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The Journal, October 1, 1987

In Amsterdam

Needle exchange hits 700,000 mark

AMSTERDAM — The approach is clear-headed and pragmatic; the aim is to control the spread of the HIV virus in the IVdrug using population and from them to the general public. The results? It's too early to tell, but authorities at the Municipal Health Service here hope to hold back what one clinic worker calls "typhoon AIDS."

At left, Krishna Kanhai, MD, medical director of one of the city's suburban clinics, with boxes of sterile needles and a garbage can filled with dirty needles.

In the first of a series of special reports, The Journal's Contributing Editor, Harvey McConnell, looks at Amsterdam, where 700,000 sterile needles will be distributed this year.

See pages 7/8

In Amsterdam:

The greatest threat of the spread of AIDS in society in North America and Western Europe is via intravenous drug users and prostitutes. The most effective prevention efforts are an end to needle sharing, use of condoms, and more methadone maintenance programs. But, while the politicians in North America procrastinate, agonize, or avoid the issues, and many drug experts debate them, a number of countries in Western Europe have moved ahead with vigorous prevention programs.

Leading is the Amsterdam Municipal Health Service. The Dutch have a reputation for clear-headed, pragmatic, and business-like approaches, and its programs are just that. The aim is to contain, as far as possible, and with every means possible, spread of the HIV virus. Contributing editor Harvey McConnell, in the first of a series of reports, talks to Giel Brussel, medical director of the service's drug program, and Krishna Kanhai, medical director of one of the city's suburban clinics.

Amsterdam's Municipal Health Service will distribute 700,000 free needles and syringes this year among 8,000 heroin users as part of its concerted effort to contain the spread of the HIV virus

"It is rational, but it is not a miracle," is the pragmatic view of Giel Brussel, medical director of the drug abuse program. "We doubt it will be totally efficacious in prevention, it's slow."

It is too early to find if the needle exchange program has slowed the spread of the HIV virus. However, it is clear, after a year, that provision of free needles does not entice people into IV drug use and it has dramatically cut the rate of needle-sharing among addicts.

■

The needle exchange program is allied with a free methadone maintenance program and unceasing education and prevention efforts among drug users, and their sexual partners, and professional prostitutes, their clients, and their pimps. Even the streets are scoured for dirty needles.

Amsterdam's heroin user population includes some 2,000 from the former colony of Surinam, and a floating population of about 1,500 foreigners. About 60% "chase the dragon" (smoke heroin), and most users combine it with cocaine, alcohol, and tranquillizers when available.

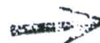
"Amsterdam is only a small city, about 400,000 in the centre, so our percentage of heroin users is on an American (United States) level," Dr Brussel points out. "Fortunately, the heroin user population is older (median age 30 years), and there are few young users."

■

Dr Brussel says that "at the moment our infection rate is fairly comparable with the international situation, but you have to bear in mind that our needle exchange program has only really existed just over a year." It could be some time before the constant research on every aspect of their programs shows any slowing of HIV transmission.

On the other hand, there is no evidence that providing free needles and syringes has either created new heroin users or changed the pattern of use among those already involved.

"At the start, we did wonder if



the people would begin to shoot up instead of chasing the dragon," Dr Brussel adds, "but we have found people do not change their drug use behavior because of this system.

"We do not find people shooting up more because they have access to free needles."

A study of IV users shows, however, that provision of free needles has cut needle sharing to 15% from 70%, and most sharing now is with a sexual partner.

Most AIDS cases at the moment in the Netherlands are among the homosexual population — only 12 have been recorded among drug users — but voluntary testing has shown that at least 1,500 users are HIV-positive.

Dr Brussel, who has been with the service for 10 years, points out that a radical decision taken in 1979 to tackle a drug epidemic which burgeoned in Amsterdam in the early 1970s has enabled workers to move effectively with the arrival of AIDS.

Prior to 1979, Amsterdam tried conventional therapeutic communities, United States-style methadone programs, and programs which accepted drug use.

Dr Brussel: "None of these programs seemed to work out in the sense they reached only a small proportion and the results were deplorable. On the therapeutic side, only a small number kicked off, and, of these, you could ask the question whether even without any therapeutic involvement they would have become clean.

"On the other hand, social programs which accepted drug abuse had serious side-effects in the sense of public disorder, dealing, crime, and so on.

■

"In 1979, we started a policy we call 'harm reduction.' This means if you can't cure people, which would be preferable, maybe the best thing to do is to try to minimize the harm concerned with drug abuse, as well as the social problems.

"We started a methadone program which is aimed specifically at reaching the drug epidemic as a whole. We gave out methadone to people with a long history of addiction, who didn't want to stop, and who wanted to apply to a methadone program so they could, in a manner of speaking, lead less hazardous lives.

"I think it was a very important step because we reached the drug abusers as such. This means we have a medical model and a business-like approach. There is a fairly large amount of medical supervision as to their physical condition, as well as supplying them with methadone."

Addicts are given the freedom to choose a methadone level at which they can function well, although the maximum allowed — 60 milligrams a day — is lower than in some US programs. Those who have only been addicted a short time either get no methadone or a low dose for a short period.

■

Each day, buses tour the city either to give addicts oral methadone or to bring them to one of five clinics around the city. Again, pragmatically, workers give some addicts enough methadone for several days if there is a good reason why their daily attendance would be impractical. Doctors can also prescribe methadone for short periods.

The system has worked well, "and this is important because it has given us a good way to approach the AIDS problem."

Dr Brussel is blunt: "AIDS is an overriding disease. It is a threat to all IV drug users, and because of prostitution it is a threat to all of society. This means you have a big

Draper on public health

COPENHAGEN — Many West European governments are confronting the AIDS threat among both the general public and intravenous drug users with a vigor still lacking in North America, even though the threat in Europe is not as great at the moment.

Ron Draper, Health and Welfare Canada and currently with the European office here of the World Health Organization, believes the issue is being addressed in Western Europe with "clearer public health considerations than in North America." (Mr Draper is director-general, Health Promotion Directorate.)

Attitudes can vary between the extremely repressive, as in the Soviet Union (see page 3), to the extremely liberal, as in Denmark and the Netherlands.

However, Mr Draper points out that while the problem of AIDS in North America "gets mixed up with people's attitudes toward sex and homosexuality and what one is permitted to say in public, the Danes, for example, don't have that problem." He cites an advertisement here that depicts a condom stretched the length of a Copenhagen city bus. "You couldn't do that in Canada."

Lowell Leven, PhD, professor, public health, Yale University, New Haven, Connecticut, and a long-time WHO consultant, says: "There is a growing feeling in Western Europe that this is a problem which involves communal action rather than individual behavioral change. You can't approach what is happening (with AIDS) as you would a smoking-cessation program."

public stake in controlling or reaching an effective containment of drug use."

In late 1984, Dr Brussel's department started its first distribution of sterile needles in exchange for dirty needles. By the end of 1987, it will approach the million-a-year mark, which he considers is about the right figure.

"We apply the principle that AIDS is a problem with many side-effects. We think it is very important to keep the streets clean of used needles, because used needles can contain the AIDS virus and the virus can remain active for a few weeks."

People are encouraged to scour the streets for used needles, as people scour the beaches for empty pop bottles, and some make a living by bringing in from 500 to 1,000 used needles in plastic bags. They are given sterile needles and syringes in exchange, "and they get whatever someone who is shooting up wants to give for it."

■

Amsterdam is a magnet for many drug users especially foreigners who use heroin.

One positive factor in Amsterdam is that the heroin-using population is older, and there are very few young Dutch people who now become involved with the drug.

"We don't see them, the police don't see them, the first-aid posts don't see them, the hospitals don't see them, and the doctors don't see them. So if we don't see them anywhere, we suppose they don't exist," Dr Brussel explains.

The city and the police make a sharp distinction between cannabis — which is openly sold in "coffee houses" — and opiates and cocaine. Police immediately close a "coffee house" which tries to sell any drug but cannabis.

Dr Brussel and his colleagues have a close working relationship with the police, and one of their physicians sees every drug user who is arrested. If there is any threat of violence to a staff member, the police immediately respond.

"People tend to be aggressive, and we know some methadone is sold on the streets. So there are certain people we don't want to give it to, but still they insist on coming," he adds with a sigh. The street market for methadone is among foreigners who cannot get the drug from clinics.

Dr Brussel thinks there is a lot of cocaine in Amsterdam, but it is mainly confined to heroin users. "About 70% of the heroin users use cocaine — if they can — as sort of a dessert. We have not seen any crack, and we have not seen many 'normal' people with cocaine problems. I do not think it is attractive to the Dutch culture, and we are lucky with that."

■

Dr Brussel would have liked to continue distributing free condoms to IV drug users and their partners. But it has proven financially prohibitive, and there is now a small charge. For now, it appears there is no HIV infection among non-drug-using prostitutes, but it is probably high among both male and female drug-using prostitutes, he says.

Dr Brussel observes: "It appears to us that many drug users are motivated to use clean syringes because of concern for their health. We know it is always being talked about among users. Most prostitutes want to use condoms but many of their client's don't, and we have an educational problem there."

■

When time and the HIV virus start to take their toll among drug users, Dr Brussel is considering ways in which experimental AIDS drugs can be administered in this population. Because the Netherlands, like most of Western Europe, has a national health service system, the researchers will be able to work closely with hospitals.

"You will have to reach certain populations to control AIDS effectively, which means if you give out dangerous drugs, you have to be sure they are taken properly and research is done into side-effects.

"In most other countries, the drug population is a forgotten group: people say you cannot reach them effectively. I think that here, with our system of methadone maintenance and control and containment as such, we can provide a good medical background for treatment."

A Drug Against AIDS and Crime A38

It sounds like a President's dream: a way to strike powerfully against drug abuse and AIDS ... possible to put into effect virtually overnight ... with no need for new legislation or significant new public cost. The dream is a plan to relax rules for methadone distribution. Yet so far, the Reagan Administration hesitates to make it a widespread reality, apparently because of old arguments that have lost their force.

Heroin abusers eventually weary of their enslaving addiction. When they do, many think first of methadone, a drug that blocks the heroin craving and permits a stable, productive life. In New York City alone, some 30,000 heroin addicts are now on methadone. The treatment programs are oversubscribed and addicts requesting help can wait for months.

Why not expand the programs? Money isn't the issue; methadone costs little. It is distributed on an outpatient basis through established clinics that could physically accommodate many more patients without strain, or community opposition.

The issue is Federal regulations. The addict must be enrolled in a comprehensive program of counseling and other services, with one counselor available for every 50 patients. To inhibit unauthorized use, the rules even forbid giving out methadone as pills; it must be served as a liquid in paper cups. State laws often repeat and elaborate upon the Federal regulations. Distributing more methadone in compliance with such rules would require heavy expenditures for staff and clinic space.

Supporters of the rules point out that methadone is itself an addictive drug, however benign its effects. Heroin addicts are likely to abuse other drugs as well, so methadone addresses only part of the problem. The best treatment, they say, is psychological counseling designed to alter dependent personalities.

Those who favor greater access to methadone say psychotherapy remains impractical. Freeing addicts of all drug dependency remains chancy. The intensive psychotherapy must take place in residential centers that can't hope to accommodate the need — New York City's have places for only 3,000. Expansion would mean wrangling with communities over new sites.

Relaxed rules, however, could permit immediate distribution of methadone to thousands more outpatients. While some might continue to abuse other drugs, their escape from heroin still would be a step forward. Since February, several clinics have been distributing methadone more freely in pilot programs under a waiver of the rules, apparently without adverse effect.

AIDS adds new urgency. It spreads rapidly through needles shared by addicts. Methadone, administered orally, reduces needle use. And fear of AIDS motivates more and more addicts to seek methadone.

Relaxing the rules would require no new legislation, just action by the Food and Drug Administration. Such a revision at the Federal level surely would prompt states to relax their rules as well — and so reduce waiting, crime and AIDS.

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Paul Kreisberg and Harry Blaney

AIDS Is a Foreign Policy Issue Too

It affects travel, business, national security.

National awareness of the challenge of AIDS is intense—for schools, prisons, the workplace. All these are on the agenda for the president's AIDS commission. But one major element is missing: the looming prospective effect on foreign policy.

After months of heated debate, the U.S. government decided in August to demand AIDS tests after Dec. 1 for all immigrants, refugees and amnestied individuals wanting to legalize their U.S. presence. Justification for this move comes from a provision of the Immigration and Naturalization Act requiring exclusion of immigrants with contagious diseases, but the technical and human problems involved are immense. What is a valid "test" and who should give it? Can amnestees, who are assured by law of the inviolability for law enforcement purposes of their files, be deported? How much will all this cost? And should the screening process be extended to other groups?

BY LOCHER

Discussion over whether to extend mandatory testing to include foreign students and teachers has already been mooted. But what about tourists or businessmen visiting America for more than a few months? The Soviet Union, Saudi Arabia, Iraq, China and India already require AIDS tests for all but short-term visitors, and the number of governments contemplating similar requirements is almost certain to grow in the coming year.

The risk of slowing down or impeding international travel and exchange is enormous. The U.S. government continues to be divided, the State Department urging as few limitations on freedom of international movement as possible, the attorney general and the Department of Health and Human Services taking a harder position on prospective AIDS carriers entering the United States.

Access for American ships, aircraft and other military forces to foreign bases or normal ports-of-call could become a serious security problem. The armed forces have tested 90 percent of all American servicemen for AIDS, including all those embarking on overseas tours of duty. So far a fairly low and stable rate of 1.6 cases per thousand individuals has been found, but—as occurred in mid-September when a Navy ship was turned away from a routine port call in Costa Rica—responsible military officers are not always able to offer firm assurances that all of their troops are certifiably free of the human immuno-deficiency virus. The Department of Defense is uncertain how frequently AIDS tests should be conducted, but assurances that every member of a ship or aircraft crew or an overseas-based troop unit is uninfected at a specific time will be difficult if not impossible to provide.

Defense officials profess not to be worried that the Costa Rican example—the only one of its kind thus far—will spread to other Latin American countries or elsewhere. Yet the Defense Department is also reluctant to initiate discussions on the subject with our allies in NATO or in Asia. Privately, however, civilian and military officers from friendly nations have begun to express concern. Allegations—which Soviet propaganda has fed—that American troops spread AIDS have begun to appear as a new anti-U.S. issue among groups opposed to U.S. military bases in the Philippines and elsewhere. Can detailed and frank discussions with countries with which we engage in joint maneuvers, which send officers and troops to the United States for training and with which, in emergencies, we would share medical services, be avoided very much longer?

The effect of the spread of AIDS on international business and tourist travel—most immediately for the hotel, food, entertainment and transportation industries—is already evident in a number of African countries, where tourist travel and safari business dropped sharply in the past year. International institutions such as the World Bank, some private American companies and U.S. government agencies are also finding it harder to fill vital overseas jobs in countries with a high incidence of AIDS.

Human rights issues are partic ly complex. Should refugees, who erwise qualify for admission to United States, or foreign wives children of U.S. servicemen be cluded because they test HIV tive? America has not fully dec how to treat its own AIDS vict but their fundamental rights are tected by law. Should it take a ha er, more discriminatory appr toward HIV-virus carriers from o countries? Some countries—Swe for instance—require that individ who test HIV positive be reporte their governments. Should the Un States cooperate? What are the in cations for confidentiality and priv for damage to careers and fami from large-scale requirements testing before international travel curs?

The global implications of AIDS already become apparent for con ued freedom of travel, for the un stricted conduct of business, for maintenance of security, for inter tional health cooperation and as tance, and for human rights. Nev theless, U.S. government agencies thus are focused on implications of the dise primarily in terms of specific agency int ests. There appears to be no coordinat overview of the foreign policy implicatic and no framework for how or whether when to discuss such policy issues w other friendly countries.

There is still serious debate in the me cal profession over the gravity of the AII epidemic. Will it spread with increasing ea to broader segments of the U.S. public a global population, or will it remain confine as at present, to relatively restrict groups, at least in the United States? T World Health Organization believes th some 5 million to 10 million people worl wide have been exposed to the AIDS viru including 1.5 million Americans. But th 100 percent margin of error of this estimat suggests how little is really known of th risks.

Policy steps that intensify global fears an damage international relations should b avoided if the threat is of limited dimensio But what if it is not? The time may be rip for intensified U.S. government interagenc consultation, coordinated by the Nationa Security Council, as well as discussions o the issues between allies.

Paul Kreisberg is a senior associate at the Carnegie Endowment for International Peace. Harry Blaney was a research associate at Georgetown University's Institute for the Study of Diplomacy.

NIDA AIDS PREVENTION INITIATIVES
(REDUCING TRANSMISSION ASSOCIATED WITH INTRAVENOUS DRUG ABUSE)

A. IMPROVING OUTREACH

- Reaching more addicts (use of indigenous workers, etc.)
- Making treatment more attractive (reducing restrictions on methadone use, increasing accessability and availability of services, providing treatment vouchers, etc.)
- Diversion of addicts to treatment from criminal justice system

B. INCREASING TREATMENT CAPACITY

- Providing more treatment slots (increasing capacity of methadone maintenance programs)
- Providing more treatment space/facilities (overcoming community resistance, destigmatizing addiction)
- Training more treatment personnel (counselors, administrators)
- Utilizing other treatment resources (NIMH Community Mental Health Centers, Criminal Justice System)

C. IMPROVING TREATMENT EFFECTIVENESS

- Developing alternatives to existing treatments (pharmacotherapies, psychotherapies)
- Use of more behaviorally-based treatment strategies
- Improving efficiency of existing treatment modalities
- Providing treatment for seropositive addicts or addicts with ARC, AIDS

D. IMPROVING AFTERCARE

- Developing relapse prevention strategies
- Enhancing social support networks for addicts, sexual partners
- Developing post-treatment followup programs
- Developing self-help strategies (Narcotics Anonymous)

E. PROVIDING VOLUNTARY HIV TESTING AND COUNSELING

- For addicts, sexual partners, children of addicts
- Monitoring prevalence of HIV infection in addicts

F. PROVIDING INFORMATION AND EDUCATION

- For addicts, sexual partners, children of addicts
- Distribution to treatment programs, emergency rooms, clinics, etc.
- Importance of treatment/stopping drug use or needle sharing
- Awareness of risk factors for AIDS
- Risk-reduction measures (needle/syringe cleaning, use of condoms)

G. TECHNOLOGY DEVELOPMENT

- Development of buprenorphine, LAAM
- Development of single-use needles/syringes
- Evaluation of needle-exchange programs

7/27/87

NATIONAL INSTITUTE ON DRUG ABUSE
AIDS Demonstration Projects

I. Comprehensive Community Outreach Demonstration Project

This project is designed to reach and effectively communicate information about AIDS to three high-risk populations--intravenous drug abusers, sexual partners of intravenous drug abusers, and prostitutes who are intravenous drug abusers or sexual partners of intravenous drug abusers.

The goals are to encourage high-risk individuals to enter drug-abuse treatment and/or to change behaviors (using drugs and sexual practices) that put them at risk for AIDS. The project will focus on outreach to intravenous drug abusers who are not in drug abuse treatment programs.

Grants will be awarded to five cities having a high incidence of AIDS among intravenous drug abusers. Community resource networks will be established in each city, providing coordination between local institutions, service agencies, and community organizations, and City, County, State, and Federal agencies.

II. Targeted Outreach Demonstration Project

This project is designed to test the effectiveness of various strategies for delivery of AIDS information to three target populations--intravenous drug abusers, sexual partners of intravenous drug abusers, and prostitutes who are intravenous drug abusers or sexual partners of intravenous drug abusers.

NIDA will be testing the effectiveness of five outreach strategies across 15 cities. The strategies will include use of indigenous workers, contact through emergency rooms, etc.

The project will also allow NIDA to direct monies to communities and neighborhoods that are identified "hot spots" of drug abuse and AIDS.

DATA COLLECTION
+
TEST STRATEGIES

16M Res.
10 Communication
4.5 Training
30.5M = FY 87 NIDA AIDS Budget

NATIONAL INSTITUTE ON DRUG ABUSE

OVERVIEW OF AIDS ACTIVITIES

NIDA's AIDS initiatives are planned within the context of the Institute's AIDS policy, which is to (1) encourage intravenous (IV) drug abusers to enter drug abuse treatment; and (2) educate intravenous drug abusers and their sexual partners about risk factors for HIV infection and transmission. This policy will be operationalized by awarding grants and contracts that will (1) expand availability of drug abuse outreach and treatment services; (2) improve efforts at treating and preventing drug abuse; and (3) develop educational materials about AIDS for drug-abuse treatment personnel and populations at risk (primarily heroin addicts, their sexual partners and offspring).

Drug Abuse Treatment Expansion

- Funds are available through the President's 1986 Initiative on Drug Abuse for drug abuse treatment program expansion. These funds can be targeted by States to treatment of intravenous drug abusers.

Research on Health Education/Risk Reduction

- Improving IV drug abuse treatment (develop alternatives to methadone)
- Improving IV drug abuse prevention (focus on gateway drugs, high risk youth)
- Improving understanding of IV drug abuse (basic knowledge expansion)
- Evaluating effectiveness of HIV risk reduction strategies

Research on Etiologic Agents and Co-Factors

- Identification of co-factors to HIV infection in IV drug abusers
- Studies of the potential role of drugs of abuse as co-factors in the development of HIV disease outcomes, such as dementia or Kaposi's Sarcoma
- Studies of sexual and perinatal transmission of AIDS and HIV infection among IV drug abusers, their sexual partners and offspring
- Studies on etiology of IV drug abuse (including needle sharing and vulnerability factors)

Research on Immunology

- Studies of drug effects on the immune system
- Clinical immunological studies (including drugs used in treatment)

Epidemiological Studies (Natural History)

- Determining prevalence of IV drug abuse (and needle sharing)
- Determining the natural history of HIV infection among IV drug abusers

Surveillance

- o Monitoring prevalence of seropositivity in IV drug abusers

Community Demonstrations

- o Comprehensive community demonstration program

  - Focus on outreach and AIDS risk reduction strategies for IV drug abusers not in drug abuse treatment programs
  - Grants to large cities with high prevalence of IV drug abuse and AIDS

- o Targeted demonstration program

  - Focus on assessing effectiveness of strategies (e.g., indigenous workers, emergency rooms, health care facilities) for reaching specific high-risk populations (IV drug abusers, their sexual partners, or prostitutes associated with IV drug abuse)
  - Contracts to communities and neighborhoods that are identified "hot spots" of intravenous drug abuse and AIDS

Training and Technical Assistance

- o Development of AIDS informational modules for drug abuse treatment staff
- o Technical assistance to drug abuse authorities and treatment programs
- o AIDS prevention workshops for drug abuse agencies
- o AIDS counselor training videotapes for drug abuse treatment staff
- o AIDS adolescent outreach training
- o AIDS guides for counseling minority populations

Communications

- o AIDS information for drug abusers and sexual partners of drug abusers (in English and Spanish)
- o Involvement of entertainment community in AIDS education
- o Market research and materials development
- o Marketing AIDS public education programs
- o AIDS/drug information and referral toll-free telephone line

Testimony Before the President's Commission on AIDS.

10 September 1987

You have invited me to present an overview of the activities of the Department of Justice relating to the AIDS epidemic. The Department has addressed the issue of AIDS in three primary areas. First, in the Federal prison system, we have been dealing with inmates who suffer from AIDS and who carry the AIDS virus. Second, in the Immigration and Naturalization Service we are encountering the problem of AIDS in the course of our responsibility to screen immigrants for dangerous and contagious diseases. Third, in our Office of Justice Programs, we are involved in giving advice to law enforcement officers at all levels of government concerning situations that involve AIDS in a law enforcement context, such as handling of criminal suspects who may have AIDS or carry the virus, administering of paramedic assistance, and dealing with AIDS as it affects victims of crime.

Following a meeting with his Domestic Policy Council on May 28 of this year, President Reagan asked the Department of Justice to expand our AIDS testing program for federal prisoners and to screen aliens who seek permanent residence in the United States in order to identify those who carry the AIDS virus. On June 8, the Attorney General announced a Departmental program to address

the problem of AIDS within areas of the Department's responsibility.

Bureau of Prisons. Before June of this year, the policy of the Bureau of Prisons, established in consultation with medical authorities in the government, had been to test prisoners only when a medical examination indicated the prisoner had symptoms that appeared to be an active case of AIDS. Prisoners who were determined to have AIDS were sent to separate facilities, male prisoners to the Federal Correctional Institute at Springfield, Missouri and female prisoners to the Federal Correctional Institute at Lexington, Kentucky. Appropriate medical attention and care was then given to these prisoners at those locations.

In accordance with the Attorney General's announcement in June, the Bureau of Prisons undertook a pilot program to test all incoming prisoners for the AIDS virus and also to test all prisoners who were being released.

The Bureau performs these tests by taking blood samples at the prison where the individual prisoner is assigned, as part of a routine physical examination. At the same time, prisoners are given a questionnaire that asks them whether they have been involved in types of high risk behavior. Blood samples are drawn by Bureau of Prisons physicians, and are analyzed by outside laboratories on contract to the Bureau. The Bureau has recently entered into a nationwide contract for these tests, at a cost of $4.74 per person tested. This cost includes the initial

screening test and a follow-up confirmatory test that is administered when the initial screening test is positive. The Bureau plans to conduct follow-up tests three months and six months after the initial test, and then every six months thereafter.

The results of the tests are closely held; they are given on a need to know basis only to appropriate officers in the Federal Correctional Institute, such as the prison warden, the unit chief, and a limited number of other security officers when necessary to ensure the protection of inmates from spread of the virus. Administrative measures such as segregation are as necessary to guard against spread of the virus.

The results of the tests of prisoners who are to be released from the Federal system are given to the head probation officer. The U.S. Parole Commission on August 17 of this year published a proposed rule in the Federal Register, inviting public comment on various questions pertaining how the Parole Commission and parole officers should use the information of a positive AIDS test for a prisoner released and on probation.

The Bureau of Prisons will be reassessing its policy toward AIDS after September 30, when the initial testing period is complete and the Bureau proceeds to compile and analyze the resulting data. We will then examine various questions concerning how to continue, modify, or expand our current testing

program, as well as related issues of concerning appropriate management of Federal prisoners who test positive.

Immigration. The second part of the Department of Justice program concerns Immigration. In June of this year, in accord with the President's decision, the Attorney General directed the Immigration and Naturalization Service to develop a testing program for all immigrants, refugees, and applicants for legalization. The Department's policy is based on the Immigration and Nationality Act, which provides in Section 212 that applicants for visas shall be excluded from the United States if they carry a dangerous contagious disease. The Department of Health and Human Services, which has responsibility for administering this provision of the Act, published a final rule on August 28 of this year, following a period of public comment, in which it designated HIV infection -- the AIDS virus -- in addition to active cases of AIDS, as a dangerous contagious disease within the meaning of the Immigration and Nationality Act. The Immigration and Naturalization Service is prepared to commence testing on the effective date of this rule, which will be December 1, 1987.

Testing of persons seeking to enter the United States as permanent residents will take place at the country of origin or place of departure. Those who test positive will be denied entry. Aliens inside the United States who apply for legalized status under the Immigration Reform and Control Act of 1986 will

also be tested. This testing will take place of the time they initially apply for legalized resident status and at the time they apply for adjustment to permanent resident status.

The third aspect of the Department of Justice program concerning AIDS addresses the special problems and needs of law enforcement officers at the federal, state, and local levels. The suspects and offenders with whom the justice system deals at all levels on a daily basis include a number of persons who have active cases of AIDS or who are carriers of the AIDS virus. Accordingly, the Attorney General has directed the National Institute of Justice, within the Office of Justice Programs, to perform several functions designed to assist the law enforcement community. First NIJ is to collect information on incidents alleged to involve transmission of the AIDS virus to criminal justice professionals in the line of duty. Second, NIJ is to distribute reference materials on AIDS in relation to the criminal justice system, working in conjunction with the Centers for Disease Control. Third, NIJ is to provide technical assistance and training to help law enforcement officials understand the facts about AIDS and the relevant considerations for developing policies concerning AIDS. Finally, NIJ has set up a hotline to provide information concerning AIDS in the law enforcement context to callers.

In this work, NIJ is building on extensive research and analysis that it has already done in the area of AIDS. NIJ has issued a detailed report, based on four years of study, on AIDS

in correctional facilities. This report, updated in 1986 and soon to be updated again, summarizes current medical information, reviews AIDS-related policies of correctional systems nationwide, and sets forth a range of specific policy options available to administrators. NIJ has issued a similar study on AIDS and the Law Enforcement Officer, released earlier this summer. NIJ also issues AIDS Bulletins which offer concise, nontechnical information about AIDS related to criminal justice policies.

I am glad to provide these NIJ publications to the Commission.

Finally, concerning the effect of AIDS on victims of crime, the Bureau of Justice Statistics and the Office for Victims of Crime are currently studying ways in which the criminal justice system can deal with AIDS as a threat to victims of crime.

Conclusion. In all these areas of activity, the Department of Justice is motivated by a desire to acquire information concerning AIDS that will be of assistance to the medical community, law enforcement professionals, and the public at large. Concerning those individuals in the custody of the Department of Justice, we are concerned to prevent the transmission and spread of AIDS by all feasible means possible, including a systematic education and information effort within the Federal prisons. We hope that the data from our testing of immigrants and Federal prisoners will be of some help in the

vital task of assessing the nationwide incidence, the means of transmission, and the rate of increase of the AIDS virus.

Thank you for the opportunity to appear before this Commission; you have our firm support for the important work that you are undertaking.

Washington Report . . .

HOUSE PANEL HOLDS HEARING ON AIDS AND IV DRUG ABUSE

More than one-third of the AIDS cases in New York City involve intravenous drug users -- twice the national average -- House Select Committee on Narcotics Abuse and Control Chairman Charles B. Rangel (D-N.Y.) said on Nov. 26 in New York City.

"New York City has long been a major illicit drug market with a high percentage of IV drug users," Rangel said in opening a Select Committee hearing on the problems of drug trafficking and abuse in the New York City area and the relationship of IV drug abuse to AIDS.

"None of these IV users, none of us, ever anticipated that even greater suffering than commonly associated with drug abuse and dependency could be possible," he said. "No one ever anticipated AIDS. At a time when I wondered what possibly greater tragedy could befall IV drug users, the spectre of AIDS reared its head."

The hearing was the first by a congressional panel to delve into the connection between IV drug abuse and AIDS.

"The Select Committee has become convinced that additional exposure needs to be given to the link between intravenous drug users and Acquired Immune Deficiency," added Rep. Benjamin A. Gilman of New York, the ranking Republican on the Select Committee.

Gilman noted that AIDS has become the nation's No. 1 public health concern.

"Although I regret that the majority of concern only shifted when it became known that the populace at large could be affected," he said, "it is indeed time for us to explore in depth the manner in which the heterosexual population can acquire this fatal disease. The most imminent threat appears to us to be from the drug-abusing population."

Rangel also expressed alarm about the increasing availability and purity of heroin and cocaine in New York City. He cited figures showing the number of drug seizures has increased, along with the number of admissions to treatment programs.

"Viewing these kind of statistics, it is clear that we are losing the war against drug trafficking and abuse in our nation," he said. "Drugs are being produced, trafficked and imported at unprecedented rates. To make things even worse, innocent people -- people not involved in this dirty business -- have been seriously injured, and even killed by drug traffickers."

Editor's Note: For more information, please contact: Pat Remick, Select Committee on Narcotics Abuse and Control, Rm. H2-234, House Office Bldg. Annex 2, Washington, DC 20515. Phone: 202-226-3040.

DRUG ADDICTION EXPERTS SAY U.S. WILL NEED TO GIVE ADDICTS STERILE NEEDLES TO CURB AIDS

Sixty of the world's leading authorities on drug addiction research and treatment met in Camden, N.J., in July to confer on drug addiction and the spread of AIDS by drug abusers. The conference, hosted by the University of Medicine and Dentistry of New Jersey School of Osteopathic Medicine, was chaired by Jerome J. Platt, Ph.D., director of the Medical School's Center of Excellence in Addiction Treatment Research.

Prominent scientists from the Netherlands, the United Kingdom, Canada, Israel, Germany, Belgium and the United States joined Dr. Platt in presenting papers that outlined the latest research on drug addiction and its attending problems, including AIDS.

The experts agreed that AIDS is being spread among intravenous drug users at an alarming rate. Herman Joseph, a social worker with the New York State Division of Substance Abuse Services, reported that AIDS surpassed cancer as the No. 1 killer of women between the ages of 25 to 34 in New York City last year. AIDS has been the leading cause of death of men aged 24 to 44 there since 1985. Joseph reported that 80 percent of the women diagnosed with AIDS were intravenous drug abusers who have shared needles or had intimate sexual contact with an infected drug abuser.

Several speakers pointed to prostitution as another source of AIDS infection. Dr. Claire Sterk, an adjunct instructor of psychiatry at UMDNJ School of Osteopathic Medicine, and a research associate at Erasmus University in Rotterdam, has done in-depth studies of prostitutes in the U.S. and the Netherlands. She reported that 35-45 percent of all prostitutes are intravenous drug users, and that 57 percent of drug-using prostitutes test positive for the AIDS virus. Prostitutes infect others with AIDS through sexual contact and through sharing the needles they use to inject drugs, Dr. Sterk said.

Give Users Sterile Needles?

According to Dr. G. F. Van de Wyngaart, head of the Addiction Research Institute at the University of Utrecht in the Netherlands, the Dutch have cut down on AIDS transmission by instituting bold prevention measures. For example, methadone is delivered to addicts throughout the large cities in specially equipped vans. Clean needles and syringes are given freely to drug users.

"In the Netherlands, where drug users can buy or exchange clean needles and syringes," Dr. Van de Wyngaart says, "we have seen only an extremely limited incidence of AIDS among native Dutch I.V. drug users."

Other experts at the week-long conference on addiction echoed Dr. Van de Wyngaart's point of view. Donald De Jarlais, Ph.D., of the New York State Division of Substance Abuse Services, said that in Amsterdam, distribution of sterile needles in exchange for dirty ones had increased from 25,000 to 600,000 last year as a result of the addicts' fear of AIDS.

"There is a movement toward making sterile equipment available to I.V. drug users in the United States," said Dr. De Jarlais. "Twenty years from now, when we are asked what we did to help stem the epidemic of AIDS among heterosexuals, are we going to say that we went on running our agencies in the same way and providing the same kinds of services as we did before there was an AIDS epidemic?"

Herman Joseph concurred, saying, "The AIDS epidemic is making people rethink a lot of their attitudes about providing clean needles and expanding methadone availability to stem the use of shared needles." Joseph also advocated "front line medicine," which he says includes making methadone available in non-traditional places, such as "shooting galleries," jails, probation offices and homeless shelters.

Other topics covered by speakers at the conference included new treatment and rehabilitation programs for drug addicts. Dr. Platt reported on a program at the osteopathic medical school that has succeeded in providing employment training for drug addicts in methadone treatment.

"We have found that drug addicts have impaired problem-solving skills. Their ability to logically work problems through and find alternative solutions is not well developed," he said. "Importantly, we have been able to show that when we have methadone clients go through our program, they search for and obtain employment at a higher rate than other methadone clients." Dr. Platt's program is sponsored by the National Institute on Drug Abuse (NIDA).

Dr. Platt added that the ability of addicts to connect their own actions with ultimate consequences appears to be impaired. But, he stated that when good therapy is combined with methadone treatment, and training is tailored to the individual addict's needs, drug addicts can become useful and productive members of society. ■

DRUG-LINKED AIDS CASES UP

The number of AIDS cases linked to intravenous drug use — once concentrated in New York City and northern New Jersey — are increasing across the nation, it was reported recently.

Dr. James Curran, head of the AIDS branch of the Centers for Disease Control (CDC) in Atlanta, said that quick action will be required to halt further proliferation of the disease through contaminated needles.

Dr. Curran said the latest statistics indicate that AIDS has become the leading cause of death among New York prisoners, principally because of intravenous drug use before an inmate is jailed. He said there are indications that similar conditions are developing in prisons elsewhere.

AIDS cases involving drug addicts, their sex partners and children have occurred mainly in New York City and northern New Jersey in the past. But cases among intravenous drug users have now been reported in 44 states. ■

DID YOU KNOW that Washington Crime News Services also publishes **Computer Crime Digest, Crime Control Digest, Corrections Digest, Juvenile Justice Digest, Security Systems Digest, Organized Crime Digest, Training Aids Digest** and **Criminal Justice Digest.** Sample copies of these publications are available upon request.

THE WHITE HOUSE

WASHINGTON

July 15, 1988

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

SUBJECT: Report of the Presidential Commission on the Human Immunodeficiency Virus (HIV) Epidemic

Issue: Allegations that OMB actions are an impediment to progress by the National Institutes of Health (NIH) against AIDS and HIV infection.

Background: On June 27 you received the final report of the Commission and directed me to prepare a response for you within 30 days. On Wednesday, Admiral Watkins and one of the Commissioners, Dr. Burton Lee, testified before the Senate Committee on Labor and Human Resources. Their testimony was in part a reiteration of the Commission's recommendations (see Attachment A). The Commission recommends that, for a two year minimum period, NIH be given special administrative status under which it will receive its budget directly and "have discretionary authority over all subsequent allocations of personnel and resources within NIH," including exemption from standard OMB review.

Discussion: Due to the urgency of AIDS and HIV infection, we should give priority to reducing impediments to progress, especially in scientific research areas. However, the priority must not subvert necessary administrative and fiscal controls or establish a priority-setting system independent of your overall policies. The Commission's recommendation may be overly simplified. In my report to you on July 27, I expect to make recommendations which address this complex issue -- resolving the problems identified by the Commission yet preserving the integrity of the budget and administrative review process.

TAB A

Recommendation: (extract from Chapter four)

4-14 To better meet the research mission of the National Institutes of Health (NIH) through a facilitated management process, the Secretary of Health and Human Services and appropriate authority as required by law should mandate that the Director of NIH report directly to the Secretary for a period of two years. The Director will receive the budget directly from the Secretary, and will have discretionary authority over all subsequent allocations of personnel and resources within NIH. For the two-year period, Congress, in conjunction with the Secretary, shall exempt NIH from OMB regulation of personnel and resource allocations within all of NIH. During this two-year period, NIH will continue to operate within all remaining confines of law.

Following the two-year period, Congress should authorize an independent audit to measure the effectiveness of this change. The Director and the Secretary will report to Congress, and if the change in procedure has resulted in greater flexibility for NIH to achieve its scientific mandate, it shall become permanent. If it has not, Congress should consider giving NIH a more independent funding status, similar to that of the National Science Foundation.

CHAPTER FOUR: BASIC RESEARCH, VACCINE, AND DRUG DEVELOPMENT

Basic biomedical research continues to make vast and unprecedented advances in key scientific areas directly applicable to the HIV epidemic. However, significant obstacles confront both the scientist seeking a cure, and the individual with HIV infection seeking treatment. Our national system of research programming and funding is not equipped to reorganize rapidly in response to an emergency. The process of individual initiatives by scientists, followed by peer review, while essential, produces results at a rate too slow to be understood or accepted by a country at risk. Innovative initiatives are urgently needed that will both maintain scientific integrity and shorten the time from discovery to trial, and from trial to safe and effective treatment use.

In its hearings on research issues, the Commission identified several areas of serious concern. Foremost among these is the need for broader basic research activity to more rapidly model and develop a broad range of anti-viral and immune modulating drugs and the need for immediate implementation of broadly accessible clinical trials of all potentially therapeutic agents.

In the area of basic research, other problems identified were:

- the need to free federally sponsored research from many of the bureaucratic restrictions that delay progress and constrain exploration.
- the need to create new ways of thinking about basic biomedical research and science education and to establish them as much higher funding priorities.
- the need for greater collaborative research, both nationally and internationally.
- the need to upgrade many of America's aging research facilities and properly equip them for HIV research.
- the need for an even greater emphasis on basic biology, virology, and immunology.
- the urgent need for the establishment of a data base that would provide a description of the natural course of the disease from which "historic controls" might be derived for research on the full spectrum of HIV-related illness.
- the need for greater communication of research results, both within the research community and to the general public.

In the areas of drug and vaccine development, problems include:

- the need for increased access by a broader spectrum of the infected population to a greater variety of experimental treatments.
- the need to eliminate whenever possible the use of placebo-controlled trials in patients whose disease is immediately life-threatening.
- the need for a public information system that would collect and make available current information on drug development and open clinical trials.
- the need for direct federal support of quality-assured community-based drug trials.
- the need to set aside counterproductive competition as much as possible in favor of greater collaboration among pharmaceutical industry members, and between industry and government, especially in times of medical emergencies.
- the need for additional Food and Drug Administration (FDA) resources to process more rapidly all HIV-related applications without compromising standards of safety or efficacy or causing delays in the review of promising drugs for other diseases.

Hearings on these and many additional research problems yielded the following information and recommendations.

Section I. Basic Research—The National Institutes of Health

AIDS is a complex and aggressive biomedical syndrome which was initially recognized in this country at a time when there was no knowledge of what caused the disease, how it was transmitted, or how it could be stopped. There were no therapeutic drugs with known effectiveness, no vaccines, and no hope for early intervention in what seemed to be an endlessly escalating process. When an etiologic (causative) agent was identified by Dr. Robert Gallo at the National Cancer Institute (NCI) and Dr. Luc Montagnier at the Pasteur Institute in Paris, it was found to be a retrovirus, a type of virus about which comparatively little was known.

Within a short time, however, the research community responded to the challenge posed by the new disease by attacking it on many fronts. Even before the virus was isolated and the etiology of the disease established, many of the complexities of the syndrome had been delineated, and information had been gathered on transmission and possible co-factors. As soon as HIV was identified, intensive laboratory work began with "off the shelf" drugs to find agents that might be viricidal or interfere with viral replication. Trials of promising drugs and vaccines are underway. That these successes were achieved relatively rapidly was due to the presence of a major research infrastructure that worked -- one that was built upon several decades of serious research commitment at the National Institutes of Health (NIH).

America's investment in basic research 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. The latter includes investment in training and support mechanisms which enable investigators to pursue innovative ideas. This research takes place on university campuses, in medical institutions, and in independently sponsored research centers. Although other federal sources exist, the distribution of federal funding for research programs in these varied sites is centralized in NIH. The largest proportion (87 percent) of HIV research funding provided by NIH is given to institutions and individuals by means of direct grants or contracts.

The advances made to date in research rest on a foundation of research excellence established many years ago at NIH and accelerated in the 1970's by the "War on Cancer," primarily within 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 HIV epidemic, NIH scientists answered the challenge by turning their research efforts to the new disease even though technically they were funded to do other work. As knowledge of the severity of the problem increased, funding followed so that research at NIH, the universities, and medical centers could continue and broaden in order to explore the disease more aggressively.

Initial NIH funding for AIDS research was authorized by Congress in 1982 at $3.5 million. During FY 1988, NIH funding for HIV-related research is expected to reach almost $468 million, an 80 percent increase over the previous year, over 13,000 percent higher than in 1982. Of these funds, $407 million will be given in grants to support programs in universities, medical centers, and other extramural institutions, as well as to individuals. The remaining $61 million (13 percent of the total) will support intramural research at the National Institute of Allergy and Infectious Diseases (NIAID).

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.

HIV-related basic research is expected to have high yield benefits to Americans who suffer from cancer, viral diseases, and immune diseases, which collectively kill an estimated 650,000 individuals each year. Research areas that require additional long-range funding include:

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

Cell biology and host genetics: What viral mechanisms function in infected cells during the viral replication cycle, and how can we interfere with these mechanisms? What genetic co-factors, present in some individuals and not others, influence susceptibility and resistance to infection with HIV and the occurrence and rapidity of progression from a symptom-free state to overt disease?

Pathogenesis: What are the mechanisms by which HIV spreads from cell to cell within the body, kills certain cells and interferes with the normal function of others, and undermines the host immune response to many serious opportunistic infections?

Reagents, Animal Models, and Research Information Exchange

For information obtained in different research laboratories to be comparable, certain common resources must exist. Biologic materials such as viral strains, genetic probes, polyclonal and monoclonal antibodies must be standardized and made widely available.

To date, adequate animal models have not been developed for human HIV-related research. An appropriate model is one in which the animal can be infected with HIV and can develop disease similar to that produced by HIV infection in humans. In this way, experiments critical to our understanding of the virus, and of disease progression can be conducted without the use of human subjects. Difficulties with animal models for HIV research persist. Chimpanzees, for example, can be infected with HIV, but, to date, have not developed AIDS. In addition, chimpanzees, the only primates that can be infected with HIV, are an endangered species. Their breeding, care, and use in experiments must be carefully monitored by strict application of ethics and peer review, and they should be used only when there is no other alternative. It is important to ensure that experimental animals are treated humanely and used as sparingly as possible. Progress against HIV would be achieved much more slowly, at best, if animal studies were not permitted.

Simian Immunodeficiency Viruses (SIV) are a group of viruses very similar to HIV-2 which infect rhesus macaques, a possible animal model candidate. In addition, SIV and HIV are lentiviruses, a virus characterized by a long latency period and slow progression of disease. Animal studies in lentiviruses are well documented, and use of these models may prove valuable correlates to HIV. In addition to SIV, candidate viruses include visna-maedi (sheep), caprine arthritis encephalitis virus (goats), and equine infectious anemia (horses). Ideal animal model HIV research would use small animals that can be relatively easily and inexpensively maintained (e.g., mice). As these animals may be infected using genetically altered materials, issues such as biocontainment and liability would require serious attention.

Work with virus-infected animals requires the strictest application of proper biocontainment procedures to protect research workers. Additional obstacles to developing an appropriate animal model for HIV infection and AIDS include criticism from organizations concerned with animal rights, and a decrease in the animal population overseas, resulting in ethical and legal restrictions against both animal importation and conducting research in the animals' native setting. Researchers foresee long delays in the development of HIV drugs and vaccines, especially for use by pregnant women, if animal research is precluded.

Witnesses before the Commission indicated a need for better mechanisms of information exchange and communication about work in progress, especially in basic research, but noted that competition often precludes such exchange. Within the federal government, the importance of interdepartmental communication on research programs is underlined by the HIV-related research being conducted at the Department of Defense. Research from the Strategic Defense Initiative (SDI) has, as a side benefit, produced valuable medical advances that may be useful in the fight against the HIV epidemic. One project under study is a dye laser system, which has been found capable of destroying certain viruses within the blood. Another spinoff of the SDI applied technology program is the development of a virtually impenetrable yet pliable material which will be used to make protective gloves that could be worn when conducting surgery or other medical procedures.

Several research witnesses testified that research liability problems should be addressed by the Commission because they create serious obstacles to research. Witnesses indicated that some institutions have been reluctant to under-

take HIV research until such liability problems have been resolved, fearing the cost of liability protection or liability actions would be unaffordable. Basic research liability issues relate primarily to worker safety, and are of special concern to those individuals working with live virus or virus-infected animals.

Facilities

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

In the research community outside NIH, few universities and research institutions have funds immediately available to create or convert facilities for HIV-related work. The cost of upgrading existing laboratories to P-3 level is approximately $250,000 per laboratory. Many laboratories now exist around the country that could be upgraded in this manner, providing space for additional HIV-related research. This diverse pluralistic distribution of research space was highly recommended by several witnesses as offering the greatest potential for discovery.

Testimony 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 this 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. Such centers would have a great impact by providing opportunity to young researchers.

A highly specialized type of facility that is in very short supply is a laboratory equipped for advanced research on the structure of protein constituents of viruses such as HIV. These studies involve the art of making crystals of these proteins and mapping the internal structure of the protein molecule by the study of their X-ray diffraction patterns. Knowing these structures will greatly facilitate the development of antagonists to the functioning of these molecules in the course of disease development.

In order to conduct rapidly expanded research on HIV that is safe and scientifically expedient, facilities and instrumentation must be brought up to date. Funds for this type of upgrading come primarily from the federal government.

NIH last received major construction appropriations in the late 1960's. Much of the construction authorization for the research institutes has since expired. Institutes within NIH used to have independent construction authority but only three institutes are currently able to authorize and grant funds for construction. NIAID, the lead agency on HIV research, is not one of them. This has created an obstacle to NIH funding of extramural university construction and reinstrumentation, as well as prevented NIH from answering its own intramural construction needs. A new AIDS research building has been planned for the NIH campus at a cost of $30 million. After two years, this building is still in the early planning stages.

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 an area of several square miles, some distance away from the Clinical Center at 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, in close proximity to the patients.

Space on the NIH campus has been set aside for the building, architectural plans drawn, and funds approved by Congress; yet 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. At this point in time it would require no new dollars, and may in fact save money if construction were expedited. Documents, specially requested by the Commission and sup-

plied by NIH, indicate that calculations of net present value have been carried out for three alternatives, with the following results:

- Continue present leases—$147.2 million
- Lease-purchase on NIH campus—$95.0 million
- Federal construction on NIH campus—$97.5 million

Delay in the construction of this building is one of the most serious research administrative obstacles the Commission has encountered.

Administrative Processes

HIV was isolated in 1983 and because the disease known as AIDS was then determined to be a virus-induced infectious disease, NIH designated NIAID as the administrator for HIV-related federal research management. Much of the pre-1983 HIV research was done at NCI, and work continues at that institute. Senior leadership within NIH, especially in NIAID and NCI, responded to the challenge of the epidemic 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 NCI, which had been 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 an infectious disease crisis.

Witnesses critical of the NIAID response have testified that little funding was received by outside institutions until late in 1984. They believed that this was due to the lack of a pre-existing administrative structure similar to that of NCI for clinical trials, and also due to the complexity of the grant funding process.

The NIAID clinical trials program has currently enrolled nearly 4,000 patients and is expanding into 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. This should cut grant review and turnaround time to less than six months. Both the accelerated grant review and community involvement in clinical trials are significant breaks with research and funding tradition. They 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. However, as stated in the Commission's interim report, a greater sense of urgency throughout the government is needed to implement the increased funds already approved by Congress and to supplement improvements already underway by NIH.

The diversity and multiplicity of HIV research projects at NIH requires management at the level of the Office of the Director. NIH recently announced the initiation of the Office for AIDS Research, which was established in April of 1988, and will eventually have 12 to 15 full-time equivalent positions (FTEs). It is operating under a current budget of $400,000 which is expected to double in the following fiscal year. The Commission endorses the Director's establishment of this office and encourages its full staffing and support.

The Commission's examination of HIV research programs has revealed that despite NIAID's commitment to rapid response, limitations in the federal system must be addressed if this nation's goal of controlling the epidemic is to be realized. One of the greatest obstacles cited by NIH administrators is the inflexibility of Office of Management and Budget (OMB) regulation of internal resource allocation and program development. Currently, OMB acts as a surrogate Secretary of HHS, in effect, micro-managing research on the institute level within NIH. The Commission favors allocating pools of resources (funds and personnel) to NIH and allowing the Director greater discretionary powers to make subsequent personnel and funding allocations to each institute. NIH witnesses have repeatedly indicated their desire to be held accountable for results and asked for greater flexibility to employ innovative methods through which to achieve those results.

The mandate of science is exploration and discovery, and this requires flexible management to allow for the creative application of ideas. Such flexibility is often difficult to achieve in a bureaucracy as massive as that of the federal government. NIH is an organization much like the National Science Foundation (NSF) in that its mission is broad scientific exploration, often in uncharted territory. However, there is a significant difference between the two in that NSF is less encumbered by layers of bureaucracy. Therefore, to allow NIH the greatest potential for discovery in HIV research, as well as in research on cancer and other diseases, the Director should have full

authority and responsibility to manage the resources appropriated by Congress as needed.

Personnel and Recruitment

From FY 1984 to FY 1988, a total of 371 new FTEs were added to NIH for HIV-related activities. Over the same period, the total number of NIH personnel positions dropped from 13,493 to 12,461. This represents an overall loss of 1,032 positions, even though HIV positions have been increased. The Commission is deeply concerned that the much needed increases in HIV research personnel are being implemented to the detriment of research on other diseases. Although research on HIV must be expanded, we cannot afford to cut back on cancer or heart disease research to achieve this goal.

One serious obstacle, discussed in the Commission's interim report, is presented by FTE ceilings imposed by OMB that prohibit the recruiting of individuals above those ceilings, even in short-term emergency conditions. This contributed to both NIAID's inability to put its own programs into motion, and to the public's 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 be eligible for ongoing benefits such as retirement. The approval system has entrenched inflexibilities intended to guard against such growth, but can in fact leave government agencies funded but unable to hire in response to a crisis. The National Cancer Act of 1972 created NIH short-term personnel slots that were to be filled by visiting scientists, or "cancer experts," who were not counted in FTE ceilings, as they were not likely to retire on government payroll. Four years ago, however, OMB regulations for such appointments changed, and currently these and other temporary positions count against personnel limits.

NIH administrators also indicated that, given funds and personnel positions, they are still unable to complete hiring of some individuals because of "business as usual" paperwork delays in other agencies. Although the Office of Personnel Management (OPM) has begun discussion with NIH to streamline personnel recruitment, no practical change has been noted since the Commission's interim report. The Commission favors greater flexibility on the part of OMB and OPM to allow the NIH Director the ability to more rapidly hire greater numbers of technically specialized research personnel.

Witnesses before the Commission testified that modest salaries and the lack of other incentives deter many talented individuals from working at NIH. NIH recently proposed the creation of the "Senior Biomedical Research Service," a career track similar to the federal Senior Executive Service, which would enable NIH to recruit scientists at salary levels similar to those in the private sector. The model cited for this proposal is that used by the Uniformed Services University of the Health Sciences. Legislation creating these University pay scales exempted them from standard government levels, and enabled the University to attract personnel with salaries similar to those of other medical schools. To date, the proposed Senior Biomedical Research Service has not been approved.

Additional research hiring difficulties involve a zero tolerance for poor technique, which, when working with live virus, could prove fatal. This, coupled with the long hours, close quarters, and poor salaries, also contributes to personnel hiring delays.

Grant Processing and Research Funding

Traditionally, NIH has sponsored grants for projects that were initiated by researchers and proposed by them for funding. In response to the HIV crisis, NIH took a more centralized approach, funding a large number of specific contracts and issuing specific requests for grant applications for areas of needed research in which there was a lack of scientific interest or of readily apparent benefit. 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 on the outside as overly restrictive and limiting research options.

Two of the most significant hindrances of NIH have been restricted spending authority and the lack of significant pools of discretionary funds that can be used in medical and scientific emergencies or immediately to implement promising programs.

Administering taxpayer money for varied yet targeted exploration in a multifocal medical and scientific crisis requires great skill and balance. Given a limited amount of total funds, and if spending is so broad that all possibilities

are touched, there may not be enough money in each grant to permit a thorough exploration. If funded research is too highly focused in one area, an answer lying outside that area will not be found. Advisory 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 researchers testifying before the Commission indicated a preference for investigator-initiated research, citing its ability to offer multivaried exploration of any given topic. Many also considered highly controlled directed funding 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.

Primary to all recommendations for the advancement of basic biomedical research is the concept that these funds must be new monies and not subtracted from other programs.

Basic Science Education and Research Training Grants

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 members of the scientific community that the next generation will not produce adequate numbers of capable scientists willing to work in federally funded laboratories.

Current NIH training grant programs include:

- university/medical center grants, given to ten research centers;
- individual research scientist grants, to support ongoing work;
- Career Development Awards ("K Awards"), to allow a specialist in one field to acquire technical knowledge in another; and
- Research Scientist Awards, for achievement in one research area.

In the categories above, there are 200 awards of approximately $50,000 each. In addition, there are program slots for 250 summer students, each with a stipend of $1,500.

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. Some, in fact, have been eliminated. Additional appropriations for greatly increased numbers of awards as well as the authority to execute these programs are 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 youth, especially minority youth, to participate in government research training and to work with recognized research leaders.

Many more research personnel are needed now and will be needed in the future, as technology expands research potential. A greatly upscaled investment must be made now to guarantee the availability of researchers in the year 2000.

Obstacles to Progress

Basic research

- A lack of standardized reagents makes information coming from separate experiments difficult to assess.

- The lack of appropriate animal models for HIV research makes the application of animal research results to humans uncertain.

- Information exchange between individual researchers could be improved, as could research information exchange between federal departments and agencies.

Facilities, Administration, Personnel, and Grants

- OMB micromanagement and FTE ceilings prevent the deployment of a sufficient number of researchers to deal with pressing problems.

- The current structure of NIH management oversight by OMB and HHS means external staff are allowed to set personnel allocations at the unit program level, and to block fund shifts within categories which would contribute to the achievement of its intended goal.

- There is an inadequate number of laboratories equipped to carry out HIV work -- both at NIH and at research institutions around the country.
- A more rapid response by all elements of government is needed in order to speed NIH research efforts.
- Funds for basic research are inadequate to meet the new research priorities of the HIV epidemic.
- De-emphasis of investigator-initiated grants may threaten or constrain broad exploration in HIV research.
- Grants for HIV research projects are not made quickly enough, and funds for these projects do not allow for longer-term investigation.
- Scientists and health care professionals are not attracted to work at NIH because salary and benefit levels are not comparable to private sector institutions.

Basic science education and training

- The lack of basic science education programs in elementary and secondary education could lead to a shortage of research personnel in the future.
- There are not enough training programs in existence to supply the necessary number of future researchers.

RECOMMENDATIONS

To facilitate basic biomedical HIV-related research, the Commission offers recommendations in the following categories:

Reagents, Animal Models, and Research Information Exchange

4-1 Escalate existing efforts of the National Institutes of Health to establish a repository for reagents to be used in HIV research.

4-2 Investigate a fee-for-use basis for reagent distribution that would assist in supporting this program in private sector collaboration.

4-3 Make the development of appropriate animal models for HIV-related research an immediate and high priority, and make additional funds available to enhance primate center development.

4-4 Establish a federally funded central registry of animal model resources for HIV and other diseases.

4-5 The National Institutes of Health should develop a computerized network of all HIV-related research activities to promote greater exchange of information and data between researchers.

4-6 Increase funds to the National Institutes of Health Divisions of Research Services and Research Resources for additional animal model, reagent, and database program support.

Facilities

4-7 The National Institutes of Health intramural construction and reinstrumentation needs should be assessed and the information forwarded to the Office of the Secretary for inclusion as a high priority in future budget requests.

4-8 Construction of the National Institutes of Health Consolidated Office Building should be made a high priority and General Services Administration's approval be expedited.

4-9 The National Institutes of Health (NIH) construction authority should 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. Construction funds should be made available in FY 1989.

4-10 Funds for construction and modification of university facilities, as well as upgrading of instrumentation, should be provided through federal matching grants.

4-11 Funds should be made available to the National Institutes of Health Division of Research Resources to upgrade or renovate 20 existing laboratories to P-3 level.

4-12 Funds should be made available for the construction of four regional structural biology centers, equipped for X-ray crystallography.

4-13 The National Institutes of Health should implement a plan for the development of regional retroviral research centers and provide renovation of construction funds for two such centers.

Administration

4-14 To better meet the research mission of the National Institutes of Health (NIH) through a facilitated management process, the Secretary of Health and Human Services and appropriate authority as required by law should mandate that the Director of NIH report directly to the Secretary for a period of two years. The

Director will receive the NIH budget directly from the Secretary, and will have discretionary authority over all subsequent allocations of personnel and resources within NIH. For the two-year period, Congress, in conjunction with the Secretary, should exempt NIH from OMB regulation of personnel and resource allocations within all of NIH. During this two-year period, NIH will continue to operate within all remaining confines of law.

Following the two-year period, Congress should authorize an independent audit to measure the effectiveness of this change. The Director and the Secretary will report to Congress, and if the change in procedure has resulted in greater flexibility for NIH to achieve its scientific mandate, it shall become permanent. If it has not, Congress should consider giving NIH a more independent funding status, similar to that of the National Science Foundation.

4–15 In order to discourage a "business as usual" response to HIV-related requests from the Department of Health and Human Services, representatives of the Office of Personnel Management, General Services Administration, and Office of Management and Budget should participate as active members of the Public Health Service (PHS) Executive Task Force on AIDS in order to assist in rapid implementation of high priority requests from PHS.

4–16 The Office of Personnel Management and the General Services Administration should respond within 21 days to HIV-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 designated by the Secretary of Health and Human Services. Since the Commission's interim report, no identifiable change has occurred regarding this problem.

Personnel and Recruitment

4–17 To alleviate personnel delays resulting from current procedures, the Director of the National Institutes of Health should continue to work with the Office of Personnel Management to develop an improved package of incentives to facilitate recruiting of scientific talent.

4–18 The Director of the National Institutes of Health (NIH) should be given greater flexibility in both hiring and personnel (FTE) allocation within NIH. All new HIV-related FTEs must be *new* and not diverted from other programs.

4–19 The proposed "Senior Biomedical Research Service" should be enacted, with the necessary legislation to provide for the recruitment of scientists at salary and benefit levels competitive with private sector research institutions and medical centers.

4–20 Basic research FTE needs should be given high priority review by the Secretary of Health and Human Services and a minimum of 100 new positions should be approved for HIV-related basic research.

4–21 The Secretary of Health and Human Services should evaluate the current FTE ceilings at the National Institutes of Health in terms of the Institutes' overall ability to respond to a national medical crisis and should work with the Office of Management and Budget to determine ways to add flexibility as needed.

4–22 The Director of the National Institutes of Health (NIH) should immediately assess the incremental loss of personnel from other NIH research areas, who have been reassigned to HIV research. As these individuals are not fully accounted for in personnel allocation figures, a detailed assessment must be made of the actual impact HIV research is having on other research areas. Results of this assessment should be forwarded to the Secretary of Health and Human Services for evaluation of future resource allocation.

4–23 Research initiatives at the National Center for Nursing Research (NCNR) should be expanded. Priority should be given to areas already identified by NCNR and the National Institutes of Health, and the grant funding process for HIV-related research should be expedited. Nurses should be encouraged to submit proposals for HIV-related research to the appropriate institutes at NIH.

4–24 Fast-track recruitment programs to bring more nurses and patient care support personnel into the Clinical Center should be immediately implemented. Appropriate incentive and retention packages should be designed.

4–25 The National Institutes of Health Clinical Center should assure that the salaries

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of registered nurses and support personnel are competitive with local standards.

4–26 The National Institutes of Health Clinical Center should assure that an adequate ratio of support personnel to each registered nurse should be maintained.

4–27 The National Institutes of Health Clinical Center should utilize innovative nursing practice strategies to make the work environment more attractive to nurses.

Research Funding and Grants

4–28 All funds appropriated for HIV-related basic research must be new "add-on" monies and should not be transferred from existing programs.

4–29 Continue and expand support for basic science research, including virology, molecular biology, genetics, immunology, pharmacology, and pathogenesis.

4–30 To encourage the greatest possible breadth of HIV-related research exploration, place greater emphasis on investigator initiated grants.

4–31 Increase funds for "Director's Awards" at the National Institutes of Health for rapid start-up of projects to pursue new basic research ideas, and increase the upper funding limit of these awards from $50,000 to $100,000.

4–32 A discretionary fund should be created to make available to the Office of AIDS Research funds for rapid implementation of HIV-related project grants.

4–33 Implement within all of NIH the Accelerated-Solicitation-to-Award Program (ASAP) for HIV-related grant proposals.

4–34 Establish longer-term funding mechanisms for grants, expanding three-year grants to five- and seven-year terms whenever appropriate.

4–35 Maintain the HIV-related research programs in existence at the National Cancer Institute in order to allow the National Institutes of Health the greatest possible variety and breadth of research efforts, and maximize the use of existing talent.

4–36 Publicize the rules and procedures for negotiation and implementation of cooperative agreements between the National Institutes of Health and private industry.

Basic Science Education and Training

4–37 Expand and fund the National Institutes of Health training programs to levels adequate to enable qualified student researchers to continue advanced study; minimum funding levels should include:

- 350 M.D. or M.D./Ph.D. postdoctoral fellowships;
- 150 special postdoctoral fellowships for M.D.s;
- 350 graduate fellowships for Ph.D. or M.D. students; and
- 400 undergraduate or graduate health science non-Ph.D. fellowships.

4–38 Eliminate the regulation that counts short-term "expert" appointments and students participating in summer training programs against the National Institutes of Health FTE ceilings.

4–39 Enlarge the scope of training grants to include interdisciplinary programs specially tailored for HIV-related research (e.g., psychobiology and immunology).

4–40 Shift priorities in elementary and secondary education to provide greater education in biology and other sciences to young people earlier.

4–41 Develop a prestigious and highly visible set of awards to recognize both outstanding young talent and excellence in teaching in areas relating to human biology. These could include:

- Junior Science Corps Awards for elementary school students that include small monetary awards, but are primarily for recognition;
- National Bioscience Awards for high school students, that include the opportunity to work with leading scientists;
- National Science Teachers Awards to recognize professional excellence and enable teachers to spend time with leading researchers; and
- Programs should also be developed that 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 could be a national awards ceremony that would include the President. The administrative center for the proposed

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release June 27, 1988

STATEMENT BY THE PRESIDENT

I have just been briefed on the unanimous Report of the Commission on Human Immunodeficiency Virus Epidemic by Admiral James D. Watkins, the Commission's Chairman. The Report represents an impressive effort and significantly increases our level of understanding to deal with AIDS. To begin implementing this report, I am today directing Dr. Ian Macdonald, a distinguished physician and my Special Assistant for Drug Policy, to present to me within 30 days a course of action that takes us forward.

At Admiral Watkins' suggestion, I have also directed Dr. Macdonald to include among his priorities consideration of specific measures to strengthen implementation of the policy guidance from "AIDS in the Workplace", recently issued by the Office of Personnel Management.

The report embraces the major concepts my Administration laid out over a year ago: to be compassionate towards victims of the disease; to care for them with dignity and kindness and, at the same time, to inform and educate our citizens so that we can prevent the further spread of the disease.

There is a direct relationship between drug abuse and the spread of the HIV virus that becomes AIDS. It is critical that particular attention be focused on this relationship now, while developing a national consensus on additional anti-drug abuse measures.

I want to express my sincere appreciation to Admiral Watkins and all of the Commission participants for their perseverance and diligence in completing their work. It is my hope that we can continue to approach this problem, which is more than a medical crisis or a public health threat, in a thoughtful and bipartisan manner.

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POOL REPORT

Aboard Air Force Two...6/28/88

THE VICE PRESIDENT, CLAD IN JOGGING PANTS, VP POLO SHIRT AND WIND-BREAKER, CAME BACK TO SPEAK MAINLY ON THE AIDS COMMISSION REPORT WHICH PRESIDENT REAGAN RECEIVED YESTERDAY, (Monday).

THE VERBATIM OF THE Q & A FOLLOWS:

Q: BUSH WAS ASKED HIS VIEWS ON THE REPORT AND SPECIFICIALLY IF HE SUPPORTED THE NEED FOR ANTI-DISCRIMINA ION LEGISLATION:

A: "I think so. I was very impressed with Jim Watkins' briefing yesterday. I haven read all 240 pages but I have looked at the recommendations that lls for both an Executive Order , following up or simultaneousl ere with some federal legislation. I think it is needed.

ARE BOTH NEEDED, THE EXECUTIVE ORDER AND LEGISLATION?

I think so. AGain I'd like a little chance to study the report, but I was very much persuaded by what he said when he talked about the needs of people in the workplace to be able to come forward especially if this report endorses testing and I think it does. They are not going to come forward if they think they are going to be thrown out of their jobs.

SO YOU WOULD SIGN THAT ORDER?

Well, that depends on what the order says. But I mean the concept that Watkins is talking about is the need for an Executive Order and legislation. I support it. I would never say what I would sign before I read it. But I would support it. I think it is important to do a lot to lay to rest some of the fears. There is a lot of misunderstanding. They've concluded that the danger of discrimination against little kids, you know, can't go to a school, and the only reason they can't go there is people think they communicate the disease and the facts show that doesn't happen. So, I think, wait till I read the whole report, but I think they did a great service on this report. It started off with a heckuva lot of criticism, pounding. I don't know if it's in the report, I haven't read if it's like a Supreme Court thing with minority views and everything...

THE DEMOCRATS HAVE BEEN RELUCTANT TO ENDORSE THIS ANTI_DISCRIMINATION APPROACH?

Well, I do.

THE WHITE HOUSE IS REFUSING TO ENDORSE IT, TOO?

I'm endorsing the approach.

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A LOT OF PEOPLE ARE VERY MUCH FEARFUL OF THEIR CHILDREN AND THEMSELVES BEING SUBJECTED TO A DISEASE FOR WHICH THERE IS NO CURE?

I thought the report addressed itself to that. Again I haven't read the whole report, but to get at the principle I'm talking about, the principle of discrimination based on unfounded medical fears, I think it is in order.

WHY DO YOU THINK IT'S SO HARD FOR THE WHITE HOUSE TO COME AROUND TO THAT VIEWPOINT?

Look, they just saw the report yesterday. How can the White House be asked to take an instant position on a report that was just handed to the President's designated agent yesterday?

WHITE HOUSE OFFICIALS HAVE INDICATED FOR WEEKS THAT THEY OPPOSE THE NEED FOR LEGISLATION. THIS IS NOT A NEW ISSUE?

Let these White House officials speak for themselves. The President yesterday asked Dr. McDonald to take a real hard look at it. He did the right thing.

DO YOU EXPECT THE PRESIDENT TO SUPPORT SUCH LEGISLATION?

I don't know.

WHY SHOULD Not THIS BE A STATES' ISSUE RATHER THAN THE FEDERAL GOVERNMENT TELLING EVERY STATE HOW THY SHOULD REACT?

I think you have a national health problem and therefore I think there is some national, federal responsibility. But in terms of diversified treatement programs or... The states have an enormous contribution to make.

DO YOU THINK MORE MONEY IS NEEDED FOR AIDS RESEARCH [illegible] TESTING?

No. I base that on a conversation at my house at dinner two nights ago with Dr. Tom Fauci, NIH. He thinks that we have [illegible] the proper level of funding, close to a billion and the rest is up [illegible] ent or something over that 9 point whatever it is. He tells me right. He's a real expert on this, his very responsibility [illegible] the National Institutes of Health.

WHY DO YOU THINK THE PRESIDENT HASN'T BEEN AS QUICK AS YOU HAV[illegible] TO MAKE THIS DECISION THAT AN EXECUTIVE ORDER IS NEEDED?

He just saw this thing yesterday.

BUT SO DID YOU, DIDN'T YOU?

Well, he's not running for president. He wasn't asked the question either.

-more-

WERE YOU SURPRISED BY ANYTHING YOU READ IN THE REPORT?

I haven't really studied it. I had a funny feeling that this point might come up. So I read about it.

MR. VICE PRESIDENT CLEARLY YOU REALIZE THAT THIS IS GOING TO BE SEEN AS A FURTHER DISTANCING FROM THE WHITE HOUSE?

Shouldn't we wait and see what the position is before we say one's distancing oneself.

YOU ARE OUT AHEAD OF HIM ON THIS, WOULD YOU ACKNOWLEDGE THAT?

Well in response to the question on this, yeah, I would acknowledge it...you've got a different role here. I want to say what I think. I've said all along I was going to do that, doing it on education, doing it on drug programs, doing it on this, doing it on whatever else there is. I don't think that should be taken that the White House is slow in having an official response to a report that was handed yesterday to the President.

ARE YOU CONCERNED THAT THIS WILL BE MADE INTO A GAY RIGHTS ISSUE?

It shouldn't be made into it and therefore, I am not concerned that it will be. It should not be. This is a national health problem. We're talking about children, innocent victims. Barbara was up at a Harlem Hospital, they call them throwaway babies. The doctors of these babies have to go out and bury them because they don't have a mother or a father anywhere around. The report I'm told, stresses the increasing impact of narcotics on this AIDS threat. And there is a human dimension in caring for these children. I'd hate it if a kid of mind got a blood transfusion, my grandson had AIDS, and the community discriminated against that child, that innocent child, particularly when the report concludes, Surely Dr. Koop would agree, that the AIDS is not, cannot be transmitted in the ways that some have feared. So it is a human dimension, innocent children, that concerns me. about this. And that's why I would say, you know, right quickly that this ought to be done. It's the child, it's the child, the best in our children. It's a theme I feel strongly about, in this problem of AIDS......

YOU ARE NOT TALKINTG ABOUT AN ANTI-DISCRIMINATION POLICY JUST AFFECTING CHILDREN, YOU ARE TALKING ABOUT ADULTS, HOMOSEXUALS?

Yes, people coming forward to be tested ..... I am still convinced that testing is very important and I am also conviined that you ought to have confidentiality and I am also convinced that the more knowledge you have out there on how this disease can and cannot be communicated the better society is. I abhor discrimination against innocent people.

DON"T PARENTS HAVE A LEGITMATE RIGHT TO BE CONCERNED ABOUT (AIDS BE TRANSMITTED BY CASUAL CONTACT SINCE THERE IS NO PROOF TO THE CONTRARY)?

MORE

Certainly parents have a right to a legitmate concern.

WELL AN EXECUTIVE ORDER WOULD STRIP THEM OF THAT RIGHT?

I think the parents of an innocent child have the right, too, and that is that that child is not the victim of invidious discrimination. Now if you can show me, then i would change my view on this. If you could convince me with medical evidence that shows me that it can be communicated in casual ways. I think the preponderance of evidence is on the other side. But again I woould like the option of reading this report in this regard.

WHO HAS BEEN ADVISING YOU ON AIDS?

My conscience has been advising me on AIDS...... I have had very intersting conversations with Dr. Fauci and Dr. Koop .....Little bit of] contact with Jim Watkins, no so much.
And as I say, Barbara has had some experience with various hospitals. I' been out to NIH.....everybody has to have an interest in this thing.

REGARDING McGOVERN'S COLUMN IN TODAY'S WASHINGTON POST, IS IT FAIR TO RUN AGAINST MC GOVERN?

I don't see anything unfair about the analogy. Let the facts ...I think it's better having made the analogy for me to spell out my differences in a factual, fair way with Gov. Dukakis. That's what I"ll be attempting to do and that's what I have- been doing. I will try to make sure that what I say is accurate and fair and then let other people decide whether the opponent fits into the political spectrum and where I do.

ARE YOU GOING TO STOP USING HIS NAME?

I haven't used it recently because I set a premise there.

NOTE: A STATEMENT ON AIDS IS EXPECTED TO BE PASSED OUT LATER.

Gerald Boyd, NY TIMES
Carole Simpson, ABC

THE WHITE HOUSE

Office of the Press Secretary
(Santa Barbara, California)

For Immediate Release July 20, 1988

STATEMENT BY THE PRESIDENT

Today, I have signed into law H.R. 4567, the Energy and Water Development Appropriations Act for Fiscal Year 1989. I want to take this opportunity to commend the Congress for two reasons: first, the responsible speed with which they produced this bill; and second, for keeping funding contained in this Act at acceptable levels.

The Energy and Water bill was presented to me earlier than any other appropriations bill during my two terms in office. During the past several years appropriations bills have been enacted as part of omnibus continuing resolutions. As I noted in my State of the Union address earlier this year, the use of such patched-together, multi-purpose spending bills does not permit the Legislative and Executive branches to exercise proper scrutiny of government spending. In contrast, this bill has been submitted in a manner to allow thorough review by all participants in the budget process. The public interest is best served when budget laws are enacted individually, after careful deliberation over the spending measures by members of Congress and the President, and well before the crisis atmosphere sets in at the end of the fiscal year in September. I therefore strongly urge the Congress to complete consideration of the remaining 12 appropriations bills and to transmit them to me in a timely manner as well.

The funding provided by this Act totals $18.0 billion in budget authority and $17.8 billion in outlays. These funding levels do not exceed the amounts I requested in my budget while fully funding the essential requests for atomic energy defense activities. This action by the Congress is consistent with the plan for 2-year budget reductions, the Bipartisan Budget Agreement, that members of my Administration developed with the leaders of the Congress. I encourage the Congress to work with me to insure that all remaining spending legislation complies with this Agreement.

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Editors: vote will be taken at unspecified time in evening<
AMA calls for new approach in drug war@<
@^By CELIA HOOPER@=
@^UPI Science Writer@=

CHICAGO (UPI) _ The American Medical Association, close on the heels of President Reagan's AIDS commission, Tuesday debated whether to call for a major realignment in the nation's war on drugs.<

The 420 members of the AMA's house of delegates were presented with a proposal that urged less emphasis on interception of illegal drug supplies and more emphasis on drug treatment and education, including treatment on demand.<

Dr. M. Roy Schwarz, assistant vice president of the AMA for medical education and science, said the proposal reflects ``growing alarm on the part of the AMA at the failure to stop the epidemic _ it's exploding out from under us.''<

He said this concern was coupled to the organization's alarm over ``the AIDS epidemic _ the two are tied hand and glove.'' The proposal was also designed to express concern over the increasing numbers of adolescents who illegally use drugs.<

The recommendation wasn't intended as criticism of the Reagan adminstration's war on drugs, Schwarz said, but he insisted current efforts were ``not going to turn it. We've got to go beyond these efforts with treatment, education and prevention.''<

The delegates also debated resolutions calling for a ban on plastic handguns that are invisible to metal detectors, and on toy guns that look like the real thing.<

Other reports urged states to revise product liability laws, which the AMA said are impairing development of life-saving drugs, vaccines and medical devices.<

The delegates represent more the AMA's membership of more than 280,000 doctors and about 70 medical specialty organizations.<

In the lengthy report on the issue, AMA doctors said drug abuse lay at the heart of ``America's most pressing social problems _ crime, disease, poverty, corruption,'' but said in spite of good intentions there has been no progress in the war on drugs due to ``a failure over many years to design and pursue a ... comprehensive policy against drug abuse.''<

The doctors note that 12 million Americans used cocaine at least once in 1985, 500,000 individuals are addicted to heroin, and said ``use of cocaine in its smokable form _ crack _ appears to be increasing among minority youth.''<

They condemned past federal efforts that focused primarily on intercepting drug supplies. Although officials seized more than 60 percent more cocaine in 1987 than they did in 1986, and although more coca plants and laboratories in Latin America were cut back, ``these efforts have had no noticeable impact on the price or availability of coca in this country,'' the AMA said.<

The resolution urged more effort to reduce use of drugs through educational programs and an expansion of drug abuse treatment programs. Like the President's Commission on the Human Immunodeficiency Virus Epidemic, the AMA report calls for treatment to be available on demand for addicts. Currently treatment slots are available for only a small fraction of those who have sought help.<

The recommendation urged that private doctors be allowed to administer methadone. The drug is helpful in weaning people off heroin.<

The doctors also recommend that the president appoint a single ``ranking official of the executive branch to coordinate federal drug policy,'' and encourage drug testing in the workplace as part of pre-employment exams for jobs that affect others' safety, when an employer has reson to suspect an employee's performance is impaired, or as a monitoring service in a rehabilitation program.<

They also urge efforts to block discrimination in employment or services to former drug abusers, or abusers who are undergoing rehabilitation, through laws protecting the handicapped from discrimination.<

The doctors urge consideration of the role of tobacco and alcohol in abuse of other drugs and said evidence suggests use of those substances in childhood could lead to drug abuse.<

Schwarz estimated providing treatment on demand for addiction to illegal drugs, alcohol and tobacco would cost betwen $1 billion and $2 billion in addition to current expenditures.<

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Top 20 Recommendations

EXECUTIVE SUMMARY

The Human Immunodeficiency Virus (HIV) epidemic will be a challenging factor in American life for years to come and should be a concern to all Americans. Recent estimates suggest that almost 500,000 Americans will have died or progressed to later stages of the disease by 1992.

Even this incredible number, however, does not reflect the current gravity of the problem. One to 1.5 million Americans are believed to be infected with the human immunodeficiency virus but are not yet ill enough to realize it.

The recommendations of the Commission seek to strike a proper balance between our obligation as a society toward those members of society who have HIV and those members of society who do not have the virus. To slow or stop the spread of the HIV virus, to provide proper medical care for those who have contracted the virus, and to protect the rights of both infected and non-infected persons require a careful balancing of interests in a highly complex society.

Knowledge is a critical weapon against HIV -- knowledge about the virus and how it is transmitted, knowledge of how to maintain one's health, knowledge of one's own infection status. It is critical too that knowledge lead to responsibility toward oneself and others. It is the responsibility of all Americans to become educated about HIV. It is the responsibility of those infected not to infect others. It is the responsibility of all citizens to treat those infected with HIV with respect and compassion. All individuals should be responsible for their actions and the consequences of those actions.

Developed in the full Commission report are nearly 600 recommendations to prevent further spread of the virus, manage care of those infected with HIV, and enhance our efforts to discover a cure.

The urgency and breadth of the nation's HIV research effort is without precedent in the history of the federal government's response to an infectious disease crisis. However, we are a long way from all the answers. The directing of more resources toward managing this epidemic is critical; equally urgent is the judicious use of those resources.

For the reader who does not have the time to review all the material which follows, the Commission has prepared a list of its 20 most important findings and recommendations, no one of which can stand alone or be ignored. These will be detailed in the body of the report, and together comprise a comprehensive national strategy for effectively managing the HIV epidemic.

- The term "AIDS" is obsolete. "HIV infection" more correctly defines the problem. The medical, public health, political, and community leadership must focus on the full course of HIV infection rather than concentrating on later stages of the disease (ARC and AIDS). Continual focus on AIDS rather than the entire spectrum of HIV disease has left our nation unable to deal adequately with the epidemic. Federal and state data collection efforts must now be focused on early HIV reports, while still collecting data on symptomatic disease.
- Early diagnosis of HIV infection is essential, not only for proper medical treatment and counseling of the infected person but also for proper follow-up by the public health authorities. HIV infection, like other chronic conditions -- heart disease, high blood pressure, diabetes, cancer -- can be treated more effectively when detected early. Therefore, HIV tests should be offered regularly by health care providers in order to increase the currently small percentage of those infected who are aware of the fact and under appropriate care. Since many manifestations of HIV

are treatable, those infected should have ready access to treatment for the opportunistic infections which often prove fatal for those with HIV.

- Better understanding of the true incidence and prevalence of HIV infection is critical and can be developed only through careful accumulation of data from greatly increased testing. Quality assured testing should be easily accessible, confidential, voluntary, and associated with appropriate counseling and care services. At the present time, a relatively small percentage of those infected with HIV are aware of their infected status. For their own protection and for the protection of those not infected, strong efforts should be made to provide easily accessible voluntary testing. Many of the detailed suggestions in the report with respect to testing are directed toward increasing this percentage.
- HIV is a disability and should be treated as such under federal and state law in the public and private sectors. Fear has led to discrimination against persons known to be infected. This reaction is inappropriate. Infected persons should be encouraged to continue normal activities, such as work or school, and live in their own homes as long as they are able. The average time between infection and clinical symptoms is now thought to be seven to eight years -- years which should be productive.
- Stronger protection is needed in federal and state law to protect the privacy of those with HIV, with significant penalties for violation of confidentiality standards, yet with a list of necessary exceptions clearly defined in the statutes. These exceptions are listed in detail in Chapter Nine of our report, in the section on Confidentiality.
- Preventive measures that must be undertaken immediately include:
  —Public health authorities across the United States must begin immediately to institute confidential partner notification, the system by which intimate contacts of persons carrying sexually transmitted disease are warned of their exposure.
  —Agencies which license and certify health care facilities must move immediately to require every facility to notify all persons who received blood transfusions since 1977 that they may have been exposed to HIV and may need testing and counseling.
- Intravenous drug abuse, an important facilitator of the HIV epidemic, must become a top national priority. Increased law enforcement efforts to interrupt the supply of drugs must be coupled with greatly expanded treatment capacity, with the goal of treatment on demand, to restore addicted individuals to healthful living.
- Use of other illegal drugs, as well as abuse of alcohol, are facilitators in the spread of HIV by impairing judgment and depressing the immune system. Federal and state efforts to limit HIV spread must contain major components in these areas. Drug and alcohol abuse education is essential for all school children, adolescents, and minorities as well as for all other Americans.
- New federal and state nursing scholarship and loan programs need to be enacted immediately to encourage nurses to serve in areas of high HIV impact, as well as to address the nursing shortage which impedes efficient health care delivery in all other areas. Nurses will provide the major portion of care, both inside and outside the hospital setting, to those with HIV. There is currently a severe nursing shortage, which is only projected to grow worse over the next decade.
- The National Health Service Corps, which places health care professionals in medically underserved areas, is slated for termination, but should be extended and greatly expanded. The health care industry should give special consideration to recruiting minority health professionals.
- Aggressive biomedical research is the key to unlocking the mysteries that surround finding a vaccine and cure for HIV. Greater administrative flexibility must be given to the National Institutes of Health to pursue its research goals. Liability obstacles must be removed, and clinical trials greatly expanded to include a broader spectrum of the infected population.
- More equitable and cost-effective financing of care for persons with HIV needs to be examined through a series of new or expanded demonstration programs involving federal and state government subsidy of private insurance premiums for needy patients and greater contribution to risk pools. It is important to move toward an organized system of care, with case management as a principal tool to control costs and provide quality care.
- Concerns of health care workers need to be better addressed by all levels of government as well as the private sector. All of those in the health care delivery system, ranging from the ambulance driver and other emergency "first responders," to physicians, nurses, dentists, lab technicians, social workers, chaplains, and allied health care workers, to obstetricians and surgeons performing invasive procedures, should be provided with complete information about HIV, adequate protective materials, and a safe working environment in which to provide comprehensive and compassionate care.
- Safety of the blood supply needs to be continually assured by the federal government. High priority should be placed on the Food and Drug Administration (FDA) test approval for new, less time-consuming HIV detection tests. Additionally, a restructured advisory committee needs to work with the FDA to continuously examine mechanisms that will protect our blood supply.
- In health care facilities, all reasonable strategies to avoid a transfusion of someone else's blood (homologous transfusion) should be implemented by substituting, whenever possible, transfu-

sion with one's own blood (autologous transfusion). Currently available techniques of autologous transfusion include predonation of one's own blood, recirculation of one's own blood during surgery, blood dilution techniques, and post-operative collection for retransfusion. Health care facilities should offer aggressive in-service training to their staff on these procedures, and informed consent for the transfusion of blood or its components should include an explanation of the risk involved with transfusion as well as the alternatives.

- Education programs must continue to be developed and implemented for the near term, and for the greatest possible positive impact on the next generation. Age appropriate, comprehensive health education programs in our nation's schools, in kindergarten through grade twelve, should be a national priority.
- The problem of HIV-infected "boarder babies" is one of the most heart rending the Commission has encountered; these children live their entire brief and tragic lives in hospital wards, with only doctors and nurses as family. The expected 10-20,000 HIV-infected births by 1991, also call attention to the critical need for foster homes. Unless the problems of the disadvantaged are addressed, the HIV epidemic will continue to make inroads into these populations and we will see large increases in both pediatric and drug related HIV disease.
- The problems of teenagers, and especially runaway youth, that place them at increased risk for HIV exposure must be aggressively addressed. The spread of HIV within the heterosexual population should be better defined and accurate information communicated to the general public.
- The HIV epidemic has highlighted several ethical considerations and responsibilities, including:
  - —the responsibility of those who are HIV-infected not to infect others;
  - —the responsibility of the health care community to offer comprehensive and compassionate care to all HIV-infected persons;
  - —the responsibility of all citizens to treat HIV-infected persons with respect and compassion;
  - International efforts to combat the spread of HIV infection should be encouraged and assisted by the United States, through its research community and our national contribution to the World Health Organization and the Global Programme on AIDS.

The Commission believes that if the recommendations in this report are fully implemented, we will have achieved the delicate balance between the complex needs and responsibilities encountered throughout our society when responding to the HIV epidemic.

30 f 31

AIDS RECOMMENDATIONS TO THE PRESIDENT

TENTATIVE TIMETABLE

Assignment Received: 27 June 1988

Report due: 27 July 1988

June

27-29 Contact departments/agencies for comments/observations on recommendations in report.

July

1 Receive early reports of which, if any, recommendations have already been accomplished or begun (date of start and completion if applicable).

5 **NOON** Complete comments due from departments/agencies on recommendations already accomplished or begun.

5 **COB** Interim report (compilation of recommendations already accomplished or done).

12 **COB** All comments/observations due from departments/agencies on recommendations (noting implementation status:

-- done;
-- already begun;
-- possible with 30 days, 90 days or 180 days;
-- further study required; or
-- other.

27 Deliver report to the President.

PARKLAWN BUILDING FACSIMILE TRANSMISSION RECORDS

TO: (Name, Organization, City and State)

Dr. Donald Ian Macdonald

Director, Drug Abuse Policy Office and
Special Assistant to the President

FAX 456-2246
Facsimile phone number (if known)
Confirmation number (if known)

Tel: Jane Harrison - 456-6554

FROM: (Name, Organization, Room, and Phone Number)

Roy W. Pickens, Ph.D.
~~Director, Division of Clinical Research~~
National Institute on Drug Abuse

Telephone: 443-6697

Department of Health and Human Services
Rockville, Maryland - Parklawn Bldg.
Room 13-49

Telephone (301) 443-2706 IMMEDIATELY if re-transmission is necessary

12
Number of Pages
(not including cover page)

PARKLAWN BUILDING Facsimile Numbers:
(301) 443-6463 (Automatic DEX 2100)
(301) 443-1719 (Automatic EMT 2000)
(301) 443-1726 (Automatic DEX 6500)

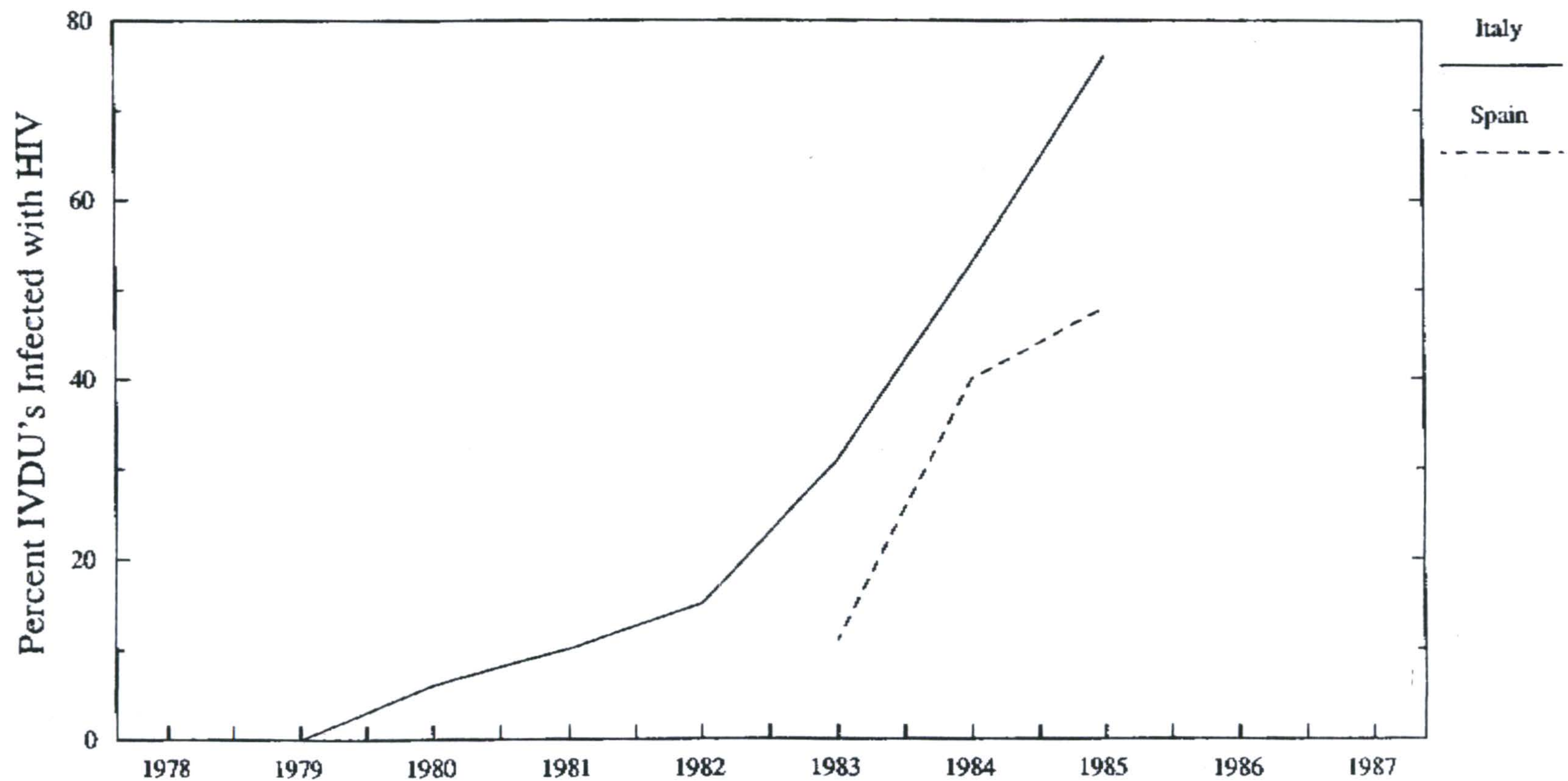
DATE: 7/5/88	OPR: [illegible]	CHARGE CODE: HWDA

Jean Bennett
(Authorized Signature of Orginator)

Instructions to CommCenter:

X (Please check one)
_Mail back copies to room 10A-38
_Call ext _______ we will pick up copies

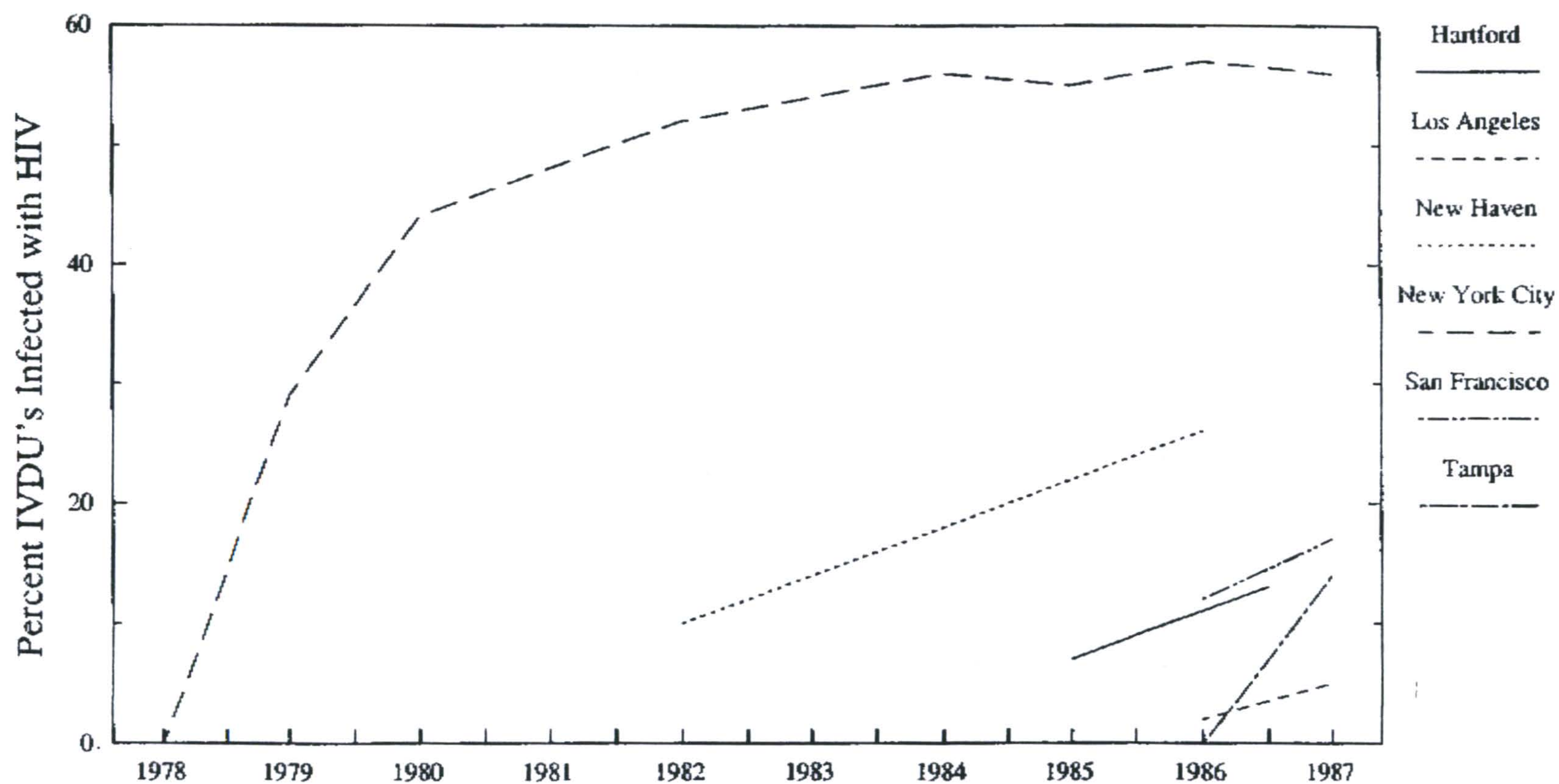
CHANGES IN HIV INFECTION RATES
AMONG EUROPEAN INTRAVENOUS DRUG ABUSERS



National Institute on Drug Abuse

ehivrate.cht
1-22-88

CHANGES IN HIV INFECTION RATES
AMONG U.S. INTRAVENOUS DRUG ABUSERS



National Institute on Drug Abuse
Preliminary Data

hivrate.cht
1-22-88

TABLE 2:

CHANGES IN HIV INFECTION RATES: PRELIMINARY DATA[1]

Jan 88 Prepared by DCR/NIDA/ADAMHA

PERCENT IVDU'S INFECTED WITH HIV

	1979-1981	1982	1983	1984	1985	1986	1987
Hartford					7	____ 13 ____[2]	
Los Angeles							
Opiates						2	7[3]
Stimulants							0
Minneapolis					0		1
New Haven		____ 10 ____				____ 26 ____	
New Orleans						1	1
New York City	____ 33 ____	52		56	54	57	56
San Antonio						2	0
San Francisco							
Drug Treatment						7	11
Not in Treatment						16	24[4]
Tampa						0	14

NOTES:

1. Data not evaluated for statistical significance. Data collected by CDC/NIDA Oct-Dec 87
2. ______ X ______ Indicates data collected over more than one calendar year.
3. 1986 data from Los Angeles are pooled from NIDA and UCLA sources.
4. We do not have permission from the investigator to publicly release Not in Treatment data from San Francisco.

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTE ON DRUG ABUSE

REQUEST FOR APPLICATIONS, DA-88-02
CATALOG OF FEDERAL DOMESTIC ASSISTANCE NO. 13.279

TREATMENT EXPANSION DEMONSTRATION PROGRAM TO REDUCE THE SPREAD OF AIDS AMONG INTRAVENOUS DRUG ABUSERS

July, 1988

Purpose:

The purpose of this request for applications (RFA) is to expand treatment for intravenous drug abuse, in order to reduce the spread of acquired immunodeficiency syndrome (AIDS) among intravenous drug abusers. While most intravenous drug abusers are heroin addicts, they include users of nonopiate drugs such as amphetamines and cocaine as well. Funding provided under this RFA is intended to create new treatment capacity, not to supplement existing treatment slots. Expansion of all types of treatment modalities is encouraged, including methadone maintenance, detoxification, drug-free outpatient, and therapeutic community programs.

Statutory authorities for these grant awards are Sections 301 and 515 of the Public Health Service Act (42 USC 241 and 290cc).

Background:

AIDS is a serious medical disorder caused by the Human Immunodeficiency Virus (HIV). One of the principal modes of transmission of HIV is needle sharing by intravenous drug abusers. By recent estimates, 31 percent of all AIDS cases involve intravenous drug use, which is the second most common means of transmission of the virus. Drug abusers may be particularly susceptible to HIV infection due to the suppressive effects of some abused drugs on the immune system.

In addition to concern regarding the impact of HIV infection on intravenous drug abusers themselves, these drug abusers are also of concern because of their potential for spreading the virus into the heterosexual population. Approximately 80 percent of all HIV infection cases attributed to heterosexual transmission have been attributed to sexual contact with intravenous drug abusers. In addition, intravenous drug abuse is a major contributing factor in the perinatal transmission of HIV, with over two-thirds of perinatal cases of HIV infection born to intravenous drug abusers or their sexual partners.

The National Institute on Drug Abuse (NIDA) has a strong commitment to help curb the spread of HIV among intravenous drug abusers and from intravenous

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drug abusers to their sexual partners and children. An essential part of NIDA's efforts in this area is the expansion of treatment for intravenous drug abusers, so that those presently at risk for HIV through needle sharing have adequate treatment available, with appropriate outreach in place to link them with treatment. NIDA is interested in supporting treatment demonstration projects directed at eliminating or reducing intravenous drug use by increasing treatment program capacity. Treatment demonstration grants funded under this RFA will provide support for the expansion of capacity in existing treatment programs, or the establishment of new programs by community organizations (i.e., State or local, including both governmental and nongovernmental organizations) capable of providing such treatment. How to expand capacity will relate to individual program circumstances or needs -- e.g., methadone maintenance programs may hire additional staff to increase the number of available slots, therapeutic communities may add beds, and programs with large waiting lists may want to create holding clinics.

In providing support for expanding treatment capacity, NIDA is interested in developing high-quality treatment that will be effective in achieving the demonstration program's goals. Therefore, in addition to expanding the capacity of existing treatment programs, NIDA is especially interested in supporting programs that improve the quality of services delivered to clients. This includes a focus on nonpharmacological issues related to needed program improvements (see below), or involve the application of pharmacological strategies with proven effectiveness that have seen only limited use (e.g, naltrexone) or the application of promising new pharmacotherapies (e.g., buprenorphine with opiate addicts, desipramine with cocaine abusers). Highest priority will be given to capacity expansions that allow clinical effectiveness of program improvements and application of new treatment strategies to be evaluated.

Within programs, funds may be expended on bed costs, rental and operation of facilities, hiring and training staff, program management, and associated costs which are normally allowable under the existing ADAMHA grants policy. Programs will be expected to conduct periodic evaluations, and to participate in NIDA data acquisition activities for monitoring purposes. Staff costs may include such positions as outreach workers, counselors, medical staff, evaluation workers, management and support personnel. Programs are expected to have adequate accounting and management controls to assure that the funds provided for treatment expansion are used to provide treatment to new clients, and not to supplement costs for existing slots.

Areas of Treatment Demonstrations Interest:

Funding to expand treatment capacity under this program will be limited to communities with high rates of intravenous drug abuse and insufficient intravenous drug abuse treatment capacity, as reflected in prevalence estimates and waiting lists for treatment. Conditions of the award will include: (1) that the funds be used to expand treatment capacity by creating new treatment slots for intravenous drug abusers; (2) that the expanded treatment capacity will employ interventions with proven effectiveness, or will employ promising new interventions that may be expected to significantly enhance treatment effectiveness; and (3) that applicants demonstrate a willingness to evaluate the effectiveness of these interventions in

6

eliminating intravenous drug use.

The expanded treatment should be of high quality, and should be designed to produce superior performance and treatment outcomes. The treatment strategies should strive for improving recruitment and retention rates, curtailing during-treatment drug use, improving treatment outcomes, and preventing relapse to intravenous drug use. Examples of treatment interventions to be employed include: application of outreach strategies to encourage intravenous drug abusers to enter drug abuse treatment; adjusting methadone doses in methadone treatment to curtail illicit drug use; application of behavioral contingencies to reduce illicit drug use and reduce treatment dropout; providing enhanced counseling and ancillary psychotherapy/rehabilitative services to patients as necessary; application of relapse prevention strategies, application of alternatives to methadone in the pharmacological treatment of heroin addiction (e.g., naltrexone); use of pharmacological agents to treat psychiatric co-morbidity in intravenous drug abusers; application of treatment interventions to underserved patient groups (i.e., chronic polydrug abusers who use heroin intravenously but not in sufficient amounts for admission to methadone treatment programs); and application of centralized information and referral units to direct patients to appropriate treatment programs in large cities. Also included may be special components to deal with problems presented by the AIDS epidemic, such as outreach to women at high risk (e.g., addicted prostitutes), outreach to bring teen age addicts into treatment early, providing treatment services to clients unable to come into the treatment clinics, and establishment of special approaches (e.g., higher dosage of methadone) for those who are HIV positive but who continue to use intravenous drugs while in treatment.

It is anticipated that approximately $40,000,000 will be available in fiscal year 1989 for treatment demonstrations to expand treatment capacity. Approximately 40 to 200 demonstration grants are expected to be funded, creating a total of slightly over 8,000 slots in expanded capacity. The expanded treatment may be delivered in a variety of settings, such as residential treatment programs, correctional institutions, and treatment research programs. Applicants are invited to incorporate strategies for monitoring implementation of the expanded treatment capacity in their project plan. The expansion should result in placement of no fewer than 10 slots in a single program, so that its impact may be assessed.

Intervention Strategies

While existing treatments have been shown to produce dramatic reductions in illicit drug use, program retention and relapse rates are problematic. The AIDS epidemic further complicates the task of providing treatment, since it cannot be assumed that intravenous drug use is limited to single drugs. Thus, while treatment modalities focused on heroin addiction will continue to be important, a broader perspective which takes into account the multiple drug use patterns involving cocaine, amphetamines, and other substances must be part of the overall approach. Well conceived and imaginative approaches must be developed and tested, addressing the major problems of today's drug abuse population at risk for HIV infection. These approaches must be targeted to increase recruitment to treatment (including reduction of waiting lists by providing special temporary treatment interventions), improve retention or extending time in treatment, improve performance in treatment, and improve

post-treatment outcomes through use of aftercare/self-help approaches, relapse prevention strategies, and improved staff training. While it is desirable to improve treatment in any or all of these areas, it is recognized that individual programs may focus on only 1-2 areas in a given demonstration proposal.

o Improving recruitment. Increased capacity should be matched by utilization of that capacity. In many communities, there are waiting lists for intravenous drug abusers who wish to enter treatment, but it also necessary to recruit into treatment those intravenous drug abusers who are not on waiting lists. Based on a needs assessment, strategies should be developed to aggressively recruit clients to absorb the new capacity. Waiting lists should be serviced by providing temporary interventions (such as "holding clinics," medical detoxification coupled with self-help groups, and short-term counseling strategies).

o Improving retention. Failure to retain clients in treatment for the amount of time necessary for meaningful behavior change has been a major problem in treatment programs. The drug abuser often enters treatment in a confused and depressed state, under pressure from legal or other authorities. High attrition during the early days of treatment is not unusual, especially in confrontational programs such as therapeutic communities. Special interventions are necessary to increase retention (or time in treatment) if we are to provide more effective treatment. Evidence exists that attrition rates can be reduced by instituting special counseling programs and involving the client's family early in treatment, employing legal pressure, using adequate maintenance doses of methadone, etc. The demonstrations funded under this RFA should address this issue and have a clear plan for enhancing retention in treatment.

o Improving performance in treatment. During-treatment performance has been shown to correlate with post-treatment outcomes. While there is a dramatic improvement at the beginning of treatment, a significant percentage (about 18-20%) of urines taken from clients in methadone programs are drug positive. Given the seriousness of the AIDS epidemic, this continuation of intravenous drug use represents a serious risk to the client, to other clients in the program, and to his/her family. A number of strategies are available to cope with client's program compliance problems -- including contingency management, urine monitoring, focused programs, adjustment of methadone dosage, and treatment of psychiatric co-morbid conditions -- and should be considered in designing the intervention.

o Improving treatment outcomes. There is ample evidence that drug abusers are a heterogeneous population, that their treatment needs may differ, and that longer-term treatment is indicated for many. Available outcome studies show that while treatment outcomes tend to have dramatic improvement for substantial numbers of clients, many relapse to drug use and re-enter treatment. Treatment strategies are needed to establish longer-term abstinence through provision of additional counseling and aftercare services, provision of specially trained counselors to train clients in coping and relapse prevention strategies, family therapy approaches and other strategies designed to strengthen the client's social

networks which support effective functioning and abstinence, vocational rehabilitation, and other interventions which are responsive to client needs.

o Aftercare/relapse prevention. Relapse usually occurs early after leaving treatment, usually within the first 90 days. A number of models are available for relapse prevention and continued social support after treatment, including cognitive behavioral models stressing learning of coping strategies, continued drug-free treatment after completion of methadone maintenance treatment, and aftercare programs which combine such learning with social networks. Given the high relapse rates which have been experienced in drug abuse populations, it is essential that provision be made for approaches which will forestall return to drug abuse, and/or permit easy re-entry into treatment at the earliest indications of relapse.

o Staff Training. If treatment is to be made more effective, training of counselors and other drug abuse treatment personnel must be upgraded. The high turnover in staff and staff burnout that has plagued drug abuse treatment presents a major problem. Expansion of treatment to provide higher quality treatment calls for a commitment to train the requisite staff during a relatively short time frame. Continued staff development which builds skill levels and imparts new knowledge regarding state-of-the-art treatment should improve treatment effectiveness and contribute to greater job satisfaction. Training should be focused on developing staff clinical and assessment skills and in improving delivery of services, and should be directly related to the goal of improved treatment effectiveness (e.g., better retention, fewer incidents of during-treatment drug use, less alcohol consumption).

Evaluation Requirements

In order to assure that treatment expansions funded under the present RFA are managed in a purposeful manner and serve the knowledge development needs of the drug abuse treatment field, explicit evaluation and reporting requirements are established for treatment programs obtaining funding under this RFA. Specifically, the following are required: (1) These projects must have a clear, workable evaluation component built into the application; (2) Applicants must explicitly agree to cooperate with NIDA in collecting common data on selected client characteristics and treatment measures; and (3) Applicants must agree to cooperate with NIDA in a national drug abuse treatment outcome research effort. With regard to this third condition, NIDA plans to begin a contract study, the Drug Abuse Treatment Outcome Study (DATOS), in 1989 and may invite programs receiving funding for treatment expansion under the present RFA to participate in this project. Participating programs are expected to cooperate by making clients available for interview and follow-up, by making clinic staff available for interview, and by allowing access to clinical records for validation of client interviews. The contractor will be under strict requirements to safeguard confidentiality of all data obtained in this study. Programs selected to participate in DATOS will receive separate funding from the DATOS contractor for a research/data acquisition staff person.

Progress Reports and Final Report Requirements

Grantees are expected to provide reports at 6 month intervals describing their progress in expanding treatment capacity, implementing their evaluation plan, problems encountered if any, and plans for resolving such problems. At the end of the period of NIDA support, 3 copies of a final report should be submitted to NIDA within 90 days. This final report should include a complete description of the intervention and related services provided, manuals used in providing the intervention where appropriate, a thorough discussion of the evaluation methodology, and a summary of evaluation findings, together with a discussion of the significance of these findings for treatment of intravenous drug abuse.

APPLICATION PROCEDURE

Eligibility

Applications may be submitted by public or private nonprofit or profit-making community organizations or programs such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Funding to expand treatment capacity under this program will be limited to communities with insufficient intravenous drug abuse treatment capacity, as reflected in prevalence estimates and waiting lists for treatment. The term "community" refers to geographic service areas, and may include States as well as metropolitan areas and rural districts. Organizations headed by women and minority staff are encouraged to apply.

Application Process:

State and local government agencies should use forms PHS-5161. All other applicants should use the standard PHS-398 (revised 9/86) research grant application form. "AIDS Research: 'Treatment Expansion Demonstration Programs to Reduce the Spread of AIDS Among Intravenous Drug Abusers' should be typed in Item #2 on the face page of the application.

Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 10-25
Rockville, Maryland 20857
(301) 443-6710

The signed original and thirty-two (32) (original and 32 copies if using PHS-5161) permanent legible copies of the complete application should be sent to:

Division of Research Grants, NIH
Westwood Bldg., Room 240
5333 Westbard Avenue
Bethesda, Maryland 20892

Applicants are strongly advised to contact the Chief, Treatment Research Branch, NIDA, prior to submitting applications to discuss the nature and extent of their project plans. Further information and consultation on program requirements can be obtained from:

Chief, Treatment Research Branch
Division of Clinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-30
Rockville, MD 20857
Telephone: (301) 443-4060

Facilities and Staff

Applicants should provide adequate information regarding available facilities and staff, so that the review process may take into account the applicant's capability and the feasibility of the planned expansion.

Local Review and Coordination

A copy of the application should be submitted to the State drug abuse authority no later than February 1, 1989, for review along with notice that the State drug abuse authority may, if it wishes to do so, send comments to the Chief, Treatment Research Branch, Division of Clinical Research, NIDA, 5600 Fishers Lane, Room 10A-30, Rockville, MD 20857, by February 15, 1989.

Review Process

Applications received under this RFA will be reviewed for scientific and technical merit by an Initial Review Group (IRG), consisting primarily of non-Federal technical and scientific experts. Notification of the review outcome will be sent to the applicant after the initial review. Applications will receive a secondary review by the National Advisory Council on Drug Abuse which may be based on policy as well as scientific merit considerations. Applications submitted in response to this RFA are not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through Department of Health and Human Service regulations at 45 CFR Part 100.

Application Receipt and Review Schedule

Applications received under this RFA will be reviewed under the accelerated special applications process (ASAP) provisions established for AIDS research. The deadlines and award dates shown below have been established by Division of

Research Grants, NIH. However, it is possible that a second application date may be announced subsequent to that shown below if sufficient funds remain available and circumstances permit timely award of additional grants.

Receipt of Applications	Initial Review	Advisory Council Review	Awards to be Made by
January 2, 1989	February 1989	May-June 1989	June 30, 1989

Review Criteria:

Criteria for merit review of applications will include the following:

- the potential of the proposed project to provide treatment capacity for intravenous drug abusers in areas of high HIV prevalence;
- association of the proposed treatment expansion with a plan to deliver high-quality treatment services to intravenous drug abusers;
- the qualifications and experience of the clinic director, clinical staff, and other key personnel;
- a clear statement of support by the applicant for the evaluation requirements of the proposed project, and inclusion of a clear, workable evaluation plan;
- the availability of adequate facilities, other resources, and collaborative arrangements necessary for the treatment demonstration;
- the appropriateness of budget estimates for the proposed treatment expansion; and
- the adequacy of provisions for the protection of human subjects, if applicable.

Award Criteria:

Applications recommended for approval by the National Advisory Council on Drug Abuse will be considered for funding on the basis of:

- HIV prevalence and excess of demand over supply for treatment of intravenous drug abusers, as evidenced by available data from program and other sources;
- overall scientific, clinical, and technical merit of the proposed treatment expansion, determined by peer review;
- commitment of applicant to cooperate in development of knowledge in connection with the treatment expansion effort, as evidenced by an evaluation design with appropriate controls;
- commitment to cooperation with NIDA's national treatment evaluation plans, and agreement to participate in a client-oriented data reporting system;

- potential contribution to reducing the spread of HIV infection through effective treatment of intravenous drug abusers; and
- the availability of funds.

Terms and Conditions of Support

Grant funds may be used for expenses clearly related and necessary to conduct treatment demonstration projects, including both direct costs which can be specifically identified with the project and allowable indirect costs of the institution. Funds are expressly to be used to establish, expand, or add a component to, and operate a treatment, rehabilitation, or service program. Support for evaluation may be requested as part of the demonstration. These costs must be justified in terms of evaluation objectives, methods, and designs which promise to yield generalizable knowledge and/or make a significant contribution to theoretical concepts.

Grants must be administered in accordance with the PHS Grants Policy Statement (DHHS Publication No. (OASH) 82-50-000 GPO-017-020-0090-1 (rev.) January 1, 1987, available for $5.00 from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402). Title 42 of the Code of Federal Regulations, Part 52, "Grants for Research Projects," is applicable to these awards. While references to other applicable regulations may be found in the aforementioned reference, special attention is called to 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records."

Period of Support:

Support will be provided for a period of up to five years (renewable for subsequent periods) subject to continued availability of funds and progress achieved.

HHS
DHHS

THE WHITE HOUSE
WASHINGTON

FTE

HRSA
PHS
NIMH
HHS
NHSC
NIH
NCNR
AID
HCFA
SSA
FDA
ADAMHA

DOT
DOEd
allergy
NIAID
ADM
Blk grt.
@ HCFA prog
om 64th tr
NIOSH
~~OSAH~~
OSHA

Schedule

Week 1

T-W = Call & assign

Th-F = Mtg on key issues ($, Discrim, other

F/July 1 = Rcv early rpts
c̄ HCFA/CDC/Bower/OMB/HRSA/NIH/ADAMHA

July 5 = COB ≈ 1 pgs of "doable"
↳ w/pros & cons
$ FTE > consid

July 5/6 Assemble & Decide (2pm w/others)
July 7 Release 1st done deeds

12 T Tues COB - Plans for 30 day Statement

- 30 days
- 90 days
- 180 days
- later implement

Pros & Cons

Adm/Exo/Leg/State/other

19 W - Plan prepared
Tune-ups ad, stmt - write EO/pres desc. paper/other

27 - 20 days/deliver to RR

$3.25B

Q's: good idea
when do it
cost
pros & cons
recommendation
- which doing already
- which never doing

Already done
Easily doable
adm., cheap & right
↳ soon
↳ worthwhile
↳ legis/adm
↳ $ (reprogrming
Looks good

Rec for ~~Act.~~ Incoming ~~Admin~~ Pres.
↳ study
↳ FY91 Budget

Bowen
Cribb
OMB
HHS ~~[illegible]~~ Brad Reynolds.
Roper - HCFA
Mason - CDC
Fauci - NIH
Koop - SurGen
Greenleaf - VP
DOD
HUD
DOT
SSA
IOM (Inst of Med)
Policy (Commission)
Hobbs
Ed.

Agency
Cost
Subject

Done
Short-term done
Reagan done
Other

→ State/Local
→ Private sector
→ fed. stuff

Labor — OSHA
HHS — ADAMHA, NIDA, NIAAA, NIMH, NIH, FDA, HCFA, HRSA, IOSHA
Trans
DOJ
State — A.I.D.

mng?

Time table

- this wk
- nxt wk
- 12 - 30 - 90 day clock

all by 12th

what now

NLT 7/5 = 1 pgr.
* done
* doable

NLT 7/12 = everything
↳ done
↳ doable
w/in 30-60-90
180
day
or further
study

Kevin Cantanasie

cc! SD
DW

THE WHITE HOUSE

WASHINGTON

June 28, 1988

MEMORANDUM FOR MAC MACDONALD

FROM: NANCY RISQUE

SUBJECT: AIDS COMMISSION REPORT

Mac, I've reflected on your questions of how to get quick responses from the "system" and on process.

I suggest that you do a memo, today, to the heads of HHS, Education, Justice, Labor, OPM, Defense, State, and OMB, as well as to Gary Bauer (and to any others you deem appropriate). You might outline your task and indicate how you intend to proceed on your "business plan."

You should forward the report to them and ask that they assign one person to be responsible for getting to you an analysis/ comments by a date that fits your timeline needs. It probably would be useful to specify categories of recommendations such as those that are consistent with and enhance current policy guidelines; those that would require legislative actions; those with budget implications; etc.

When you "report," Rhett will circulate and I'll pick up agency comments again at that time.

Let me know whenever and whatever we can do to help.

cc: Ken Duberstein
Rhett Dawson

cc: SD
DW

THE WHITE HOUSE

WASHINGTON

June 28, 1988

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cc: Ken Duberstein
Rhett Dawson

AIDS RECOMMENDATIONS TO THE PRESIDENT

TENTATIVE TIMETABLE

Assignment Received: 27 June 1988

Report due: 27 July 1988

June

27-29	Contact departments/agencies for comments on recommendations in report.

July

1	Receive early reports of which, if any, recommendations have already been accomplished or begun (date of start and completion if applicable).
5	**NOON** Comments due from departments/agencies.
5	**COB** Interim report (compilation of recommendations already done, implemented or planned).
7	Release Interim report (White House Press Office).
12	First draft implementation plan (30 day, 90 day, 180 day, other).
19	First draft Presidential response (e.g., statement, executive order, presidential memorandum, other).
27	Deliver report to the President.

AIDS REPORT RECOMMENDATIONS

Code	Chapter 1: Incidence and Prevalence	
1-1	Appropriate Federal, state and local agencies must enact, execute and enforce anti-discrimination laws within the context of HIV as a handicap.	Leg.
1-2	CDC must provide clear direction for expanded and improved surveillance, including endorsement and support by national leaders, other Federal agencies and state and local leaders.	Adm.
1-3	States should require reporting of HIV infections. This information should be given to the CDC in appropriate form for statistical analysis, without identifiers.	Leg. Adm
1-4	National, state and local leadership must work cooperatively to make any HIV testing programs useful as data sources for surveillance.	Adm.
1-5	All public health agencies must select and use terminology carefully to make the public more aware of the importance of the entire spectrum implications of HIV infection.	Adm
1-6	In all federal agencies all relevant job and program titles should clearly reflect HIV infection as the target of concern.	Adm
1-7	Public health officials should provide education, training and funding resources to expand greatly the use of counseling directly linked to any testing program.	leg adm
1-8	Widespread, voluntary testing should be strongly encouraged at the Federal, state and local levels to improve the monitoring of incidence and prevalence, to enable those with HIV to protect themselves, and to help protect against the spread of the disease.	Adm
1-9	State public health departments should be fully supported in their role of coordinating the various federal programs and resources that are targeted for HIV, AIDS and AIDS-related issues within their states.	?
1-10	All state health agencies not now doing so should move to require reporting, and use this information to augment special studies to better understand HIV incidence and prevalence.	Leg Adm
1-11	The CDC should accumulate HIV testing reports from all federal agencies conducting testing, without identifiers, for inclusion in national incidence and prevalence calculations. data source	Adm

1-12 DHHS should explore a federal program to attract and recruit scientific and medical experts to serve as consultants and advisers to federal and state public health departments during a health crisis.

1-13 Where the data produced are needed for surveillance, programs of HIV testing sponsored by a state or local public health agency should be coordinated with the CDC and the methodology made consistent with the national effort.

1-14 State and local public health departments not eligible to participate in the specially designed prevalence studies conducted by the CDC should be given incentives to be involved in alternative data gathering activities.

1-15 All health care practitioners and institutions should be educated on procedures for reporting HIV infection and encouraged to provide requested HIV-related data in a timely manner, as required under public health reporting laws or requested in conjunction with special studies.

1-16 Without delaying day-to-day responses to requests for data, CDC should establish a review group composed of representatives from state health organizations, the research community, community-based organizations and members of CDC staff, which can evaluate requests for data, to review the methods of processing requests and to make recommendations on improving the provision and presentation of data pursuant to requests.

1-17 CDC should break down data by sex, race, age, marital status, geographical location and presumed mode of transmission, as well as combinations thereof, to the degree possible without potential compromise of identities. Age at diagnosis should be broken down into smaller groups so that researchers can better interpret the estimated age of infection from the date of diagnosis. CDC should develop an improved method of identifying multiple risk factors present in any one case.

1-18 CDC should oversee the collection and reporting of additional statistical data needed on specific groups, such as women, teenagers (10-13 years old and 14-19 years old), younger men (20 to 24 years old and 25 to 29 years old), intravenous drug users, and bisexual men and women.

1-19 CDC should be responsible for quickly communicating to the research community the need for appropriate studies where statistical analysis is hampered by lack of other needed information, such as size of population subgroups, (e.g. homosexual men, heterosexuals, sexually active teens).

1-20 Extensive research should be conducted and continually updated, and results should be widely disseminated to provide more accurate information on the spread of HIV into the heterosexual population.

1-21 The Secretary of HHS should coordinate data collected by the various entities involved with monitoring the HIV epidemic so that it is as compatible as possible, relating to Census Bureau geographic and demographic data and data from other standard sources, for comparative research purposes and to facilitate the appropriate targeting of prevention and care resources.

1-22 State and local public health agencies should make available local data directly to community-based organizations and other interested parties with regional or national needs in order to reduce the requests to the CDC.

1-23 The federal research agenda should include demographic studies necessary to better estimate the size of the various population groups in the U.S.

1-24 The research being conducted on infectivity, the possible delay between infection and infectivity, the efficiency of HIV transmission and progression from infection to death should be quickly communicated to those modeling the epidemic.

1-25 The public health system should expand the amount of available sentinel data from various high- and low-risk populations (e.g. hospital patients, penitentiary inmates, high school students, runaway youths, newborns) to improve the estimates of incidence and prevalence.

1-26 The research community should be actively engaged in developing innovative models that better describe and explain the transmission of HIV within the population.

Code	Chapter 2: Patient Care
2-1	All members of the health care provider community should treat patients with HIV infection with professionalism, and every effort should be made to maintain an individual's autonomy, sense of self-worth, and personal dignity.
2-2	Health care facilities should provide or arrange for a case manager or some equivalent mechanism for assuring continuity of care for HIV-infected persons who use their facilities.
2-3	All physicians and primary care providers should regularly utilize the HIV anti-body test as a diagnostic tool, and incorporate the test and counseling into the normal range of services offered to patients.
2-4	The CHCP should be increased in high incidence areas to allow for the provision of additional services to persons infected with HIV. The federal allocation would provide primary medical and dental care for patients and would also allow for the training of current and new staff.
2-5	The federal government, through the DHHS, and the state should provide funds for home health care services for under-insured persons with HIV infection. Each state's federal allocation for home health care would be based on the ratio of the number of persons with HIV infection in the state to the total number of persons with HIV infection 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.
2-6	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 counselors, sex counselors and therapists, family counselors, or religious counselors, as appropriate. ALl providers of psychosocial services should be enlisted in efforts to prevent HIV transmission.
2-7	Federal 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 ADMS Block Grant funding should be increased.
2-8	HRSA should evaluate health care provider attrition from municipal hospitals in high prevalence cities, to determine means by which incentives can be developed to retain nurses, physicians, and other direct health care providers.

2-9 The HRSA, through the Maternal and Child Health Program, should provide funding for demonstration grants for Regional HIV Comprehensive Family Care Centers in areas where inadequate pediatric services exist and the prevalence of HIV infection is high. These centers would provide a full range of services to HIV-infected children, adolescents, 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. (SEE: 10-10)

2-10 Where pediatric infection rates are high, based on pediatric seroprevalence information, obstetricians and pediatricians should counsel patients and advise testing as appropriate.

2-11 The 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 PHS 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 service. Systems created should include a continuum of services, emphasize alternatives to hospitalization, and utilize a case-management approach. (SEE: 10-11)

2-12 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 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.

2-13 In areas were availability of intermittent or chronic care services 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.

2-14 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.

2-15 The DHHS should take steps to ensure that all Comprehensive Hemophiliac Diagnostic and Treatment Centers are fully prepared to offer HIV-related care to any patients, and to extend the network of centers to the remaining 25 percent of the hemophiliac population not now being served.

2-16 Municipal hospital systems in high prevalence cities should assess their current five-year anticipated demand for HIV-related services and forward these projections to the Secretaries of the U.S. Departments of HHS and HUD for incorporation into a plan for increased funding for patient care in community and long-term care settings.

2-17 The DHHS should make the development of new strategies for diagnosing, educating, and caring for adolescents at risk for HIV infection a high priority.

2-18 The Pediatric AIDS Health Care Demonstration Projects grants announced by the HRSA should be funded through 1991. Grants should be awarded to programs which are family-focused and community-based, include a coordinated, comprehensive network of services, and should utilize a family case management approach.

Code	Chapter 3: Health Care Providers
3-1	DHHS should administer a competitive grant or contract program, or organized consensus conferences, to construct HIV treatment guidelines for practitioners in differing practice environments encompassing a range of medical specialties and including other disciplines. The guidelines developed should then be made available to all practitioners who request them.
3-2	Health care profession schools should assure that all students are educated about HIV infection and those related subjects most needed in providing care to HIV-infected patients and their families, include: death and dying, pain control, palliative care, human sexuality, substance abuse counseling, ethics, and infection control.
3-3	Health care professions schools should be given incentives to recruit medical students into specialties that are under-represented but needed due to the HIV epidemic.
3-4	Eligibility for financial scholarships and grants should include evaluation mechanisms that take into account the adult financial responsibilities of adult students.
3-5	HRSA should develop a model program to create innovative techniques to recruit, train, and retain nonprofessional health care providers.
3-6	The Federal government, through NIMH, 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 are in the future.
3-7	Institutions which employ health care providers serving persons infected with HIV should provide psychosocial support to their staff on a proactive and continuing basis.
3-8	PHS's Division of Nursing should fund demonstration projects to evaluate models of nurse-managed care for persons with HIV infection or other chronic illnesses. 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, employing nurses in differing job descriptions based on varying levels of education, should be evaluated.
3-9	PHS's 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. Special emphasis should be given to nurses pursing advanced degrees in community health nursing, school health nursing, and occupational nursing.

3-10 NIMH should reinstate funding for traineeships to educate psych-mental health nurses at the masters and doctoral levels who will be needed for counseling efforts.

3-11 Funding for current Nursing Student Loan Program should be increased, and eligibility requirements for low interest loans should be modified.

3-12 Nursing work payback 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 that meet the expanded definitions of medically underserved areas.

3-13 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 nurses to pursue advanced degrees in nursing.

3-14 Nursing organizations in conjunction with the Division of Nursing in the HRSA 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.

3-15 Additional funding should be provided through the PHS's 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.

3-16 The DHHS should fund grants to Schools of Nursing that seek collaborative relationships which agencies to demonstrate the cost-effectiveness and quality of utilizing the nurse as a case manager who:

* assesses the patient and family needs for short-term and long-term care;

* mitigates medical costs by facilitating the patient's optimal level of independence through access to appropriate levels of care both in the hospital and in out-of-hospital settings;

* organizes and sequences those services and resources needed to adequately respond to patient's health care needs by working with the attending physician to assess the patient's medical needs; and functioning as a liaison between the patient and specialized facilities and other providers.

3-17 The DHHS should fund tuition and stipend grants for students in innovative nursing education programs, which offer advanced degrees in nursing as a professional degree in nursing in order to:

* meet future health care provider needs as defined by HHS;

* address the shortage issue by stimulating interest in nursing careers among those in a non-traditional, older population, who may seek professional nursing as a second career.

3-18 The HCFA should restructure the Medicare and Medicaid reimbursement systems to allow for direct reimbursement systems to professional nurses caring for persons with HIV-related illnesses and other chronically ill patients in acute and community care settings.

3-19 The PHS Office of Minority Health should identify funding for recruitment of minorities into advanced levels of nursing education programs.

3-20 Congress should amend the Nurse Training Act to include the provision: that up to 85 percent of a borrower's loan plus interest would be canceled at the rate of 15 percent for each completed year of full-time employment as a professional nurse.

3-21 The NHSC scholarship funds 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 areas, including HIV-endemic areas.

3-22 The NHSC should establish scholarships, loans, and workstudy opportunities to recruit, train, place, and retain 200 nurses per year to staff facilities in underserved areas, including HIV-endemic areas.

3-23 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 HIV-endemic areas to meet their outstanding obligations.