, to be administered by HRSA Bureau of Health Professions, and with matching State funds.

Estimated cost: Federal dollars: $5 million
State dollars: $5 million

(EDU-4) Health professional organizations and societies should immediately develop plans for assessment of their members' HIV-related educational needs, design ongoing educational programs to overcome identified problem areas, and periodically evaluate effectiveness of these programs. Where possible, educational offerings should be multidisciplinary and incorporate hands-on experience.

(EDU-5) The Department of Health and Human Services should administer a competitive grant or contract

program, or organize consensus conferences, to construct HIV treatment guidelines for practitioners in different practice environments encompassing a range of medical specialties and including other disciplines. The guidelines developed should then be made available to all practitioners who require them.
Estimated cost: Federal dollars: $1.5 million.

(EDU-6) The Centers for Disease Control, in collaboration with the Department of Transportation, the National Institute of Justice, and State and local agencies, should immediately assess current HIV-related educational needs of pre-hospital emergency health care providers (paramedics, emergency medical technicians, police, and firefighters), and implement a program to provide adequate education and training about infection control, to assure that emergency care remains immediately available regardless of HIV infection status, and to allay unrealistic fears. In addition, infection control materials such as gloves, masks, goggles, and protective breathing devices must be available to all providers likely to need them. The certification process of pre-hospital care providers should confirm a sufficient knowledge base about HIV.

(EDU-7) Institutions which employ health care providers, or which benefit from the services of volunteers, should assume responsibility for assuring that personnel are educated about HIV, including epidemiology, modes of transmission, and methods of infection control; also, such institutions should assure that appropriate infection control materials are continuously available and that proper infection control techniques are utilized.

SECTION 2. HEALTH CARE SYSTEMS

It is very clear that the HIV epidemic has had an uneven impact on the U.S. health care delivery system. In low prevalence areas, such as Minnesota, the care system has been much less challenged than areas such as New York, California, or New Jersey. As a result, most of the country has not yet experienced the extraordinary demands on health care delivery systems as are now being experienced in New York. As the epidemic continues, however, most areas should anticipate a significant impact.

As noted throughout this report, persons with HIV infection have a variety of complex medical and psychosocial needs depending on the clinical diseases that they experience and the environment in which they live. During the course of illness, a person may sometimes need acute hospitalization,

at other times may benefit from home care or hospice care. Periodic outpatient follow-up and psychosocial support services may be necessary. The mortality rate for AIDS is very high, and the incidence of neuropsychiatric problems associated with HIV-associated dementia complicates the care provided to people with AIDS.

Although attention is frequently focused on caring for persons with AIDS, many of the same difficulties within the care system are often encountered in meeting the needs of persons with the entire range of symptoms related to HIV infection.

Witnesses before the Commission, in agreement with most experts in this area, noted the importance of establishing comprehensive and coordinated service delivery systems for people impacted by the spectrum of HIV infection in order to reduce fragmentation and cost. San Francisco, largely through the intensive efforts of its gay community, has developed an integrated community-based system of comprehensive services for people with HIV infection. Several other communities are currently developing similar service networks utilizing the San Francisco model.

Currently there are 22 AIDS Service Delivery Demonstration projects being conducted in the United States. These projects are being funded by the U.S. Public Health Service, Health Resources and Services Administration (13 projects), and by the Robert Wood Johnson Foundation (9 projects). These projects are attempting to demonstrate an effective comprehensive model or network of out-of-hospital community-based care for people with HIV infection which is coordinated, efficient, cost-effective, and humane. Recognizing the specific needs and existing resources of its own community or region, each program has or is developing a coordinated network of services including:

- outpatient care (diagnostic, treatment, follow-up, and psychosocial care services)
- in home care (such as high tech home therapies, hospice care, homemaker and attendant care)
- long term care not in the home
- medical support services

Each project includes linkages with acute care hospital facilities which provide care to people with HIV infection and in some cases includes services to children. To assure continuity, a case management model is utilized in each project. Evaluation of these projects will allow the

development of service delivery models which will be available for replication by other communities and regions.

A population which poses unique challenges to the health care system are children with HIV infection. By 1991, there will be an estimated 10,000 to 20,000 cases of pediatric AIDS in the United States. Most cases of AIDS in children are a result of perinatal transmission from infected mothers. Infected mothers and children are typically from poor, drug-abusing, fragmented families. They rely heavily on public insurance like Medicaid and on care and services provided by public hospitals and community agencies. HIV-infected babies, born to mothers who may be unable or unwilling to care for them, often live their brief and tragic lives in the ward of a hospital.

Individuals with hemophilia (especially hemophilia A, a deficiency of Factor VIII), had been a group at very high risk of developing AIDS due to exposure to HIV through contaminated factor concentrate prior to heat treatment of factor VIII. As of January, 1988, the CDC reported 560 cases of AIDS in hemophiliacs (42 in children less than 13 years old). Studies show that 70-80% of hemophiliacs are seropositive for HIV, and 5-20% of their spouses are infected. Approximately 75% of hemophiliacs are served by one of 214 federally funded regional Comprehensive Hemophiliac Diagnostic and Treatment Centers. These centers offer multidisciplinary services including medical, preventive, physical therapy, psychosocial support, dental services, and financial, vocational, and genetic counseling. Data compiled by these centers have shown substantial savings by decreasing hospitalizations and clinic and emergency room visits.

To date, hospitals are the primary providers of care for persons with AIDS through inpatient hospital admissions. A number of acute care hospitals in the U.S. have developed discrete, dedicated inpatient and outpatient units as the core of their AIDS program. Persons advocating these structures assert that quality patient care can be provided in a more efficient and effective manner when delivered by a multidisciplinary team of health care providers dedicated to the care of persons with AIDS. In many areas, specialized AIDS health care teams or units do not exist and persons with AIDS are placed on general medical/surgical units of hospitals (so called "scattered placement") and cared for by a variety of practitioners with different levels of experience in caring for persons with HIV infection.

The costs of caring for persons with AIDS has been shown to be extremely high. Estimates from recent studies calculate the hospital bill for 1985 at $380 million, and economists

project costs of greater than $8.5 billion for AIDS-related medical care by 1991. Financing of care for persons with AIDS is complex, coming primarily from private insurance, Medicaid, and other state, local, and private monies.

The availability of inpatient beds staffed by knowledgeable practitioners for the care of HIV-infected persons is essential. As has been stated, there is also a vital need for a coordinated system of other services to provide quality and cost-effective care. Home care should be made available, particularly for the indigent, covering the range from high tech intravenous therapies to chronic care by attendants or hospice care, as well as long term care and hospice beds for those who do not have a home or cannot be adequately cared for in the home. Reimbursement and funding for these services should be available from a variety of sources.

The Commission has heard testimony both in session and on site visits that indicated that one of the most serious care-related problems facing persons with AIDS is loss of housing. Treatment-related costs and other factors, such as joblessness and loss of family support, contribute to the loss of individual housing, accompanied by a loss of personal autonomy and a decreased ability to continue treatment or maintain good health practices.

Homeless persons with AIDS remain in the hospital because they have no home address to which they can be discharged. Nowhere is this more evident than with the hospitalized infants and children with HIV infection, so-called "boarder babies." Often these children are the product of fatherless homes in which the mother is also sick and destitute. HIV infection in these families is most often transmitted through IV drug abuse. The cost of maintaining a child in a municipal hospital pediatric ward for one year is in excess of $250,000.

Congregate living facilities have been identified as a potential alternative to hospital-based care, and are often able to provide a quality home environment for $60-100 per day, versus $500-1,000 per hospital day. Private sector institutions have begun to provide high quality, cost-effective, and compassionate care for homeless persons with AIDS and their families.

The Commission will continue to evaluate the problems of the homeless persons with AIDS, and the potential solutions posed by model congregate living facilities and scattered site apartments or group homes. The Commission's Finance hearings will study federal and state funding available for these enhanced local services.

Community based organizations (CBOs) have played an enormous role in providing services for persons with HIV infection. The prototypes for these organizations were developed within gay communities nationwide and illustrate, through their diversity and numbers, a self-reliant and vigorous response in coping with the HIV epidemic. CBOs are service and/or information agencies which often provide services not otherwise available through the health care delivery system. They are not-for-profit, indigenous to the locale, rely heavily on volunteers, and are controlled by voluntary boards of directors. CBOs vary greatly in size, number of clients served, and types of services offered. Many CBOs serve a large percentage of poverty level income, minority, and other underserved clients. Services offered by CBOs often include:

- education to clients and the community
- individual, family, and group therapy
- counseling and support groups
- HIV testing and counseling
- outpatient medical services
- home chore teams or buddies for help with day to day tasks
- hotlines
- referrals to home care or hospice care

Most CBOs are funded from a mixture of sources including private donations from clients, families, community members, and religious institutions; other monies come from private foundations, United Way funds, local (municipal and county) government funds, and fundraising efforts. In a few states some financial support is available through the state government. In general, limited Federal funding is available for CBOs. Many medical and social services provided by CBOs are not reimbursable under normal mechanisms. A very large percentage of such services is provided by volunteers.

In addition to the work of CBOs, the Commission recognizes the tireless efforts of many church and other religious organizations in providing compassionate care for persons with AIDS, particularly for those who are most indigent.

The Commission has identified the following obstacles to progress in systems of health care delivery to persons infected with HIV:

- Witnesses before the Commission and other experts expressed concern that our health care delivery system currently is structurally and financially unprepared to deal with the diverse needs of people with HIV infection, as well as those with other chronic illnesses.

- Currently, the vast array of services required for people with HIV infection are uncoordinated or may be available only in pieces. A person with HIV infection is confronted by a complex system of fragmented and expensive services. Reimbursement for these services is variable and generally inadequate particularly for out of hospital care. Indeed, a large and growing number of persons with AIDS are poor and medically uninsured, or covered only by Medicaid or other forms of public assistance. If a wider range of coordinated out-of-hospital services were available, hospitalizations and presumably costs would be decreased.

- The range of services is inadequate to meet the diverse and often complex needs of HIV-infected families (including mothers and children). Again, services that do exist are often not coordinated into any comprehensive system. If a wide range of medical and support services such as day care, home care, respite care, and psychosocial services were available and accessible it would serve to decrease the number of hospitalizations of children with AIDS, possibly increase the quality of life they have, and help to maintain the intactness of the natural family. A striking and costly problem associated with HIV-infected infants is that of babies abandoned to the hospital's care, the "boarder baby" problem. Community-based services designed to support the natural family as well as coordinated programs for foster placement and the availability of transitional placement would substantially reduce the need for boarding babies in hospitals.

- Although hemophilia treatment centers are models of comprehensive care for hemophiliacs, there are unique needs of HIV-infected hemophiliacs and their families which these centers are not adequately funded or prepared to provide.

- Much remains to be learned about the most cost-effective way to manage the care and associated needs of HIV-infected persons without compromising the availability or quality of the care they receive.

- In many areas, zoning restrictions prevent utilization of facilities which might otherwise have provided a site for cost-effective care to persons with AIDS.

- Current systems of care are often fragmented and, in some areas, a large amount of resources are utilized primarily on inpatient care. Focusing more of these resources on outpatient services, home health care, or hospice care is likely to improve continuity of care and to be cost-effective.

In addressing these obstacles to progress in systems of delivery of health care delivery to persons infected with HIV, the Commission recommends the following:

(SYS-1) The Community Health Center Program should be increased to allow for the provision of additional services in high incidence areas to persons infected with HIV. The Federal allocation will provide primary medical and dental care for patients and will also allow for the training of current and new staff.
Estimated cost: Federal dollars: $20 million.

(SYS-2) Federal funding for block grants awarded to the states should be: matched by the states, increased, and made available through the states to community-based organizations providing services for people with HIV infection. Specifically, those funds designated for Community Development should be used for developing housing and day care facilities; those designated for Preventive Health and Health Services should include, but not be limited to, training and support of volunteers; those designated for Education should be used for HIV-related prevention, education, and risk reduction programs; and money for mental health services under the Alcohol, Drug Abuse, and Mental Health Service block grants should be used for, but not be limited to, counseling and support group grants.
Estimated cost: Federal dollars: $25 million.
State dollars: $25 million.

(SYS-3) The Department of Health and Human Services should provide funding to local governments for development of foster care programs for infants whose parents are either unable or unwilling to care for

them and for respite care programs which provide intermittent relief for parents. Foster care programs should include recruitment, training, support, and incentives for foster parents. Respite care should be available to provide respite for natural or foster parents and should include substitute caregivers as well as shelter. Where appropriate, foster and respite care provided through religious institutions should be supported through Federal and State funds.
Estimated cost: Federal dollars: $10 million.
State dollars: $10 million.

(SYS-4) The proposed Pediatric Demonstration Projects (funded by the FY88 Continuing Resolution and allocated to Health Resources and Services Administration) should continue to be funded through 1991. Grants should be awarded to programs which are family-focused, community-based, include a coordinated, comprehensive network of services, and utilize a family case management approach.
Estimated cost: Federal dollars: $5 million.

(SYS-5) The Health Resources and Services Administration, through the Maternal and Child Health Program, should provide funding for demonstration grants for Regional AIDS Comprehensive Family Care Centers in areas where inadequate pediatric services exist and the prevalence of HIV infection is high (this is in addition to demonstration grants mentioned in SYS-4). These centers would provide a full range of services to HIV-infected children, teenagers, and their families including: diagnostic, treatment, and follow-up services, prenatal and well-baby care, testing, counseling, psychosocial support services, day care, respite care, education, and linkages with home care and acute hospital care.
Estimated cost: Federal dollars: $10 million.

(SYS-6) The Federal government, through the Department of Health and Human Services, and the states should provide funds for home health care services for under-insured persons with AIDS. Each state's federal allocation would be based on the ratio of the number of persons with AIDS in the state to the total number of persons with AIDS in the U.S. States should have the option to utilize this allocation for grants to home health care agencies for the provision of care to eligible individuals, for compensation for the planners and providers of care, and for education and training of home health care providers.
Estimated cost: Federal dollars: $12.5 million.
State dollars: $12.5 million.

(SYS-7) The Department of Housing and Urban Development should provide renovation grants to public hospitals to convert acute care beds into long-term care beds for care of HIV-infected patients requiring hospice or other long-term institutional care. In addition, the use of HUD 232 program funds, which help finance construction and improvement of nursing homes and related facilities, should be encouraged in order to make additional long-term care and hospice care facilities available. Eligibility for HUD 232 loans should be expanded to include hospitals for the conversion of acute care beds to long-term care beds. Modifications made should anticipate the likely needs of patients in the 20 to 40 year old age group, recognizing that most current long-term care beds and facilities are designed for care of the elderly.
Estimated cost: Federal dollars: $25 million.

(SYS-8) Current funding to the Comprehensive Hemophiliac Diagnostic and Treatment Centers should be increased to cover the costs of HIV testing, counseling, evaluation of immune system function, and supportive services for the patient and family. Funding of immune system evaluation will enhance the use of the centers for clinical research.
Estimated cost: Federal dollars: $4 million.

(SYS-9) In areas where intermittent or chronic care services availability is encumbered by local restrictions or zoning requirements, such as number of exits required for a building or allowable number of occupants of a facility, local governments should provide reasonable variances to permit such care to be available. The necessity of health care, for both adults and children, should be balanced with local zoning priorities.

(SYS-10) The Department of Health and Human Services, in collaboration with the Department of Housing and Urban Development, should make available construction or renovation grants to communities, with matching State, local, or private funds, for the creation of small group or transitional homes for HIV-infected children, or other children in need awaiting placement in foster homes. These facilities should be constructed for use for day care and respite care as well as transitional homes.
Estimated cost: Federal dollars: $10 million.

(SYS-11) The Health Resources and Services Administration (HRSA) should widely disseminate findings from the AIDS Service Demonstration Projects so that other communities can select and develop the most appropriate and feasible model. The Public Health Service through HRSA and in collaboration with the states should provide initial funding and technical assistance to communities in order to establish services to fill existing gaps and to develop coordinated networks of services. Systems created should include a continuum of services, emphasize alternatives to hospitalization, and utilize a case management approach.
Estimated cost: Federal dollars: $5 million.

(SYS-12) The National Center for Health Services Research should compile data from hospitals using dedicated AIDS units and those using scattered placement in order to compare their effectiveness with respect to cost and quality of care, patient satisfaction, and the effect on staff (i.e., on recruitment, retention, turnover rate, and satisfaction). Findings should be disseminated to hospitals nationwide to help them plan and design the most appropriate structure for service delivery to people with HIV infection.
Estimated cost: Federal dollars: $500,000.

(SYS-13) The Federal government, through HRSA, should provide funding for demonstration grants to study capitation systems for comprehensive HIV care through specialized AIDS care teams, similar to current systems for oncology patients. Examination of this potential care mechanism should be contrasted with currently existing mechanisms to determine which care reimbursement system will result in optimal patient care.
Estimated cost: Federal dollars: $500,000.

SECTION 3. PSYCHOSOCIAL NEEDS

Persons with HIV infection and their loved ones, suffer high levels of distress, depression, and anxiety due to the great degree of uncertainty associated with the diagnosis. There is an often overwhelming task of sorting through changing medical and scientific information in order to make accurate decisions regarding health care and life planning. Much anxiety is created by the many questions about HIV infection which remain unanswered.

More recent findings about involvement of the central nervous system in HIV infection and the possibility of early cognitive deficits, have raised additional concerns. Frequently, dementia occurs in AIDS and, as a result, memory and decision making capacity may be impaired. These issues are of increasingly greater importance as more data become available. Central nervous system involvement of otherwise asymptomatic HIV-infected persons has only recently been recognized and many providers of mental health care may remain unaware of HIV infection as a possible organic etiology in the differential diagnosis of mental dysfunction. Because certain of the central nervous system problems associated with HIV infection, such as secondary infections of the brain, are treatable, this issue is of increasing importance.

Psychosocial and neuropsychiatric services for persons with AIDS are provided by paid or volunteer social workers, psychologists, religious counselors, nursing staff, primary care physicians, or psychiatrists working in a hospital, private office, or community-based outpatient setting. Services include psychiatric assessment, crisis intervention, individual or group therapy, marriage and family counseling, and sexual counseling and therapy. Less intensive counseling, from a variety of sources with a wide range of expertise, is also generally provided with HIV testing.

The Commission has identified the following obstacles to progress in HIV-related psychosocial services:

- Availability of trained personnel qualified to provide psychosocial services for persons infected with HIV or their significant others, varies across the country. In many areas, an insufficient number of staff are available to respond to current needs and this shortage will increase as the number of persons with AIDS increases.

- Psychosocial services are frequently unavailable to persons needing this type of care because of reimbursement policies which often do not allow for outpatient counseling or mental health services. Commonly, only the services of a psychiatrist are reimburseable.

- Counseling about sexual behavior as a potential means of transmission of HIV to others is not always available to HIV-infected persons during hospitalization.

- The psychological burden on health care providers who care for persons with AIDS is severe and many providers may leave the profession if they have difficulty coping with these stresses. They may also face suspicion or intolerance from members of the general public who may fear that the providers themselves have become infected through their work.

- Many health care providers have not received adequate education about the psychosocial needs associated with death and dying and also have not received sufficient education about the psychosocial aspects of human sexuality. As a result, some providers are limited in their ability to meet these specific needs in HIV-infected persons or their loved ones.

In response to these obstacles to progress in psychosocial services, the Commission recommends the following:

(PSY-1) The Federal government, through the Health Care Financing Administration, should conduct a three month study of costs and reimbursement policies for mental health services for persons infected with HIV and should report these findings to the Commission by June 1, 1988.

(PSY-2) Facilities which currently care for persons infected with HIV should be encouraged to make available psychosocial care as needed, within the limitations of each facility's resources. Care may be provided by psychiatrists, psychologists, psychiatric nurses, social workers, marriage counsellors, sexual counselors and therapists, family counsellors, or religious counselors, as appropriate. All providers of psychosocial services should be enlisted in efforts to prevent HIV transmission.

(PSY-3) Institutions which employ providers of health care to persons infected with HIV should provide psychosocial support to their staff on a proactive and continuing basis.

(PSY-4) Health care provider educational institutions should critique current curricula and make changes necessary to assure that students are provided adequate education regarding human sexuality in order to be prepared to provide appropriate care to all patients including those infected with HIV.

(PSY-5) Health care provider educational institutions should assure that students are educated about patient and family needs associated with death and dying and prepared to provide care appropriate to these needs.

(PSY-6) Federally funded community mental health centers should develop programs targeted for persons infected with HIV and their loved ones. To ensure the availability of these services, the Alcohol, Drug Abuse, and Mental Health Services block grant funding should be increased.
Estimated cost: Federal dollars: $5 million.

(PSY-7) The Federal government, through the National Institute of Mental Health, should continue to provide funding for development of psychosocial and neuropsychiatric provider education and training programs to ensure continued availability to those who need such care in the future.
Estimated cost: Federal dollars: $5 million.

SECTION 4. NURSING CARE ISSUES

The role of nursing in providing care to people with HIV infection cannot be studied without acknowledging a deepening shortage of nurses in the workforce. In addition, the stresses associated with providing care for chronically ill patients in need of long-term and terminal care, combined with a potential, albeit small, risk of exposure to infectious agents may influence the choice of nursing as a career for some people.

The American Nurses' Association is clear about nurses' ethical obligation to care for HIV-infected persons. The Committee on Ethics states "Nursing is resolute in its perspective that care should be delivered without prejudice, and it makes no allowance for use of the patient's personal attributes or socioeconomic status or the nature of the health problems as grounds for discrimination." Nurses have a basis of scientific knowledge which enables them to provide quality care to HIV-infected persons in a safe and effective manner. Nurses are educated to provide for the physical, psychological, emotional, social, and spiritual needs of clients in their care. Nurses have the responsibility, as do all health care professionals, of equipping themselves with accurate information about HIV and the care of HIV-infected persons.

Nurses are currently providing care to people, including people with HIV infection, in a variety of health care settings such as hospitals, clinics, home care, hospice, nursing homes, schools, occupational sites, and others.

However in the hospital setting alone, the vacancy rates for registered nurses exceed 13%. Recommendations to ensure an adequate supply of appropriately prepared nurses for care of the HIV-infected patient will be within the context of a general shortage of nurses in the workforce. Planning must include strategies for retaining nurses in the workforce once educated. The issues of salary compression (the narrow range of salaries in which nurses top out early in their careers) and restrictions of full use of judgment are major causes of nurses leaving nursing for other careers.

The Commission has identified the following obstacles to progress in the delivery of nursing care to people with HIV infection:

- Preliminary projections by the Department of Health and Human Services for the year 2000 indicate that 1,743,000 nurses will be needed. This reflects a need for 38% more nurses than were required in 1985. Simultaneously, enrollment in schools of nursing continues to decline necessitating clear, deliberate action on the part of the health care industry and the State and Federal governments to promote the profession of nursing.

- The level of compensation provided to nurses is markedly lower than necessary to attract and retain adequate numbers of individuals to the field. Reports have repeatedly been made that different levels of education, skills, and expertise, as well as the personal sacrifice requisite in a nursing career are inadequately rewarded at current compensation levels.

- Federal funding for nursing training and education has remained constant over the last several years, rather than being increased to meet increased need.

- The traditional mechanisms available for students to finance nursing education consist of a patchwork combination of scholarships, loans, workstudy programs, work payback programs, and traineeships. Sources of these funds for BSN, MSN, and doctoral nursing students have been cut or lost. In addition, the average age of nursing students is rising, creating a large number of non-traditional students. The way in which financial need is calculated at times penalizes adult learners by disallowing deductions for adult financial obligations such as dependents, home mortgages, etc. These criteria limit a student's ability to obtain grants or loans.

- The U.S. Public Health Service Division of Nursing traineeship funds are available only to RNs who seek to continue their professional education by pursuing a higher degree. Non-RNs pursuing nursing as their first professional degree are not currently eligible for traineeships.

- The demand for highly educated nurses to manage the sophisticated health care needs of tomorrow exceeds the supply. The projected supply of BSN nurses for the year 2000 is 596,600 full time equivalents, while the projected demand is set at 853,800. The supply of masters and doctorally prepared nurses is projected to be 174,900 while the requirement is projected to be 377,100. The most acute shortage in nursing generally -- that of nurses with higher levels of education -- is made more acute by the intensive training needed for the care of patients affected by HIV. The number of nurses trained to the associate degree or diploma level is projected to be more than adequate for the nursing positions which can be filled by those at these lower educational levels. It is not, then, so much a problem of overall numbers of these nurses, but an acute problem of too few nurses pursuing training beyond the most elementary level of registered nursing education.

- The nursing care of persons with AIDS is complex and intensive and consumes a disproportionate amount of nursing time and hospital resources.

- The acuity of disease of persons with AIDS, the complexity of their physical and psychosocial needs, the high fatality rate, and the fear of exposure to HIV, along with understaffing in many facilities, create a potential for considerable stress, burn-out, and turnover.

In response to these obstacles to progress in HIV-related nursing care, the Commission recommends the following:

(NUR-1) The PHS Division of Nursing should fund demonstration projects to evaluate models of nurse-managed care for persons with AIDS or other chronic illness. Included should be an evaluation of the Community Nursing Organization concept (as described in the Community Nursing and Ambulatory Care Act of 1987) applied to the care of HIV-infected persons. In addition, models of differentiated nursing practice based on educational preparation should be evaluated. Estimated cost: Federal dollars: $5 million.

(NUR-2) Research initiatives at the National Center for Nursing Research should be expanded. Priority should be given to areas already identified by the NCNR and the NIH and the grant funding process for AIDS-related research should be expedited. Nurses should be encouraged to submit grants for AIDS-related research to the appropriate institutes at the NIH.
Estimated cost: Federal dollars: $1.5 million.

(NUR-3) The Public Health Service Division of Nursing should alleviate restrictions for nurse traineeships and provide funding for stipends for full-time and part-time nursing students. Traineeships should be available for RNs pursuing higher degrees as well as for those students who are not yet registered nurses but are pursuing nursing higher education.
Estimated cost: Federal dollars: $8 million.

(NUR-4) The National Institute of Mental Health should reinstate funding for traineeships to educate psych-mental health nurses at the BSN, MSN, and doctoral levels.
Estimated cost: Federal dollars: $1.5 million.

(NUR-5) Funding for the current Nursing Student Loan Program should be increased and eligibility requirements for low interest loans should be modified.
Estimated cost: Federal dollars: $3 million.

(NUR-6) Nursing work-study programs should be established by the federal government to provide tuition support for education and living expenses. Such programs would have a greater forgiveness clause for students working in facilities which provide care to persons who are infected with HIV, including hospitals, long term care facilities, community-based organizations, drug treatment facilities, and others.
Estimated cost: Federal dollars: $10 million.

(NUR-7) Hospitals, other employers of nurses, and schools of nursing should be encouraged, in conjunction with the federal government, to provide both financial and scheduling incentives for Associate Degree and Diploma nurses to pursue more advanced degrees in nursing (BSN and MSN level) because of a greater need for BSN and higher degree nurses in the workforce.
Estimated cost: Federal dollars: $5 million.

(NUR-8) Nursing organizations in conjunction with the Division of Nursing in the Health Resources and Services Administration should establish guidelines for health care institutions for the implementation of

counseling and support services for nurses caring for HIV-infected persons with appropriate mechanisms for assuring their implementation.
Estimated cost: Federal dollars: $50,000.

(NUR-9) The Area Health Education Centers Program (AHEC) Special Initiative Funding should be increased to include funds to establish communication channels and outreach programs to reach nurses in all settings within the region. These channels should be used to disseminate updated information concerning the care of HIV-infected persons. The AHECs should establish appropriate training strategies for nurses within their region to learn about HIV and AIDS, including strategies such as "train the trainer," and clinical hands-on experiences.
Estimated cost: Federal dollars: $5 million.

(NUR-10) Additional funding should be provided through PHS Division of Nursing Special Project grants in collaboration with the American Hospital Association, the Association of Nurse Executives, and other professional organizations for the development of innovative strategies designed to increase retention of nurses in practice.
Estimated cost: Federal dollars: $250,000.

SECTION 5. UNDERSERVED AND MINORITY POPULATIONS

In 1985, the Secretary's Task Force on Blacks and Minority Health reported that minorities suffer excess deaths from several diseases including cancer, cardiovascular disease, and chemical dependency. The report also described the problem of minority access to health care for persons living in medically underserved areas.

The impact of HIV infection on minority communities has been felt very strongly. While Blacks and Hispanics comprise 19 per cent of the U.S. population, cases of AIDS reported to the Centers for Disease Control show 39 per cent are occurring among Blacks and Hispanics, with Asians and American Indians accounting for another 1 per cent. The heterosexual transmission which is occurring affects significant numbers of minority women and their children.

During the Commission's site visit to Belle Glade, Florida, it was very clearly evident that this area and other areas like it, will face a health care crisis when the National Health Service Corps physicians, who provide the only health care available to this city, complete their obligation and leave.

It is estimated that 34 million persons in the U.S. live in areas or in groups which are in health care shortage areas. To meet the needs of these underserved areas, the services provided through the National Health Service Corps have been of extraordinary value over the last 18 years. Persons with AIDS are now underserved in many parts of the country.

The primary mission of the National Health Service Corps (NHSC) from its inception in 1970 has been to provide primary care services to isolated or underserved areas and to populations which for a variety of reasons such as economic or geographic barriers, minority status, language, cultural or other constraints are unable to obtain basic health care.

The majority of personnel serving in the NHSC have been physicians. Also included have been dentists, pharmacists and podiatrists. In 1986, the program reached its peak field strength of approximately 3200. Its current enrollment of 2800 are serving in federally funded Community Health Centers (CHCs) and Migrant Health Centers (MHCs) as well as facilities operated by the Indian Health Service (IHS), the Bureau of Prisons (BOP), and through private practice arrangements.

However, due to the elimination of scholarships since 1981, the number of obligated physicians will be decreasing to less than 100 NHSC providers available for assignments by 1994.

As of November 30, 1987, 508 NHSC physicians and 27 NHSC dentists were serving in facilities within the 30 standard metropolitan statistical areas (SMSAs) with the highest incidence of AIDS cases.

The Commission has identified the following obstacles to progress in HIV-related health care delivery to underserved and minority populations:

- Within 30 SMSAs there are a total of 237 primary care or dental care health manpower shortage areas which are served by NHSC personnel in CHCs, MHCs, etc. At these sites, AIDS patients are provided care along with other patients. As the NHSC personnel currently serving these areas are withdrawn, a severe shortage in availability will occur.

- Although on December 1, 1987, Public Law 100-177 was signed providing for the establishment of a new Federal Loan Repayment Program, a state repayment loan program and special repayment provisions for previous

scholarship recipients who have failed to comply with their service obligation, it is expected that these programs will make loans available to only 40 persons and return to service a number of earlier scholarship recipients. This is clearly inadequate to meet projected needs.

- Minority populations often have no health insurance and rely on Medicaid which may not cover needed services. Also cited as a problem severely limiting minority access to quality medical care is the fact that minorities are severely under-represented in the health professions.

- In many cities and counties, whether formally identified as health manpower shortage areas or not, the full continuum of health services required for intensive treatment of AIDS patients is unavailable.

- As the number of AIDS cases increases, finding adequate numbers of physicians, dentists, and other primary care personnel will become an increasingly significant problem, particularly in high prevalence areas where recruitment of physicians is already difficult.

- Health care availability through the Indian Health Service and the Bureau of Prisons, already limited, may worsen as the number of AIDS cases increases.

In addressing these obstacles to progress in HIV-related health care delivery to underserved and minority populations, the Commission recommends the following:

(UND-1) The Secretary of HHS should ensure that minorities are represented on Federal decision-making bodies in order that cultural characteristics are recognized appropriately. All newly Federally funded AIDS treatment service programs should include local advisory boards with appropriate minority representation.

(UND-2) The NHSC scholarship program should be reinstated to enlist an additional 400 primary care physicians in training per year, and provide loan forgiveness to 100 additional practicing primary care physicians per year, to staff facilities in underserved, AIDS-endemic areas.
Estimated cost: Federal dollars: $20 million.

(UND-3) The NHSC should establish scholarships, loans, and workstudy opportunities to recruit, train, place, and retain 200 nurses per year to staff facilities in underserved, AIDS-endemic areas.
Estimated cost: Federal dollars: $5 million.

(UND-4) Individuals who received NHSC funding for all or part of their professional education, and who have defaulted on their subsequent service obligations, should be offered the option of serving in AIDS-endemic areas to meet their outstanding obligations.

(UND-5) The NHSC should establish scholarships, loans, and workstudy opportunities to recruit, train, place, and retain 100 Masters degree-level social workers per year to staff facilities in underserved, AIDS-endemic areas.
Estimated cost: Federal dollars: $1.5 million.

(UND-6) The NHSC should permit specialist physicians who have not as yet met their NHSC scholarship service obligation to fulfill their obligations in an underserved, AIDS-endemic area. Those specialties most appropriate to HIV-related care, such as infectious disease or internal medicine, should receive priority.

(UND-7) The NHSC should ensure that all its professional staff are provided with education and training in the diagnosis, treatment, and prevention of HIV infection, particularly in AIDS-endemic areas.
Estimated cost: Federal dollars: $1 million.

(UND-8) The NHSC should provide scholarship funds at the undergraduate (college) level to minority students to allow more minorities to continue their education through the professional degree level, with repayment of these scholarships through service in underserved, AIDS endemic areas.

(UND-9) AIDS educational programs for both professional and non-professional health care providers, which receive Federal funds, must include culturally relevant and sensitive curriculum and instruction.

SECTION 6. AIDS INFORMATION COORDINATION AND EXCHANGE

Numerous private and publicly funded organizations are developing training resources for health care providers, distributing health education pamphlets, research monographs, and publishing books, articles, and newsletters in an attempt to share information about AIDS throughout the health professional community.

Information about NIH experimental treatment protocols is currently disseminated through a private contractor. Information about experimental drug trials funded outside the NIH is generally not centrally collated for retrieval by practicing providers, researchers, or the public.

Agencies and organizations which are attempting to coordinate or develop AIDS information exchange include:

- The Centers for Disease Control AIDS Clearinghouse
- The Centers for Disease Control AIDS Hotline
- The HRSA AIDS Education and Training Centers Program (ETC)
- The HRSA Area Health Education Centers Program (AHEC)
- The National Library of Medicine
- Medical societies, specialty organizations and professional associations
- AIDS advocacy and support groups

Community planners and administrators who are in the position of designing treatment systems to meet significant anticipated increases in their patient populations need access to research findings which suggest the most humane and cost effective approach to AIDS care.

The Commission has identified the following obstacles to progress in coordination and exchange of HIV information:

- Complete and up-to-date information about AIDS is generally not currently accessible to front line providers, persons with AIDS, or the general public except through certain limited commercial enterprises or medical libraries at academic institutions. The attempts to create centrally coordinated access have not been successful.

- In communities where the prevalence of HIV infection has been relatively low, primary care physicians who encounter an AIDS patient in their practice may have no awareness of central sources of information about AIDS. Because they do not know where to direct their questions concerning treatment modalities, evaluation and management may be suboptimal and unnecessarily expensive.

- Information about experimental AIDS treatment protocols is not adequately communicated to those who need it. Information about existing treatment protocols is being compiled by a private organization, the American Foundation for AIDS Research (AmFAR), with support through a National Institute of Allergy and Infectious Disease sub-contract, but many practitioners and persons with AIDS are not aware of this. In addition, data about non-NIH funded experimental protocols is incomplete.

In addressing these obstacles to progress in HIV information coordination and exchange, the Commission recommends the following:

(INF-1) The Federal Government through a central database/hotline should provide:

- general information about HIV to the public
- treatment information for those with HIV and for health care professionals
- experimental treatment protocol information to practitioners and the public.

Estimated cost: Federal dollars: $2 million.

BASIC RESEARCH, DRUG AND VACCINE DEVELOPMENT RECOMMENDATIONS

Introduction

Manifold obstacles confront both the individual with HIV infection and the scientist seeking a cure. In its hearings on research-related issues, the Commission identified several areas of serious concern, foremost among them:

- the need for increased access by a broader spectrum of the infected population to a greater variety of experimental treatments;
- the urgent need for the development of a database that would provide a description of the natural course of the disease from which "historic controls" could be derived for HIV/AIDS research;
- the need to eliminate wherever possible the use of placebo-controlled trials in patients with life-threatening HIV-related illness;
- the need for greater information gathering and sharing on drug development and clinical trials;
- the need to free government-sponsored basic research from many of the bureaucratic restrictions that frequently constrain exploration;
- the need to set aside secrecy and competition as far as feasible in favor of greater collaboration among industry members, and between industry and government, especially in times of medical emergencies;
- the need for additional FDA resources to process more rapidly AIDS-related applications without compromising standards of safety or efficacy or causing delays in the review of promising drugs for other diseases;
- the need for collection at the Federal level of the information being gathered by community-based drug trials, as well as the need for direct Federal support of these programs.

The Commission remains concerned by the growing number of individuals who require therapeutic trials for which there is limited access, e.g., trials for women, trials for children, trials for HIV-positive asymptomatic individuals, for underserved minority populations, for hemophiliacs and transfusion-exposed persons, trials for active or recovered I.V. drug abusers, and trials for exposed individuals who have not seroconverted, i.e., those with needle sticks or other exposure. At present, drugs are going through an approval process that will allow them to be licensed for use in these populations without having been intensively tested in them. As these populations may represent the future of the epidemic, the immediate implementation of more broadly available therapeutic protocols is essential. Hearings on these and many additional research-related problems yielded the following recommendations.

BASIC RESEARCH

AIDS is a complex and aggressive biomedical syndrome initially recognized in this country at a time when there was no knowledge of what caused the disease, how it was transmitted, how it could be stopped. There were no drugs with known effectiveness, no vaccines, and no hope for early intervention in what seemed to be an endlessly escalating process, with the number of diagnosed cases doubling every twelve months. When a causative agent was identified, it was found to be a retrovirus, a type of virus about which relatively little was known.

America's past investment in basic biomedical research has enabled medical science to respond to AIDS with unprecedented rapidity, given the complexity of the problem and the number of unknowns. Within a short time, a cause was identified, a virus isolated, the complexity of the syndrome delineated, and some promising drugs and vaccines have been developed and entered into human trials.

The investment that has produced these results can be broadly categorized as an investment in research and an investment in researchers. The former includes direct Federal, state and local funding for materials, facilities, and programs, while the latter includes investment in training, and support mechanisms that enable investigators to pursue innovative ideas. This research takes place on university campuses, in medical institutions, and in independently sponsored research centers. Although additional Federal sources exist, the distribution of Federal funding for research programs in these varied sites is centralized in the National Institutes of Health (NIH), a division of the U.S. Public Health Service (PHS), Department of Health and Human

Services. The largest proportion (87%) of HIV research funding provided by the NIH is given to institutions and individuals by means of direct grants.

While the Federal government has allocated large sums of money to meet the research requirements of the epidemic, and while a great deal has been learned in a relatively short time, pressing research needs still exist. The following paragraphs summarize obstacles to progress in basic research and Commission recommendations for their elimination.

THE NATIONAL INSTITUTES OF HEALTH

The advances made to date in AIDS research rest on a foundation established many years ago at the National Institutes of Health, and accelerated in the 1970's by the "War on Cancer," primarily within the National Cancer Institute (NCI). During this period, funding was increased in the areas of epidemiology, molecular biology, microbiology, virology, immunology, genetics, and pharmacology, in an effort to find a "magic bullet" that would cure malignancies.

In the early years of the epidemic, NIH scientists answered the challenge by turning their research efforts to the new disease even though they were funded to do other work. As knowledge of the severity of the problem increased, funding followed, so that research at the NIH and universities and medical centers could continue and broaden to more aggressively explore the disease.

During Fiscal Year 1988, NIH funding for HIV-related research is expected to reach almost $468 million, an 80% increase from FY 1987, and up from an initial $3.5 million in 1982. Of that, $407 million will be given in grants to support programs in universities, medical centers, and other extramural institutions, and to individuals. The remaining $61 million (13% of the total) will support intramural NIAID research.

TARGET RESEARCH AREAS

HIV-related basic research is expected to have high yield benefits to Americans who suffer from cancer, viral, and immune-related diseases, which collectively kill an estimated 650,000 individuals each year. Research areas that require additional long range funding include, but are not limited to:

Virology and molecular biology: Much more needs to be known about viral activity and structure, so that vaccines and anti-viral drugs can be rapidly and efficiently developed. Until recently, very little was known about retroviruses and lentiviruses, and though we are still only on the threshold, our knowledge is now increasing rapidly.

Immunology: How does HIV damage the immune system? Why do some individuals remain healthy for so long after acquiring the virus, while others rapidly decline? What can be done to stimulate or support the immune system of the infected individual so that he or she will remain healthy?

Cellular biology, pathogenesis, and host genetics: How does a virus infect and kill cells, and what factors, when present or absent, cause certain individuals to be more susceptible to viral infection or disease progression?

REAGENTS, ANIMAL MODELS, AND INFORMATION EXCHANGE: OBSTACLES

For results obtained in different laboratories to be comparable, certain common resources must exist for biological materials such as viral strains, genetic probes, polyclonal and monoclonal antibodies, and others.

To date, appropriate animal models have not been developed for human HIV- and AIDS-related research. An appropriate model is one in which the animal can be infected with the human virus, and can develop disease similar to the human disease. Chimpanzees can be infected with HIV, but to date, have not developed AIDS. Ideal models are small animals that can be relatively easily and inexpensively maintained, e.g., mice.

Further, animal studies may be duplicated unnecessarily because current information sharing systems are not effective enough to indicate that such studies have been done elsewhere. The National Library of Medicine maintains a data system on clinical trials called the Physician's Data Query (PDQ) System, which might provide a starting point for a new data collection system.

REAGENTS, ANIMAL MODELS AND INFORMATION EXCHANGE: RECOMMENDATIONS

(BR-1) Escalate existing efforts of the NIH to establish a repository for reagents to be used in HIV/AIDS research.

(BR-2) Investigate-a-fee for use basis for reagent distribution that would assist in program support.

(BR-3) Make as an immediate and high priority the development of appropriate animal models for HIV-related research.

(BR-4) Establish a federally funded central registry of animal models for AIDS and other orphan diseases;

(BR-5) Establish a federally supported computerized network of all HIV-related research activities to promote greater exchange of information and data between researchers;

(BR-6) Investigate the possibility of utilizing an existing system (PDQ) within the National Library of Medicine;

(BR-7) Increase funds to the NIH Divisions of Research Services and Research Resources for additional animal model, reagent, and database program support.

FACILITIES: OBSTACLES TO PROGRESS

AIDS has added an increased burden to our already overburdened research facilities, and many scientists believe that our efforts have been slowed because of outdated and antiquated facilities. Work with viruses, viral concentrations, genetically altered and virally infected animals must be done in highly controlled settings. The model developed for such research includes construction or modification of containment laboratories designated with a P-3 level of biosafety. At the beginning of the epidemic, very few of these facilities were in existence.

In order to conduct research on HIV that is safe and scientifically expedient, facilities and instrumentation must be brought up to date. The NIH last received major construction appropriations in the late 1960's when much of the major authorization for research facilities expired. The NIH institutes used to have independent construction authority, but now only three institutes are able to authorize and grant funds for such construction, while the National Institute of Allergy and Infectious Diseases (NIAID) is not. This has created an obstacle to NIH funding of extramural (off the NIH campus) university construction and reinstrumentation, as well as prohibited NIH from answering its own intramural (on campus) construction needs.

The seriousness of this obstacle is exemplified by the lack of progress on the NIAID Consolidated Office Building. Currently, NIAID personnel work in leased office spaces scattered over a several square mile area, some distance away from the Clinical Center at the NIH, where patients are seen. The proposed building would be constructed under a lease-purchase agreement, and would enable all HIV-related NIAID personnel to work closely together and close to the patients.

Space on the NIH campus has been set aside for the building, architectural plans drawn, and funds approved; yet to date, the General Services Administration (GSA) has not given final approval for construction. NIH cost estimates indicate that operating costs of current leased properties exceed those of the new building, i.e., at this point in time it would require no new dollars, and may in fact save money, to expedite construction.

In the research community outside the NIH, few universities and research institutions have funds immediately available to create or convert facilities for HIV-related work. The cost of up-

grading existing laboratories to P-3 level is approximately $250,000. This includes construction of modified air flow and other containment devices. Many laboratories now exist around the country that could be upgraded in this manner, providing space for additional HIV-related research. This pluralistic distribution of research space was highly recommended by several witnesses as offering the greatest discovery potential.

It was suggested to the Commission that Federal funding be supplied to establish regional centers for basic and applied research in retroviral diseases. These centers would be located in a university or a research institute where a critical mass of expertise already exists, and the existing research team would be organized and expanded for maximum interaction under the leadership of an appropriate investigator. The enlarged facility would be optimally equipped for its work. It would provide an appropriate environment for training of graduate students and postdoctoral fellows, and would ideally be able to share a portion of its facilities with qualified visiting researchers from outside the parent institution who lacked facilities to advance their own research. The estimated cost of this facility is $2.5 million, and it would be expected to provide space for six to eight investigators.

In addition, there is currently a lack of incentives that encourage increased spending and joint ventures between the government, academia, and industry to improve facilities and instrumentation.

FACILITIES: RECOMMENDATIONS

To improve the current status of research facilities capable of handling HIV-related research, the Commission recommends that:

(BR-8) NIH intramural construction and reinstrumentation needs be assessed and forwarded to the office of the Secretary for inclusion as a high priority in future budget requests;

(BR-9) Construction of the NIAID Consolidated Office Building be made a high priority, and GSA approval be expedited;

(BR-10) NIH construction authority be reinstated during the Congressional reauthorization of NIH in 1988 to provide for the expeditious granting of funds to universities or medical centers for construction or renovation of research facilities;

(BR-11) Construction funds be made available in FY 1989;

(BR-12) Funds for construction and modification of university facilities, as well as upgrading of instrumentation, be provided through Federal matching grants;

(BR-13) The NIH create a plan for the development of regional retroviral research centers, and provide funds for construction or renovation of two such centers.

Citing a projected expansion of HIV-related research and programs, NIAID recently requested construction of an additional building, a $50 million request that the Commission will continue to evaluate prior to its final report.

ADMINISTRATIVE OBSTACLES TO PROGRESS

HIV was isolated in 1983-84, and because AIDS was then determined to be a virally-induced infectious disease, NIH designated NIAID to assume administrative responsibility for HIV-related Federal research management. Much of the initial HIV research was done at the NCI, and this work continues at that institute. Senior leadership within the NIH, in NIAID and NCI, responded to the challenge of this complex disease by establishing a system for organizing and funding research priorities that required almost simultaneous development and execution. Within a brief time, a new research and clinical trial structure had been conceived and implemented at NIAID that structurally paralleled that of the NCI, established over a period of years. The urgency and breadth of this effort is without precedent in the history of the Federal government's response to infectious disease.

Witnesses critical of the NIAID response have testified that little funding was received by outside institutions until late in 1984, and believe that this was due to the lack of a pre-existing administrative structure similar to that of the NCI for clinical trials, and the complexity of the grant and funding process. The clinical trials program has currently accrued over 3,000 patients and is expanding, into both additional research institutions, as well as into community- and physician-oriented programs. The funding and grant making process has recently been reviewed, and the "ASAP" (Accelerated Solicitation-to-Award-Program) enacted, which will cut grant review and turnaround time to six months.

Both the accelerated grant review and community orientation to clinical trials are significant breaks with research and funding tradition, and represent an effort on the part of NIAID to respond to the urgency of the HIV epidemic and the needs of the research and patient communities. Given their recent enactment, the effectiveness of these two programs can only be evaluated at some point in the future, and will be reviewed by the Commission prior to its final report.

The Commission's examination of AIDS research programs has revealed that despite NIAID's high level commitment to rapid

response, limitations in the Federal system exist which must be addressed if this nation's goal of conquering the epidemic is to be realized. Although the NIH has revamped existing programs and "fast tracked" AIDS related projects, one primary obstacle to progress has been the slow response on the part of other government agencies with which the NIH must interact.

For example, NIH administrators indicated that, given funds and personnel positions, they have still been unable to complete the hiring of some individuals because of paperwork delays in other agencies. A greater sense of urgency throughout the government is needed to implement the increased funds already approved by Congress, and to process the improvements already instituted by NIH. The Executive Task Force on AIDS includes senior members of departments and agencies necessary to streamline the process and expedite high priority requests.

ADMINISTRATIVE RECOMMENDATIONS

(BR-14) Representatives of the Office of Personnel Management, General Services Administration, and Office of Management and Budget should be encouraged to participate as active members of the Executive Task Force on AIDS, and to assist in rapid implementation of high priority requests issued by PHS;

(BR-15) OPM and GSA should respond within 21 days to AIDS-related priority requests from the Directors of the National Institute for Allergy and Infectious Diseases, National Cancer Institute, and the Centers for Disease Control, or any additional Director so designated by the Secretary of Health and Human Services.

GRANTS AND RESEARCH FUNDING: OBSTACLES TO PROGRESS

Traditionally, the NIH has sponsored grants for projects that were initiated by researchers and proposed for funding. In response to the AIDS crisis, the NIH assumed a more centralized control approach, funding a large number of government-directed contracts and issuing specific requests for grant applications for areas of research in which there was a lack of scientific interest or of readily apparent yield. This approach has been criticized by some witnesses, who felt unable to receive funds for work they thought beneficial. What is seen within NIAID as a process of taking control and targeting Federal resources to underexplored areas of science is seen by some outside as overly restrictive.

Two of the most significant hindrances for the NIH have been restricted spending authority and the lack of significant pools of discretionary funds that can be used in medical and scientific emergencies.

Administering taxpayer monies to varied yet targeted exploration in a multi-focal medical and scientific crisis requires great skill and balance. Given a limited amount of total funding, if spending is so broad that all possibilities are touched, there may not be enough money in each grant to permit thorough exploration. If funded research is too highly focused in one area, an answer lying outside that area will be missed. Advisory balance councils within NIAID and NCI, and the NIH Director's Advisory Council offer advice on funding direction but some witnesses cited too few grants to younger investigators, and inadequate funding for new or "unpopular ideas." In response, NIAID has created seats on its advisory councils for community representatives and younger scientists, and is considering appointing a similarly qualified person with HIV infection.

Many researcher witnesses testifying before the Commission indicated a preference for investigator initiated research, citing its ability to offer multivaried exploration of any given topic, although highly controlled government-directed funding was considered by others to be an appropriate response by NIAID that should be reserved for short-term, emergency situations. As HIV research has been stimulated, investigators have returned to NIH with new ideas and proposals in previously underexplored areas. The role of NIH in "driving" new research efforts in a national medical emergency is detailed and complex, and will be further considered, along with peer review and other aspects of the grant making process, in the Commission's final report.

RESEARCH FUNDING AND GRANTS: RECOMMENDATIONS

Primary to all recommendations for the advancement of basic biomedical research is the concept that:

(BR-16) New monies appropriated for AIDS related basic research will be considered "add on" funds, and will not be subtracted from existing programs.

To support basic biomedical research, the Commission recommends that the Federal government:

(BR-17) Continue and expand support for basic science research, including virology, molecular biology, genetics, pharmacology, and pathogenesis, and provide even greater support for immunology-related projects;

(BR-18) Place greater emphasis on investigator initiated grants;

(BR-19) Create new money for "Director's Awards" for rapid start-up of projects to pursue new basic research ideas;

(BR-20) Immediately implement "zero year money" (money that does not have to be returned if not utilized in a given fiscal year) for HIV-related basic research programs at the NCI and NIAID, with other NIH institutes to follow, subject to further review;

(BR-21) Implement within all NIH institutes the Accelerated Solicitation-to-Award Process (ASAP) for HIV-related grant proposals;

(BR-22) Establish longer term funding mechanisms for grants, expanding three year grants to five and seven year terms wherever appropriate;

(BR-23) Maintain HIV-related research programs in existence in the National Cancer Institute, to allow NIH the greatest possible variety and breadth of research efforts, and maximize utility of existing talent;

(BR-24) Publicize the rules and procedures for negotiation and implementation of cooperative agreements between NIH and private industry.

PERSONNEL AND RECRUITMENT: OBSTACLES TO PROGRESS

Witnesses before the Commission testified that modest salaries and the lack of other incentives deter many talented individuals from entering service at NIH. NIH recently proposed creation of the "Senior Biomedical Research Service" a career track similar to the Senior Executive Service, that would enable NIH to recruit scientists at salary levels similar to those in the private sector. The model cited for this proposal is the "Uniformed Services University of the Health Sciences," already in existence at the Naval Hospital across the street from the NIH. Legislation creating the University pay scales exempted them from standard government levels, enabling the University to attract personnel at salaries similar to medical schools.

"Full time equivalent" (FTE) ceilings inhibit the recruiting of talented individuals above those ceilings, even in short term emergency conditions, contributing to both NIAID's inability to put its own programs into motion, and the public perception that NIAID was slow to respond. FTE ceilings are designed to limit the size of the Federal government, i.e., the number of individuals working for the government who will at some point in the future be eligible for ongoing benefits such as retirement. The approval system has entrenched inflexibilities that are intended to guard against such growth, but can in fact leave government agencies funded but unable to hire in response to a crisis.

Research personnel also indicated that low salaries were a hindrance to hiring adequate numbers of trained nurses to staff the Clinical Center, that this caused delays in the implementation of clinical trial protocols, and that salary structures would have to be modified before this problem could be solved.

PERSONNEL AND RECRUITMENT: RECOMMENDATIONS

(BR-25) Ask the Interdepartmental AIDS Task Force to work with OPM to develop a package of incentives to facilitate recruiting of scientific talent;

(BR-26) The proposed "Senior Biomedical Research Service" should be given expedited review and enactment, with legislation as necessary to provide for the recruitment of scientists at salary and benefit levels competitive with private sector research institutions and medical centers;

(BR-27) Fast track recruitment programs to bring more nurses into the Clinical Center, should be immediately implemented, and appropriate incentive packages designed.

(BR-28) Basic research FTE needs should be given high priority review by the Secretary, and an additional 120 positions be approved for HIV-related basic research;

(BR-29) The Secretary of HHS should evaluate the current FTE ceilings at NIH in terms of the Institutes' overall ability to respond to a national medical crisis, and should work with OMB to determine ways to add flexibility as needed.

BASIC SCIENCE EDUCATION AND TRAINING GRANTS: OBSTACLES TO PROGRESS

Testimony before the Commission cited the belief that the Federal government funds the best scientists, provides access to the most sophisticated technology, and regulates to the highest standard of excellence in the world. Yet concern was expressed by the science community that the next generation will not produce adequate numbers of scientists capable of or willing to work in Federally funded laboratories.

Current NIH training grant programs:

- University/medical center grants:
  10 centers, 5 individuals each, @ $50,000 Total: $2.5M
- Individual research scientist grants:
  50 individuals @ $50,000 Total: $2.5M
- Career Development Awards ("K Awards)
  Research Scientist Awards
  (combined) 100 individuals @ $50,000 Total: $5.0M
- Summer student programs
  250 students @ $1500 Total: $275,000

The dollar amounts listed above are the yearly maximum for these programs, although in recent years they have not always been funded at this level, or have in fact been eliminated. Additional appropriations and the authority to execute these programs is needed.

A serious obstacle exists in that summer students studying on the NIH campus for three months are counted against the NIH FTE ceiling. This means that if NIAID wants to create research opportunities for 40 summer students, it must eliminate ten full time positions from its staff. The summer student program represents a unique opportunity for minority youth to participate in government research training, and work with recognized research scientists.

BASIC SCIENCE EDUCATION AND TRAINING GRANTS: RECOMMENDATIONS

In addition to increasing financial incentives for such work, the Federal government should also:

(BR-30) Expand and fund NIH training grant programs to levels adequate to enable qualified student researchers to continue advanced study;

(BR-31) Eliminate the regulation that counts students participating in summer training programs against NIH FTE ceilings;

(BR-32) Enlarge the scope of training grants to include interdisciplinary programs specially tailored for AIDS research, e.g., psychobiology and immunology;

(BR-33) Shift priorities in elementary and secondary education, to provide young people earlier with greater education in biology and other sciences;

(BR-34) Develop a prestigious and highly visible set of awards to recognize outstanding young talent and excellence in teaching in areas relating to human biology. These could include:

(BR-35) > Junior Science Corps, awards for elementary school students that include small monetary awards, but are primarily for recognition;

(BR-36) > National Bioscience Awards, for high school students, that include the opportunity to work with leading scientists;

(BR-37) > National Science Teachers Awards, to recognize professional excellence, and enable teachers to spend time with leading researchers.

(BR-38) > Ways should also be developed to bring researchers into the classroom, so that they can personally convey the excitement of their work.

This program could be rapidly established and funded at relatively low levels, patterned after the proposed "Thomas Edison Awards" for student work in areas of science that may have commercial application. One feature of the program would be a national awards ceremony that would include the President. The administrative center for the proposed bioscience awards would be the NIH, as on-campus training programs have been in place for many years.

VACCINE DEVELOPMENT: OBSTACLES TO PROGRESS

Institute of Medicine Vaccine Conference

Testimony before the Commission reported results of the recent Institute of Medicine conference on HIV-related vaccine development, citing the following obstacles:

- Lack of basic scientific knowledge about HIV activity and immune response;
- Lack of proper animal models for vaccine development;
- Vaccine testing difficulties;
- Research ethics;
- Liability issues.

A great deal has already been learned about a virus only recently discovered, and vaccine models have been developed that target not only surface proteins, but also core proteins, whole virus, and virus function, as in the case of reverse transcriptase. Lack of additional basic scientific information and proper animal models can only be addressed through additional research. The difficulties and ethics of testing vaccines are problems that will require further investigation and study.

Liability

One of the few obstacles to vaccine development which may have a relatively easy and rapid answer is liability, which could be addressed by legislation. Several models were proposed for such new legislation, including:

- establishment of dispute resolution mechanisms that provide compensation for vaccine injuries more quickly and cheaply than litigation, but that tie the plaintiff to a schedule of limited damages. This solution was recently adopted by Congress for certain pediatric vaccines.

- elimination of manufacturer liability entirely, with recourse for injuries limited to claims against the government. This was the model chosen by Congress for injuries resulting from the swine flu vaccine in the early 1980's.

The Commission will hold a full day of hearings on legal issues in April, and will hear additional testimony on liability so that substantive recommendations can be made in its final report.

Ethics

One of the key obstacles identified by the IOM conference was that of research ethics, i.e., problems surrounding informed consent, patient risk, and research physician-patient responsibilities. The Commission will be reviewing this problem in greater detail in subsequent hearings.

Prognosis

The Institute of Medicine conference presented a variety of methods currently under exploration for vaccine development, and gave a status report overall. In general, the tenor of the conference indicated that it may be many years before a vaccine is developed that is proven safe and effective, and that prevention remains the single greatest means by which to curtail extension of the epidemic.

VACCINE DEVELOPMENT: RECOMMENDATIONS

To most rapidly develop a vaccine for HIV, the Commission recommends that:

(V-1) All approaches to vaccine development should continue to be explored and developed until one or more are successful;

(V-2) The basic scientific information necessary for this development should continue to be a high Federal priority;

(V-3) The NIH, in cooperation with the Institute of Medicine, the American Bar Association and the Justice Department, should convene a conference on liability issues related to vaccine and drug development; and that a similar conference be convened with appropriate agencies and spokespersons to investigate the ethical questions surrounding vaccine development;

(V-4) The Federal government should fund these conferences in partnership with the private sector;

(V-5) The results of the liability conference should be submitted to Congress for the drafting of liability legislation.

DRUG DEVELOPMENT

BASIC RESEARCH FOR DRUG DEVELOPMENT: THE FEDERAL EFFORT

Within the NIH, the National Cancer Institute has a long established history of research directly associated with drug development. Faced with a new medical emergency, the NCI geared up its off-the-shelf drug screening program, and made it available to all pharmaceutical companies, biotechnology firms, and universities for products they had already produced and had in stock. Compounds that universities or corporations felt might be effective against HIV were submitted to NCI for *in vitro* (test tube) screening. This effort resulted in the demonstration of the antiviral properties of azidothymidine (AZT), a compound submitted for screening to the NCI by Burroughs Wellcome Co.

The high level of anti-HIV activity discovered in AZT indicated that a product could be quickly developed that had the potential to stop the progression of disease in people already infected. When it appeared that Burroughs Wellcome lacked sufficient amounts of a key ingredient to produce enough AZT for trials, the NCI, in the belief that AZT represented an extraordinary opportunity in HIV treatment, provided the ingredient at no cost.

Because no product patent application could be filed by NIH, Burroughs Wellcome retained full market control of the compound. Many witnesses have criticized Burroughs Wellcome for the high price of the drug, and NIH for contributing so greatly without retaining some control over the final cost to patients. The company indicated that its development costs were substantial, but recently lowered the wholesale price by 20%. Procedures have been instituted at NIH so that patent applications are routinely filed for all new compounds that NIH invents or originates.

Some witnesses indicated that, at this point in time, however, enough has been learned through basic research to re-emphasize drug development through rational drug modeling, the traditional approach. By understanding how the virus works, what its physical properties are, and how virus-infected cells behave, drugs can be developed that interact with the virus at various points in its life cycle.

RECOMMENDATIONS

Successful rational drug development requires additional basic research funding, and the Commission therefore recommends that:

(DD-1) As a near term drug discovery measure, the NIH should continue screening off-the-shelf compounds for anti-viral and immunomodulating activity;

(DD-2) Research funding be increased for the development of rational drug models for both immunomodulators and anti-virals, at both NIAID and NCI, and through their grants to universities and medical centers.

PRIVATE SECTOR COLLABORATIVE R&D: OBSTACLES

In times of serious medical emergency, the competition that normally fuels progress in the private sector can actually slow down the production and marketing of potentially beneficial substances. If several companies are working separately on a potential therapy that is costly and difficult to develop, they may all relinquish their efforts because the ultimate return on investment will be too low.

In theory, had they been able and willing to pool resources and collaborate on the project, they would have eliminated duplicated effort, reduced cost and development time, and been able to share in the profits. In reality, a complex set of anti-trust laws, as well as other factors, actually prohibit this type of collaboration. These and other aspects of collaborative R&D in drug and vaccine development in times of a pending or present national medical emergency will be further examined prior to the Commission's final report.

COLLABORATIVE R&D: RECOMMENDATIONS

(DD-4) The Food and Drug Administration, in partnership with the private sector, and appropriate Federal agencies, should develop a consensus conference on the subject of collaborative R&D in drug and vaccine development, outlining the potential benefits, risks, and legal obstacles;

(DD-5) Participation in this conference should be sought throughout the pharmaceutical and biotechnology industries, as well as the university research community and the NIH.

REGULATION OF SAFETY AND EFFICACY: THE FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration is the principal consumer protection agency of the Federal Government. Its primary responsibility with respect to AIDS is to ensure that drugs, biological products (such as vaccines and blood components), and medical devices are safe and effective.

Prior to its final report, the Commission will continue to review the FDA to make additional recommendations.

The Drug Approval Process

The FDA's role in the new drug approval process is to review data from the drug's sponsor and then:

- based on information from animal and laboratory studies the FDA will grant or reject an Investigational New Drug (IND) application which allows human studies to begin; and
- the FDA will review data from these clinical studies in order to grant or reject a New Drug Application (NDA) which permits marketing of the drug.

In an IND application, the sponsor must provide FDA with the results of laboratory and animal research indicating that the drug toxicity is low enough to be safe for human use, plus information, if there is any, about previous use of the drugs in humans in this country and abroad. The sponsor must also describe in detail the protocol for the planned clinical trials.

Human (clinical) trials of drugs or vaccines begin after the IND is approved.

New Drug Application (NDA) Review

An NDA must be granted before a new drug may be marketed. The application is judged on the risk-to-benefit ratio of the drug. The order in which applications are looked at is determined with the aid of a classification system based on therapeutic importance and availability of alternative therapies. Currently, all HIV-related therapies are rated 1-AA, the Agency's highest priority.

On the date FDA receives an NDA, a "review clock" is started. By law, FDA has 180 days to approve or reject the application. During the approval process, all data from 2-10 years of clinical trials are reviewed by an interdisciplinary team of scientists, as in the IND application. Some applications must be returned to the sponsors to correct errors or to provide additional data; the applications are then resubmitted to the FDA. The average approval time for an NDA is 24 months.

New Drug Application (NDA): Obstacles

Criticism of the new drug approval process dealt mainly with the length of time involved from start to finish. Critics added, however, that this delay was exacerbated by the fact that a lack of international consensus on preclinical and clinical trial standards can preclude the acceptance of data from foreign studies, necessitating the repeat of those studies in the United States. The Commission will address this issue in its International hearings.

Currently, almost all aspects of all NDA reviews are submitted on paper. Interaction between the FDA and drug sponsors are rarely facilitated by computer use.

Another obstacle cited was the fact that a new drug approval is not always "tracked" through the FDA system by the same group of reviewers, causing delays as a sponsor waited to find the right individual with information on the status of his application.

New Drug Application (NDA) Review: Recommendations

(FDA-1) The team assigned to review the IND should become involved with the product as early as possible, and remain with the product through NDA approval, and their work should remain subject to independent FDA review.

(FDA-2) FDA should work with NIH and private drug companies to develop a uniform software package which can be used to report and review data from pre-clinical and clinical trials, modified for each specific use, to shorten review time.

Treatment Investigational New Drugs (INDs)

Treatment INDs offer some hope of access to experimental drugs to those with life-threatening or serious disease, as they allow the release of the drug in non-trial use even before the end of Phase II efficacy testing, based on the Commissioner's recommendation and after safety and efficacy have been demonstrated.

Since the adoption of the new rules last year, only one AIDS related drug sponsor has applied and been approved for a treatment IND.

Treatment INDs: Obstacles to Progress

At present, the pharmaceutical industry is reluctant to participate in or make full use of this program. Some representatives expressed concern that if they did apply for a treatment IND, their subsequent NDA would not be favorably reviewed. Others indicated that some form of liability protection would be

necessary. Still others indicated that wide use of treatment INDs would limit the number of individuals willing to enroll in controlled trials, and thereby further delay drug approval.

Physicians indicated an unwillingness to order the drugs even if they were available, because they feared that their patients would be receiving inadequately tested therapies, and because of potential malpractice litigation. Proposed solutions to the problem of liability in drug trials are similar to those mentioned in connection with vaccine development.

Treatment INDs: Recommendations

(FDA-3) Information about what drugs are available under a treatment IND must be more widely disseminated. An information database must be created which should also offer information about potential toxicity as well as information about results of clinical trials involving the drug.

(FDA-4) If utilization of Treatment INDs increases, the Commissioner should be given the authority to monitor those drugs, and any drugs that are given accelerated licensing, in Phase IV, after licensing is complete.

(FDA-5) Treatment INDs should be utilized primarily by those patients who do not have access to experimental drug trials.

The entire issue of treatment IND's will be taken up more fully in the Commission's final report to the President in June.

Orphan Products

Recognition of the lack of incentives for industry to develop some products with limited commercial appeal led to the development of the Orphan Drug Act in 1983. Qualifying products must be used by fewer than 200,000 persons per year, or be products for which there is no reasonable prospect of recovering R&D costs by U.S. sales. The central features of the act included seven years of exclusive use, and tax credits for up to 63% of the clinical studies, and the ability of the FDA to grant special review status and development grants to these drugs.

Orphan Products: Obstacles to Progress

Industry-cited obstacles to utilizing Orphan Drug status for AIDS related drugs include the perceived lack of adequate incentives. If the product is not expected to ever be profitable, the tax incentives in the law may not be great enough to stimulate larger numbers of companies to invest. If the sponsor seeks a patent, the market exclusivity offered to Orphan Drugs is not considered

significant enough to be attractive. In addition, since Orphan Drugs are those limited to a population of 200,000 or less, immunomodulators and other drugs that can be used by a broad spectrum of HIV-infected individuals would not qualify, as there are currently projected to be 1.5 million such individuals who would be potential recipients.

Orphan drugs have traditionally been developed by pharmaceutical companies as a public service. Although industry representatives indicated a willingness to pursue areas of research for which there is limited market application, they also indicated the need to meet the concerns of stockholders, who require a reasonable return on their investment.

The Commission recognizes the need for the development of drugs for rare diseases, and the assistance that has been provided by the Orphan Drug Act. Perhaps new legislation is necessary to address the question of developing HIV-related drugs, usable in populations larger than 200,000, which can delay progression of disease or reduce infectivity. The Commission will be reviewing the subject of potential new legislation prior to its final report.

Orphan Products: Recommendations

(FDA-6) The FDA should meet with industry representatives and the Commission on Rare Diseases to determine the most attractive package by which to modify the existing law to both encourage additional research and development, and allow companies to provide Orphan drugs at reasonable cost to patients;

(FDA-7) Cost effective methods, such as extension of market exclusivity, should be favored over those that require additional investment.

(FDA-8) Professional pharmaceutical associations should survey members to determine what package of incentives would be most attractive to the producers;

(FDA-9) Special track approval for medical foods, such as lipids, especially those with long use in other diseases, should be considered.

FDA Personnel: Obstacles to Progress

Current advances in basic research, both within the NIH and in the private sector, have resulted in a greatly increased number of new applications for drug approvals. Each of these applications requires intensive effort on the part of a consulting and review team. Currently, the FDA is forced to "rob Peter to pay Paul." AIDS-related drugs and products should retain their fast track approval status without compromising the approval process of other products.

The number of new IND applications for HIV-related products has doubled every two years for the past four years. In addition, there are currently a large number of drugs undergoing clinical trials that will be presented for NDA review within the next two to three years. Current personnel levels are inadequate to handle this load, and an estimated additional fifty (50) FTEs are required.

Training time for a medical reviewer is approximately ten to twelve months. Currently, there is no program in place by which the FDA can bring in young personnel and train them for this work. The FDA Commissioner has suggested creating an education loan forgiveness program by which medical students could repay part of their loan debt through service in the FDA.

FDA Personnel: Recommendations

(FDA-10) Congress should immediately authorize and fund an additional fifty (50) FTEs for FDA review of new drugs and vaccines;

(FDA-11) The FTE level for reviewers should be tied to increases in the number of new IND applications;

(FDA-12) Office and other support for these individuals should be given commensurate funding;

(FDA-13) The Commissioner shall develop a plan by which medical and other graduate education loans can be repaid by FDA service, and propose this program to the Secretary of Health and Human Services for enactment;

(FDA-14) Congress should provide funds for this training program in FY 1989.

Medical Devices and Diagnostics: Obstacles to Progress

Reliability of HIV screening tests for both patient diagnosis and protection of the blood supply is essential. Many manufacturers have invested a great deal of time and money in developing and pre-market testing of a number of HIV antibody tests, HIV antigen tests, HTLV-1 tests, and a test that would screen for HIV and HTLV-1 simultaneously. AIDS researchers, clinicians, blood banks, Public Health officials, and laboratory administrators impatiently await the availability of these tests. The approval process is slowed by the limited review staff of the FDA. The staff size is limited by both budget and a lack of qualified individuals from which to recruit.

The HIV antigen test might help eliminate the danger of false negative results that permit infected blood to slip through the

"window" during which time antibodies haven't yet appeared after a recent infection. Another sexually-transmitted lentivirus is the HTLV-1, that can cause leukemia/lymphoma decades after the infection. Tests for this virus await approval by the FDA. Blood bankers have almost unanimously indicated they should be doing this screening test on all blood donated for transfusions. There is an extreme urgency to eliminate false negative tests, both at the blood banks, where on rare occasions HIV-infected blood is still slipping through, but also at testing sites where recently infected persons are given a false sense of security with a false negative test.

Condoms and surgical gloves must be efficacious if they are to be effectively utilized in prevention programs. At present, several manufacturers, domestic and foreign, produce these products with varying levels of quality control. The Food and Drug Administration samples batches of these products under a variety of stress tests, to determine their integrity, but the public remains relatively uninformed of the results.

Medical Devices and Diagnostics: Recommendations

(FDA-15) We urge the FDA to use deliberate haste in approving or rejecting the tests that are presently before them. We recommend increasing the pool of qualified individuals through support of training grants in relevant departments at colleges and universities.

(FDA-16) The Commission recommends the timely completion and release of currently ongoing FDA studies on the efficacy and safety of condoms and surgical gloves in blocking transmission HIV, and recommends that these results be publicized by the FDA.

FDA Facilities

The FDA's facilities are currently scattered among several locations. Although the FY 1989 budget for FDA included $25 million for a new building, current projections are that at least one more building will be required to house the number of new full-time employees. Suggested sites include the NIH campus and the Naval Hospital Campus in Bethesda.

(FDA-17) The Federal government should provide funds for an additional office and laboratory building for FDA drug and vaccine application review personnel.

FDA Recognition: Obstacles to Progress

The FDA needs to educate the public about its role in setting high standards for protecting the safety and requiring efficacy of all licensed medical products. Misperceptions about FDA's work have contributed to the distrust and lack of coordination which have hindered efforts to respond to the AIDS epidemic.

FDA Recognition: Recommendations

(FDA-18) To inspire pride in the FDA, an annual Presidential Award for Excellence could be bestowed on dedicated FDA scientists who creatively and expeditiously approve life saving products and discover ways to protect society from unforseen health hazards.

CLINICAL TRIALS: TESTING DRUGS IN PEOPLE

Clinical trials are carried out in three phases involving progressively larger numbers of people. Drug sponsors arrange with physicians and hospitals to conduct these trials.

Phase I trials are concerned primarily with learning more about the safety of the drug, though they may also provide information about effectiveness. They provide information on: how the drug is absorbed, metabolized, and excreted; what effect it has on various organs and tissues; and what side effects it has as doses are increased. Phase I testing is generally done on a small number of healthy volunteers. They are usually paid for their services, which essentially consist of submitting to a variety of tests to learn what happens to the drug in the human body. One of the chief causes of failure in this phase is evidence of toxicity at doses too small to produce any beneficial effect.

Phase II trials are designed to show whether the drug is effective in treating the condition for which it is intended. They also attempt to disclose short-term side effects and risks in people whose health is impaired. Most phase II trials are randomized controlled studies. Placebos are used when there is no historic or positive control available.

Phase III testing is geared to developing information that will allow the drug to be marketed and used safely. Optimum dose rates and schedules are determined and, hopefully, long-term side effects are revealed.

Data from clinical trials done in other countries are not always acceptable in the United States, due to variants in protocol design or administration. This subject will be addressed by the Commission on its International hearings.

NIAID CLINICAL TRIALS

Federally funded clinical trials for HIV-related illness are conducted through NIAID, through a system called the AIDS Clinical Trials Group. The recently redesigned program currently sponsors clinical trials throughout the country, with a total enrollment of over 3,000 patients. To date, there are thirty-five (35) funded institutions, twenty-seven (27) active protocols, and seventeen (17) agents under study.

CLINICAL TRIALS AT NIAID: OBSTACLES

There has been criticism that NIAID trials too often used AZT. When AZT was the only drug available with demonstrated efficacy, it was used in multiple trials in patients with a variety of disease manifestations, to determine its range of usefulness. As new drugs have become available, either through NIH or private sector development, the number of different drugs in trials has increased to seventeen, with multiple compounds under development and close to trials.

The Commission indicated concern that with the number of new drugs under development, the need for additional clinical trials would soon escalate sharply, and that additional personnel should be added and trained now. One witness suggested that in a national medical emergency, the NIAID system could be supplemented by the formation of consortia of smaller hospitals that could conduct cooperative trials, a suggestion that the Commission will further evaluate prior to its final report.

The AIDS Treatment Evaluation Units (ATEUs) were the universities or medical centers originally designated to operate NIAID's HIV-related clinical trials, and have been made part of the newly-formed AIDS Clinical Trials Group. Principal investigators from these centers indicated difficulties within their institutions that delayed progress with the trials, thereby slowing progress overall for NIAID.

Witnesses also indicated that information about trials was not always easy for potential participants to obtain, that placebo-controlled trials should be eliminated wherever possible, and that greater community participation in the NIAID advisory process would be welcomed.

Currently, no new NIAID trials for patients with life-threatening disease will be placebo-controlled, and NIAID has indicated a new clinical trial development strategy that will incorporate greater community participation.

NIAID CLINICAL TRIALS: RECOMMENDATIONS

The Commission will continue its review of HIV-related clinical trials, and recommends that:

(CT-1) Membership in the NIAID Clinical Trials Advisory Council should be increased to include at least one individual with HIV infection;

(CT-2) The number of FTEs available to NIAID for clinical trials should be immediately increased from 47 to 120;

(CT-3) Activities in progress at NIAID to incorporate greater participation of industry, and community physicians in protocol development and implementation should be encouraged;

(CT-4) A direct grant program should be immediately funded to assist community-based trial sponsors to develop and implement clinical trial protocols, and to encourage increased access to these protocols by underserved populations, e.g., hemophiliacs and transfusion-exposed individuals, women, children, minorities, I.V. drug abusers, and HIV-positive asymptomatic individuals;

(CT-5) Grants should be accompanied by Institutional Review Boards (IRB) and protocol approval by NIAID, and be constructed so as to continue private sector partnership with pharmaceutical companies;

(CT-6) NIAID should develop means by which clinical trials can be made available to individuals in all geographic areas of the country.

CLINICAL TRIAL INFORMATION REGISTRY: RECOMMENDATIONS

(CT-7) Information on clinical trials should be made more widely available, through the use of the CDC Clearinghouse or other mechanisms;

(CT-8) Registration of all AIDS clinical trial information should be in one central location;

(CT-9) All trials should be registered by the sponsor within seven days of approval by the FDA;

(CT-10) Consider providing additional funds to the National Cancer Institute to broaden the scope of its current database, the Physician Data Query System (PDQ), to accommodate entry of AIDS clinical trials;

(CT-11) If PDQ is selected and utilized in conjunction with the CDC Clearinghouse, a public information campaign should be authorized utilizing health and science editors of all major media to make the existence of the system more widely understood by physicians and patients alike. This should be done by cooperative agreement between CDC, NCI, and NIAID, and additional funds made available.

STUDY DESIGN

(CT-12) To decrease the need for placebo-controlled studies, immediately begin data collection to develop a "historic control" for AIDS;

(CT-13) Utilize placebo-controlled studies only for patients without immediately life-threatening disease, and positive control studies in patients with AIDS;

(CT-14) Standardize staging criteria; the selection process should favor a staging system that can most accurately establish disease stage, and therefore clinical trial endpoints, by laboratory methods;

(CT-15) Reevaluate the endpoints of current clinical trials to determine whether other markers can be used;

(CT-16) Develop means of shortening the time frame of Phase II trials, perhaps by increasing sample size or changing the endpoints;

(CT-17) Establish priority standards for all new trials, and place as a high priority trials including sufficient numbers of women, children, hemophiliacs, transfusion-infected individuals, and I.V. drug users to be statistically evaluable;

STUDY IMPLEMENTATION: RECOMMENDATIONS

(CT-18) Prior to the initiation of all new AIDS-related trials, NIAID should require a commitment on the part of participating institutions to rapid and active facilitation by their IRBs and other internal regulatory mechanisms, so that protocols are rapidly implemented;

SOFTWARE: RECOMMENDATIONS

(CT-19) The Federal Government should immediately fund a pilot study for the development of standardized computer software that could be used across all AIDS clinical

trials to standardize clinical data input, and facilitate the rapid evaluation of those trials by FDA. This pilot study should include experts from the computer support divisions of FDA and NIH, as well as clinical and review experts.

(CT-20) This software should be immediately utilized to begin collecting co-factor information on ongoing clinical trial participants;

(CT-21) Use information gathered on placebo arm participants to formulate the equivalent of a "historic control" for AIDS, so that future studies can be designed with decreased reliance on placebos as controls;

COMMUNITY ACCESS AND INPUT TO CLINICAL TRIALS: RECOMMENDATIONS

(CT-22) Community based organizations and community health centers should be utilized in the design and execution of clinical trials;

(CT-23) NIAID should seek private sector or university partnership to fund additional female cohort studies, for women who are in different stages of HIV-associated disease.

(CT-24) NIAID should convene a special advisory panel on clinical trials that would include representatives of affected minority communities, women, community health center care providers, and social workers, to determine:

- Whether the full range of the affected communities are represented in the clinical trial patient population;
- Whether additional provisions need to be made to permit the sustained participation of these population groups in the clinical trial process, (child care, transportation, primary medical care);
- That data collected be properly stratified to ensure that each patient's participation is not wasted, but contributes to a scientifically valid and expertly managed trial.

ADDITIONAL HIV-RELATED RESEARCH NEEDS

Co-Factors

HIV-related co-factors are those factors which when present or absent, influence an individual's susceptibility to infection, and the rapidity with which disease progresses. HIV-related co-factors under study include a history of other sexually-transmitted diseases, multiple infectious diseases, the effectiveness of behavior modification, and stress and other psychology-related factors that influence the immune system.

Research investigating co-factors is being conducted so that intervention efforts can be designed which prevent the onset of AIDS in HIV-infected individuals, or which ameliorate symptoms in persons already symptomatic.

Most of this research is funded by the National Institute of Mental Health. The FY 1987 funds allocation for this area of research was $3 million. There was no new money made available, however, for research training grants on AIDS.

Transmission

Research is also needed in the area of HIV transmission, to indicate the effectiveness of transmission through various routes, including both heterosexual and homosexual transmission, I.V. drug abuse, and perinatal transmission.

Behavioral Research

The broad spectrum of behaviors which influence transmission of HIV need to be more adequately funded for extensive study, so that behavior-modifying risk reduction AIDS prevention programs that can be effectively designed and implemented. Such study would include research in sexual behavior, addictive behavior, denial, and other factors that may influence prevention program design.

ADDITIONAL RESEARCH NEEDS: RECOMMENDATIONS

(AR-1) The NIMH should continue to support research on the behavioral and psychosocial factors thought to be associated with both the transmission of HIV infection and the progression of disease.

(AR-2) All AIDS-related research funded by NIAID and NIMH should be reported to a central information gathering source. In the AIDS crisis, data sharing, not data hoarding, should be the rule.

(AR-3) Funds should be made available through NIMH and CDC to sponsor summer training programs for graduate and post-graduate AIDS researchers in the following areas:

- Behavioral research;
- HIV transmission;
- Co-factors associated with onset and progression of AIDS-related diseases;

(AR-4) The NIMH should issue a competitive request for proposal (RFP) to establish a center where researchers from various disciplines could convene for several weeks in the summer to formally exchange information and offer training in their discipline to researchers in interested in integrating ideas. As the study of co-factors in AIDS is multidisciplinary, there should be cooperation between the National Institute of Mental Health and appropriate agencies whose work is also devoted to concerns surrounding intravenous and other drug abuse;

(AR-5) Funds should be allocated for training grants for pre and post-doctoral students in academic settings for research in the multidisciplinary field of psycho-immunology.

PRESIDENTIAL COMMISSION ON THE
HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

B U D G E T S

DRUG ABUSE, PATIENT CARE, RESEARCH, VACCINE AND
DRUG DEVELOPMENT RECOMMENDATIONS

DRUG ABUSE RECOMMENDATIONS

COSTS

	FEDERAL	STATE	TOTAL
Treatment Services	$750 MILLION	$750 MILLION	$1.5 BILLION
Treatment Research	18 MILLION		18 MILLION
Drug Abuse Prevention	30 MILLION		30 MILLION
Outreach Education	126.5 MILLION		126.5 MILLION
TOTAL:	924.5 MILLION	750 MILLION	1.6745 BILLION

CARE RECOMMENDATIONS

COSTS

	FEDERAL	STATE	TOTAL
Education			
Faculty Development/EDU-3	$5 MILLION	5 MILLION	10 MILLION
Treatment Guidelines/EDU-5	1.5 MILLION		1.5 MILLION
Health Care Systems			
Community Health Centers/SYS-1	20 MILLION		20 MILLION
Block Grants/SYS-2	25 MILLION	25 MILLION	50 MILLION
Foster Care/SYS-3	10 MILLION	10 MILLION	20 MILLION
Pediatric Demos/SYS-4	5 MILLION		5 MILLION
Family Care Centers/SYS-5	10 MILLION		10 MILLION
Home Health/SYS-6	12.5 MILLION	12.5 MILLION	25 MILLION
HUD 232/SYS-7	25 MILLION		25 MILLION
Hemophiliac Centers/SYS-8	4 MILLION		4 MILLION
Transitional Homes/SYS-10	10 MILLION		10 MILLION
Service Demo Information/SYS-11	5 MILLION		5 MILLION
NCHSR/SYS-12	0.5 MILLION		0.5 MILLION
Specialized AIDS Care/SYS-13	0.5 MILLION		0.5 MILLION
Psychosocial Needs			
ADAMHA/PSY-6	5 MILLION		5 MILLION
NIMH Training/PSY-7	5 MILLION		5 MILLION

	FEDERAL	STATE	TOTAL
Nursing Care			
Demo Projects/NUR-1	5 MILLION		5 MILLION
Research Initiatives/NUR-2	1.5 MILLION		1.5 MILLION
Traineeships/NUR-3	8 MILLION		8 MILLION
Psych-mental Health/NUR-4	1.5 MILLION		1.5 MILLION
Student Loan/NUR-5	3 MILLION		3 MILLION
Work-study/NUR-6	10 MILLION		10 MILLION
Advanced Degrees/NUR-7	5 MILLION		5 MILLION
Nurse Guidelines/NUR-8	50 THOUSAND		50 THOUSAND
AHEC Initiative/NUR-9	5 MILLION		5 MILLION
Nurse Retention/NUR-10	250 THOUSAND		250 THOUSAND
Underserved and Minority Populations			
NHSC Scholarships/UND-2	20 MILLION		20 MILLION
NHSC Nurses/UND-3	5 MILLION		5 MILLION
NHSC Social Workers/UND-5	1.5 MILLION		1.5 MILLION
NHSC Training/UND-7	1 MILLION		1 MILLION
AIDS Information Coordination and Exchange			
Database/Hotline/INF-1	2 MILLION		2 MILLION
TOTALS	212.8 MILLION	52.5 MILLION	265.3 MILLION

AIDS RESEARCH, DRUG AND VACCINE DEVELOPMENT RECOMMENDATIONS

Basic Research		
NIH:		
Research grants in virology, immunology and in other HIV-related areas (15% increase over last year)	$ 90	million
Reagent bank expansion	.5	million
120 FTEs	60	million
Construction: 2 regional centers	5	million
20 P-3 laboratory upgrades	5	million
Clinical Research for Drug and Vaccine Development		
NIAID:		
Additional 70 FTEs for Clinical Trials	35	million
Direct grants for Community-based trials	5	million
FDA:		
Construction and equipment	35	million
50 additional FTEs for application review	25	million
Expediting Clinical Trials and Review		
Software development for data input and review Co-factor studies, historic control data used by NIH-sponsored trials and FDA	.5	million
Centralized Information Banks		
Animal models in rare diseases AIDS Research Project Registry Expanded PDQ for AIDS clinical trials — Total:	.5	million
Task Conferences		
Drug and Vaccine Liability Collaborative R & D International Clinical Trial Standards — Total:	.5	million
Training Grants and Education		
University training grants (50 scientists)	2.5	million
Individual research grants (50)	2.5	million
"K Awards" Career development awards, and Physician Scientist awards	5.0	million
Summer Student Program 250 @ $1500	.275	million
TOTAL FEDERAL FUNDS:	$ 272.275	million

PUBLIC HEARING SCHEDULE

DATE	SUBJECT	SITE
1987		
Sept. 1-2	Site Visit	New York City
Sept. 2-3	Site Visit	San Francisco
Sept. 9-10	Federal Overview Hearings	Washington, DC
Sept. 30	Congressional Caucus	Washington, DC
Oct. 15-16	Personnel Meeting and State Response Hearings	Washington, DC
Nov. 10-12	Site Visit and Hearing	South Florida
Nov. 24	Institute of Medicine Report/American Medical Association Report	Washington, DC
Dec. 10-11	Incidence and Prevalence	Washington, DC
Dec. 17-18	IV Drug Abuse and HIV Infection	Washington, DC
1988		
Jan. 13-15	Care (Education of Health Care Workers/Pediatric Care)	Washington, DC
Feb. 18-20	Research: New Drugs/ Vaccines/Facilities	New York, NY
Feb. 29	Executive Session	Washington, DC
Mar. 1-3	Prevention/Education	Washington, DC
Mar. 16-18	Discrimination: Workplace/ Housing/Schools Ethics: Denial of Care/ Research Testing: Confidentiality/ Duty to Warn	Nashville, TN

Mar. 24-25	Municipal, Corporate, and Community-based Organization Response	San Francisco, CA
Apr. 5-6	Societal Concerns/Legal	Washington, DC
Apr. 18-20	International	Washington, DC
Apr. 26-27	Finance	Washington, DC
May 9-11	Public Health/Workplace Safety/Employment Issues	Indianapolis, IN
May 16-18	Legislative Review: Federal/ State	Washington, DC
June 7-8	OPEN	Washington, DC
June 16-17	OPEN	Washington, DC
June 20-22	Executive Session	Washington, DC

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