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REQUEST

ADDRESSEE: (NAME, ORGANIZATION,
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FROM: (NAME, ORGANIZATION & PHONE #)

Sue Daoulas

Drug Abuse Policy Office
White House

Lorraine Fishback

PHS

245-6135

TOTAL PAGES

3

FAX MACHINE PHONE NUMBER(IF KNOWN)

456-2246

DATE

1/6/89

CHARGE SYMBOL

REMARKS

I am sending you Bob Kohmescher's analysis of the
PCHIVE recommendations we scored as "under consideration"
and "disagree". Dr. Mac had asked for this analysis
several weeks ago. I am sending it to you for the files.

IF RETRANSMISSION IS NECESSARY CALL: HQS COMMEN FTS 3-245-6277 (AC 202) WAS

INSTRUCTIONS TO COMMEN: (CHECK ONE)

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89 JAN -6 AM 10:12

DEPT. OF HEALTH AND
HUMAN SERVICES

UNDER CONSIDERATION = 72

REC	DESCRIPTION	STATUS	CHANGE
02-008	HCP attrition from hospitals	Unknown	
03-005	Model recruitment program	Unknown	
03-011	Increase Nursing Student Loans	Pending Nursing Report	
03-013	Incentives for advanced RN degrees	Pending Nursing Report	
03-018	Restructure Medicare etc. for RNs	Pending Nursing Report	
03-024	Loans for MSWs	Unknown	
03-029	Central database/hotline-Fx	Active Consideration--Planned	x
04-004	Registry of animal models	Alternative approach recommended--disagree	x
04-005	Database of HIV research activity	Active Consideration--Planned	x
04-006	Additional database support	Not sure of value of approach	x
04-007	NIH intramural construction	Under study	
04-014	Dir of NIH report directly to Sec	Under study	
04-018	NIH: greater hiring flexibility	Under study	
04-019	Senior Biomedical Research Service	Under study	
04-020	Basic research FTE needs	Unknown	
04-022	Assess reassignment of personnel	Unknown	
04-026	Support personnel for RNs	Under study	
04-027	Improve working environment	Under study	
04-032	Discretionary fund	Under study	
04-044	Obstacles to vaccine development	Under study	
04-054	Software package to reduce review	Active Consideration--Fed Reg Announcement	x
04-055	Treatment IND database	Under study	
04-056	Monitor drugs in Phase IV	Under study--no update	
04-057	Use of INDs in patients	Proposal forwarded	x
04-059	Liability laws	Unknown	
04-060	Promotion of orphan drugs	Series of hearings--no update	
04-065	Increase # of reviewers for IND	Unknown	
04-067	Repayment through FDA service	Under study	
04-068	Speed approval of diagnostic tests	Progress cited; other approval planned	x
04-070	New building--FDA	Facilities plan under development	x
04-072	Membership in NIAID Advisory Com.	Planned	x
04-080	Publicity for MD Data Query System	Under study	
04-084	Use of laboratory markers	Need comment; probable disagree	x
04-088	Development of software for studies	Unknown--no current budget	
04-089	Use it to gather data on co-factors	Unknown	
04-090	Use of historic controls	Unknown	
04-092	Clinical trials in pediatric pops	Status could be changed: A or B	x
04-094	Upgrade facilities for Phase I & II	Planned	x
04-102	Report research to central database	Agree, but no system in place; under study	
04-117	Center for exchange of ideas	Still under study	
05-001	Longer term commitments--funding	Unknown	
05-009	CDC--increase staff size	CDC has requested more FTEs; under study	
05-010	Attract first rate personnel to CDC	Under study	
06-008	Incentive program: increase testing	Unknown	
06-024	FDA: new testing requirements-blood	Under study	
06-033	Model state licensing law	Proposed revision-Fed Register	
06-043	Attract more qualified counselors	Unknown	
07-038	Comprehensive school-based ed	Disagree: revised approach proposed	x
08-025	More research: cause of drug abuse	Under study	
08-053	HUD funding for homeless	Under study: no update	

(2)

REC	DESCRIPTION	STATUS	CHANGE
08-058	HUD funds: for long term care	Unknown: no update	
08-083	Reimbursement regulations	Unknown	
09-001	Bar on discrimination	Under study	
09-002	Educational messages on anti-disco.	Could be considered ongoing	x
09-003	Awards for innovative approaches	Unknown	
09-004	Anti-discrimination legislation	Under	
09-007	OCR: aggressive followup	Could be considered disagree	x
09-036	Federal HIV confidentiality legis.	Under study	
09-053	Mandate testing for sexual offender	Change to non-Federal, agree	x
10-010	HCPA: provide exceptions on Medicaid	Under study	
10-012	Stop-loss provision for Medicaid	Unknown	
10-013	Evaluate health care financing	Change to planned <i>ongoing</i>	x
10-014	Two major options for financing	Unknown	
10-015	Tax incentives for insurers	Under study	
10-016	Special underwriting problems	Under study	
11-002	State: contributions to WHO	Unknown	
11-030	Develop a portfolio of training	Unknown	
11-036	Intl HIV research support unit	Under study	
11-038	Travel restrictions	Unknown	
11-044	DoD: \$20m/year	Unknown	
11-045	HIV-related travel restrictions	Unknown	
12-002	Restructure of HHS	Under study	

(5)

Disagree = 53

02-005	Funds for home health care	Alternative approach
02-009	Funding for demo grants	Alternative approach
03-008	Demo projects for nurse care	Legislation rejected
03-010	Support for psych RNs	Alternative approach
03-020	Loan repayment	Alternative approach
03-021	Reinstate scholarship funds	Approach would not work
03-022	Establish scholarship funds	Disagrees with approach
03-027	Provide scholarships: undergraduate	No funds/no legislation authorizing
03-032	Increase funding for AHECS	Conflicts w/ intended purpose of program
03-038	Standardize research requirements	An unworkable approach
04-002	Fee-for-use basis--reagent distrib.	Would produce more problems than solve
04-012	Construction of 4 biology centers	Alternative approach
04-015	Discourage "business as usual"	Alternative approach
04-031	NIH "Director's Awards"	Alternative approach
04-034	Longer term funding mechanism	Alternative approach
04-037	Expand NIH training programs	Alternative approach
04-038	Eliminate regulation on NIH FTE	Would not have the desired effect
04-045	Conference on liability	Alternative approach
04-046	Fund in partnership with private	Alternative approach
04-047	Submit conference results to Congr.	Alternative approach
04-058	Independent review for FDA regs	Alternative approach
04-061	Use of cost-effective methods	Alternative approach
04-071	Annual Presidential Award	Alternative approach
04-081	Use of placebo-controlled studies	Alternative approach
04-083	Standardize staffing criteria	Not the best staging system
05-008	CDC: Move NAIEP to CPS	Alternative approach
05-012	Streamline budget process	Alternative approach
06-025	Restructure Blood Advisory Comm.	Alternative approach
06-027	Alternate payment for hemophilia	Alternative approach--Not a good approach
06-030	Effectiveness of donor registries	No need for such a system
06-034	Fund states to develop model law	An inappropriate Federal role
06-035	Criteria for labs--interstate business	An inappropriate approach
07-004	CDC: Weekly newsletter	Alternative approach
07-007	Effectiveness of paid advertising	Alternative approach--Dangerous precedent
08-003	ADAMHA Block Grant Funds	Alternative approach
08-057	HUD: renovation grants to hospitals	No legislative authority
08-059	Extent of homelessness among veterans	Little gain, very difficult, expensive
08-068	HUD: matching funds for group homes	No legislative authority
08-070	Direct funding of CBOs	Alternative approach
09-008	Increase funding for enforcement--504	Current approach is adequate
09-028	Confidentiality	Under consideration: CHANGED
09-052	Collect data on sexual assaults	Enormous undertaking, little gain
09-053	CDC: monitor & publish HIV & assault	Enormous undertaking, little gain
09-055	Surv studies: sexual assault pop	Enormous undertaking, little gain
10-006	HCFA: demo proj-increase matching rate	Alternative approach
10-009	Reevaluate reimbursement levels	Not permitted by law
10-018	Participation in case-managed system	Not permitted by law
10-019	Minimum Medicaid eligibility floor	Alternative approach
10-020	HCFA: amend regulations	Not permitted by law; cost
10-022	Expand medically needy provisions	Very costly
10-023	Eligibility for hospice care	Not permitted by law; cost
10-024	SSA: statutory change	Costly
11-028	A.I.D.: sources of other funding	Alternative approach



United States Department of State

Washington, D.C. 20520

1 December 1988

Dear Dr. Macdonald:

The three-year plan for the international efforts against HIV infection is in the final stages of interagency clearance. We expect to submit the final paper by December 9.

The Department of State wishes to report no change in the status of Recommendation #11-47 from the Presidential Commission.

The U.S. Agency for International Development (A.I.D.) wishes to report two changes which update its earlier submission (Enclosure A).

Finally, there are also enclosed (Enclosure B) copies of our respective personnel policies in response to the President's August 5, 1988, Memorandum for Heads of Departments and Agencies.

Sincerely,

William A. Nitze
Deputy Assistant Secretary
Environment, Health and
Natural Resource
U.S. Department of State

Bradshaw Langmaid, Jr.
Deputy Assistant for
Research
Science and Technology
U.S. Agency for
International Development

The Honorable

Donald Ian Macdonald, M.D.,

Deputy Assistant to the President and
Director, Drug Abuse Policy Office,
The White House.

UPDATE ON RESPONSES TO THE RECOMMENDATIONS OF THE
REPORT OF THE PRESIDENTIAL COMMISSION ON THE HIV EPIDEMIC
SEPTEMBER 1988

Recommendation # 11-1 Department/Agency A.I.D.

If the status of the recommendation is "Under consideration" or "Other," please mark one of the following:

☐ Planned for FY 1990	☐ Further study needed
☐ Alternative approach	☐ Other

Please elaborate on the status below:

The WHO/GPA is an extra budgetary program of the World Health Organization and, consequently, dependent upon special contributions. The United States, through the Agency for International Development, was the first government to make a budgetary contribution to the GPA in 1986 of \$1 million. In 1987, we contributed \$5 million, and in 1988 we have contributed \$15 million. In FY 1988, the Congress appropriated \$25.5 million for WHO/GPA. This is an increase of \$10.5 million above the Administration's request of \$15.0 million. This will substantially increase the U.S. share to 27% of the planned GPA FY 1989 budget. With this contribution, we will remain by far the largest contributor to the GPA.

Our policy is to fully support GPA's leadership in the international AIDS effort and the GPA program. We have stated that policy at every meeting of the GPA, at all relevant UN meetings, and in our support for the President's budget before the Congress.

However, we do not plan to make a multi-year commitment, i.e., a pledge beyond FY 1989, as this would be in advance of appropriations.

UPDATE ON RESPONSES TO THE RECOMMENDATIONS OF THE
REPORT OF THE PRESIDENTIAL COMMISSION ON THE HIV EPIDEMIC
SEPTEMBER 1988

Recommendation # 11-9 Department/Agency A.I.D.

If the status of the recommendation is "Under consideration" or "Other," please mark one of the following:

☐ Planned for FY 1990	☐ Further study needed
☐ Alternative approach	☐ Other

Please elaborate on the status below:

We have strongly urged the WHO/GPA to establish a coordinated donor evaluation program. We have provided technical assistance in evaluation to GPA. To date, the national AIDS programs approved by WHO/GPA have been weak in the evaluation area. We have expressed our concerns to WHO/GPA on several occasions. A coordinated evaluation program is now being tested in Uganda.

File: HLS

THE WHITE HOUSE
WASHINGTON

August 5, 1988

mw(fr)

ACTION: SAA/S&T as appropriate

INFO: Woods R logs, AA/PPC

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

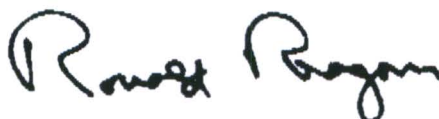
I have approved a 10-point action plan as part of my response to the Report of the Presidential Commission on the Human Immunodeficiency Virus (HIV) Epidemic.

The plan expresses my concern about fair and compassionate treatment of HIV-infected individuals and directs every Federal agency to adopt a policy based on the Office of Personnel Management's (OPM's) "Guidelines for AIDS Information and Education and for Personnel Management." I also have asked American businesses, unions, and schools to examine and consider adopting education and personnel management policies based on the OPM and the Centers for Disease Control (CDC) guidelines.

Many agencies have already adopted policies based on the OPM guidelines. If your agency has not already done so, you should proceed to do so. The Office of Personnel Management is available to answer questions or provide any needed assistance. The Justice Department and the Department of Health and Human Services offer additional sources of information and assistance.

To further encourage businesses, unions, and schools as well as housing projects, correctional facilities, and others to adopt policies based on OPM and CDC guidelines and provide the education that is vital to effective implementation, I also ask each of you to communicate through your programs the value of this approach.

I am directing Donald Ian Macdonald, Deputy Assistant to the President for Drug Abuse Policy, to monitor progress on our response to the Commission's Report and provide me with status reports in September and December, 1988. Please provide Dr. Macdonald with appropriate information about your progress.



807415

AIDS 2.6

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D C 20523

A.I.D. General Notice
PFM/PM/PCF/PP
Issue Date: October 7, 1988

SUBJECT: Acquired Immune Deficiency Syndrome (AIDS) in the Workplace

The Agency recognizes that AIDS and AIDS-related complex (ARC) present economic, health, employment and legal issues for employees. Because of the impact the disease presents in the workplace, the Agency has developed guidelines for dealing with AIDS-related employee issues.

It is Agency policy that employees with AIDS or its related conditions will be allowed to continue to work, and that co-workers will not have a basis upon which to refuse to work or to withhold their services out of fear of contracting AIDS by working with an HIV-infected person. HIV-infected employees will be treated the same as employees with any other serious illness, with AIDS-related personnel issues to be addressed within the framework of existing federal and Agency policies, procedures, guidance, statutes, case law and regulations.

For Foreign Service employees and their dependents, medical clearance examinations are required to determine employees' availability for worldwide assignment. Included in the examination, conducted by the Office of Medical Services, Department of State, is testing for the AIDS-causing virus. FS employees with evidence of immune suppression and/or symptoms are assigned to the United States. Employees who test positive without evidence of immune suppression receive a limited medical clearance, are assigned to posts with experience and facilities to monitor and provide care for this medical problem.

FS employees who have personal concerns about AIDS should contact their career counselor in the Foreign Service Personnel Division. Civil Service employees should contact Bryan Spell, Civil Service Personnel Division.

The AIDS policy is being incorporated into Handbook 29 as Chapter 6.

Att: Acquired Immune Deficiency Syndrome in the Workplace (HB29, Ch.6)

DISTRIBUTION:

AID List H, Position 5
List B-1, Position 10

Chapter 6

Acquired Immune Deficiency Syndrome in the Workplace

6A. Purpose

This chapter contains the Agency's policy statement on Acquired Immune Deficiency Syndrome (AIDS) in the Workplace, and related regulations and procedures.

6B. Applicability

This chapter applies to all U.S. citizen direct-hire employees.

6C. Authorities and References

1. FPM Bulletin 792-42, Acquired Immune Deficiency Syndrome (AIDS) in the Workplace, March 1988
2. 5 CFR Part 339, Medical Determination Related to Employability
3. Department of State notices, "AIDS Testing" (December 1, 1986) and "Testing for the AIDS Causing Virus" (January 2, 1987)
4. Office of Medical Services, Department of State, Procedures Memorandum 89 (May 1988): Human Immunodeficiency Virus (HIV) Testing Procedure

6D. Definitions

1. Acquired Immune Deficiency Syndrome (AIDS). The name given to the illness that results in the body's inability to fight infection.
2. AIDS-Related Complex (ARC). A condition caused by the AIDS virus (HIV) in which the patient tests positive for AIDS infection and has a specific set of clinical symptoms.
3. Human Immunodeficiency Virus (HIV). A virus that can infect people and destroy their immune system, the body's mechanism for fighting infection. HIV causes AIDS. Also known as HTLV-III and LAV.

6E. Policy

The Agency for International Development recognizes that AIDS and ARC present economic, health, employment and legal issues for employees. Because of the impact AIDS presents in the workplace, the following guidelines are established to handle AIDS-related employee issues.

6F

3. Employees

- a. Provide required medical documentation in connection with requests for sick or annual leave or LWOP.
- b. Seek counseling or referral to community services.
- c. Be aware of Agency efforts to provide information about AIDS.

6G. Procedures

1. No employee benefits are adversely affected by a positive test. No employee will be separated because he/she tests antibody positive.
2. Testing for the AIDS-causing virus is included in medical clearance examinations for Foreign Service (FS) applicants and employees and their dependents. The examinations are conducted by the Office of Medical Services (M/MED), Department of State.
 - a. Because FS employees must be available for worldwide assignment, M/MED recommends against hiring applicants who test positive. In the same way, M/MED recommends against hiring persons who have other medical problems or conditions that would limit worldwide availability.
 - b. FS employees with evidence of immune suppression and/or symptoms will be assigned to the United States (class 5 clearance). Employees who test positive without evidence of immune suppression will receive a limited medical clearance (class 2), and will be assigned to posts with experience and facilities to monitor and provide care for this medical problem.

United States Department of State

Department Notice



All Employees STATE

November 4, 1988

PER

Department of State Policy - Human Immuno- deficiency Virus infection in the Workplace

The Department of State recognizes that Acquired Immune Deficiency Syndrome, or AIDS, raises a number of health, employment, legal, and economic issues for employees. This notice transmits the Department's policy on AIDS in the Workplace and is applicable to all DOS Civil Service and Foreign Service employees.

AIDS is a fatal disease that cripples the body's immune system by destroying certain white blood cells (known as T-lymphocytes). This destruction is caused by a virus called human immunodeficiency virus (HIV). Because of the damage to the immune system, the HIV infected individual becomes vulnerable to infections, that healthy individuals can usually resist. Based on current medical and scientific data, the AIDS virus is an infectious disease that is transmitted by intimate sexual contact, intravenously through the use of contaminated needles, or by receipt of transfusions of contaminated blood. There is no medical evidence that the AIDS virus is transmitted through casual contact in a work environment, or through shaking hands, sneezing, coughing, eating foods prepared by a person with AIDS, or by sharing telephones or other office equipment. Therefore, subject to information changes from recognized medical authorities and directives, the Department has established the following guidelines for handling employee issues that may arise because of AIDS.

1. General Policy.

The Department of State is committed to maintaining a safe and healthy environment for all employees. In as much as the provision of accurate and consistent information about AIDS is the most effective method of prevention, the Department will actively provide information to employees about AIDS through distribution of written materials and a program of educational seminars. This will include information about the nature of AIDS, its causes and means of prevention, the rights of employees who have AIDS, and the responsibilities of managers, supervisors and co-workers of employees with AIDS.

-2-

The Department will treat employees infected with the AIDS virus in the same manner as employees with any other serious illness. AIDS-related personnel issues will be addressed within the framework of existing Federal and Departmental policies, procedures, guidance, statutes, case law, and regulations.

HIV infected employees will be allowed to continue working as long as they are able to maintain an acceptable level of performance, and do not pose a health or safety risk to themselves or to other employees.

2. Reasonable Accommodations.

AIDS is considered a handicapping condition and the medical condition of HIV infected employees may be sufficiently disabling to entitle the employee to be considered for reasonable accommodation. Reasonable accommodations will be made as long as the HIV infected employee is able to perform the essential functions of his/her position. Job restructuring and reassignments will be made in the same manner as they are for other employees whose medical conditions impact job performance.

3. Testing.

All applicants for the Foreign Service will be tested for infection with HIV as part of the routine pre-employment medical screening process. Applicants who test positive for HIV infection will be medically disqualified for the Foreign Service because of their inability to serve worldwide. Such applicants will, however, be afforded the same opportunity for a management review of this decision as are applicants with other disqualifying medical conditions.

Foreign Service employees and dependents will be tested for HIV infection as part of the required biennial medical examination for overseas clearance. Testing for HIV was prompted by the realization that our health care facilities overseas are unable to provide adequate care for those with this infection and that exposure to infections and vaccinations may hasten the disease's course. Since these conditions do not generally exist domestically, an HIV testing program of Civil Service employees is not deemed necessary.

Foreign Service personnel who test positive and show evidence of immune suppression and/or symptoms will be assigned only to positions within the United States (Class 5 clearance). Those infected with HIV without immune suppression and/or other symptoms can be assigned to posts with both adequate medical facilities and experience with this type of medical problem (Class 2 clearance). This assignment policy is no different than the assignment policy applied to Foreign Service employees with other potentially serious medical problems.

4. Leave Use.

An HIV infected employee may request sick or annual leave or leave without pay to pursue medical care or to recuperate from the effects of his/her medical condition. Medical documentation may be required to make responsible decisions about an

-3-

employee's ability to work. It is the employee's responsibility to produce medical documentation regarding the extent to which a medical condition affects job performance. Where an AIDS infected employee fails to submit proper documentation, the Department may require the employee to take a physical examination. Any determination to grant or deny leave will be made in the same manner as it would for employees with other medical conditions.

5. Access to Medical Records.

Medical documentation submitted for the purposes of making employment decisions will become a part of the file pertaining to that decision and will become a record covered by the Privacy Act. Generally, the Privacy Act forbids the disclosure of records without the consent of the subject of the record. However, access to medical documentation may be granted to Department officials with the need to make managerial decisions. Officials who have access to such information are required to maintain the confidentiality of that information.

6. Employee Benefits

Employees with AIDS will be appropriately informed of their rights to such benefits as group life and health insurance, disability retirement, leave usage and any other benefit to which they are entitled.

Employees with AIDS continue insurance coverage under the Federal Employees' Health Benefits (FEHB) and/or the Federal Employees' Group Life Insurance (FGLI) Program. Participation in either or both of these programs cannot be jeopardized because of one's health condition. Any employee who is in a leave without pay status for 12 continuous months faces statutory loss of FEHB and FGLI coverage but may convert to a private policy without having to undergo a physical examination.

Employees with AIDS may be eligible for disability retirement. Employees covered by the Civil Service Retirement System (CSRS) or the Foreign Service Retirement and Disability System (FSRDS) must have 5 years of covered Federal service to be eligible. Employees covered under the Federal Employees Retirement System (FERS) or the Foreign Service Pension System (FSPS) must have 18 months of covered Federal Service to be eligible. Applications for disability retirement from employees with AIDS are considered in the same manner as for other employees, focusing on the extent of the employee's incapacitation and ability to perform assigned duties.

7. Counseling.

All employees with personal concerns about AIDS and its related conditions are encouraged to contact Medical Service's (M/MED) Employee Consultation Service (ECS). The Employee Consultation Service can provide employees with useful information about AIDS, appropriate referrals to other resources and services within the Department, as well as referrals to other community based programs and services. The Employee Consultation Service is located in Room 2237 NS, telephone # 647-4929.

6E

HIV-infected employees will be appropriately informed of their rights to such benefits as group life and health insurance, disability leaves of absence and any other disability benefits to which they may be entitled. HIV-infected employees can continue insurance coverage under the Federal Employees Health Benefits Program (FEHB) and/or the Federal Employees' Group Life Insurance (FGLI) Program. Any employee in a leave without pay status for 12 continuous months faces statutory loss of FEHB and FGLI coverage but may convert to a private policy without having to undergo a physical examination. HIV-infected employees may be eligible for disability retirement if their medical condition warrants and if they have the requisite years of federal service to qualify.

The Agency recognizes the need for employees to be informed about AIDS and will provide employees current information to promote better understanding of the nature of the illness.

6F. Responsibilities

Federal and Agency policies, regulations and procedures regarding attendance and leave and employee relations and benefits are applicable to AIDS-related personnel situations and issues.

1. Office of Personnel Management (PFM/PM)

- a. Provides information and education programs to employees.
- b. Provides Agency managers and supervisors information on how to deal with AIDS-related personnel issues.
- c. Provides counseling or referral to employees with personal concerns about AIDS. Foreign Service (FS) employees should contact the Foreign Service Personnel Division (PFM/PM/FSP/CD); Civil Service employees should contact the Civil Service Personnel Division (PFM/PM/CSP).
- d. Makes referrals to community resources.

2. Agency administrative officers, supervisors and managers

Maintain strict confidentiality of any information regarding an HIV-infected employee with personal concerns about AIDS.

6E

The Agency is committed to maintaining a safe and healthy environment for employees, while continuing to conduct its international development mission.

Subject to information changes from recognized medical authorities and directives, it is the policy of the Agency that employees with AIDS or its related conditions will be allowed to continue to work, and that, under ordinary conditions as described above, co-workers will not have a basis upon which to refuse to work or to withhold their services out of fear of contracting AIDS by working with an HIV-infected person.

Employees who refuse to work or who withhold their services, harass, intimidate or in any other manner discriminate against an HIV-infected employee will be subject to disciplinary action. The Agency will conduct educational and information efforts to help allay employee fears about AIDS.

The Agency will treat HIV-infected employees the same as employees with any other serious illness. AIDS-related personnel issues will be addressed within the framework of existing federal and Agency policies, procedures, guidance, statutes, case law and regulations.

HIV-infected employees will be allowed to continue working as long as they are able to maintain an acceptable level of performance, and do not pose a health or safety risk to themselves or to other employees. HIV-infected employees will not be isolated from other employees in the workplace.

Reasonable accommodations will be made as long as the HIV-infected employee is able to perform the essential functions of his/her position with such accommodations. With respect to job restructuring, details, assignments, or other changes in position for employees diagnosed as having AIDS, any considerations made will be done in the same manner as they would for other employees whose medical conditions impact job performance.

An HIV-infected employee may request sick or annual leave or leave without pay (LWOP) to pursue medical care or to recuperate from the effects of his/her medical condition. Medical documentation may be required to make responsible decisions about an employee's ability to work. It is the employee's responsibility to produce medical documentation regarding the extent to which a medical condition affects job performance. Determinations to grant or deny leave will be made in the same manner as it would for employees with other medical conditions.



Error-Prone Step Found in Replication Of the AIDS Virus

Molecular biologists have discovered why the AIDS virus is mutating and evolving so rapidly, spinning off genetically different versions of itself many times more often than is the rule for other microbes.

They have found that a key step in the AIDS virus' mechanism for reproducing within cells is unusually prone to making typographical errors when it tries to copy the genes of the parent virus into the form that will dictate the genes of the offspring.

As a result, many variants of the virus that causes acquired immune deficiency syndrome are produced. As the variants go on to infect new cells and try to reproduce, the faulty mechanism makes even more errors and the number of variations grows.

The situation is analogous to a chain letter in which every recipient makes a few random typographical errors before sending out a new set of copies.

Researchers have known for years that the virus, called HIV-1, mutates at an astounding rate—so fast that the viruses isolated from individual AIDS patients are almost always found to be genetically different. Even within one patient, there may be many different strains of the virus.

The key step involves an enzyme called reverse transcriptase. It is a large molecule whose job is to transcribe the message of the virus' genes, which are encoded in a molecule of RNA, into a molecule of DNA, which is similar but different in key ways. DNA (deoxyribonucleic acid) is the molecule of which all cellular genes are made. Normally, DNA genes exert their control over the cell by having their message transcribed into RNA (ribonucleic acid). The RNA, like a foreman who has read the DNA blueprints, instructs the cell what to do.

The AIDS virus happens to carry its genes in the form of RNA. It also carries reverse transcriptase, which does the reverse of the normal enzyme that transcribes DNA into RNA. The

II.

AIDS virus' enzyme transcribes RNA into DNA. This new DNA is then spliced in among the cell's normal DNA. There the cellular foreman reads it as if it were normal DNA and instructs the cell to make new AIDS viruses.

Two research groups, both appearing in last week's *Science*, report that the AIDS virus' reverse transcriptase is unusually careless when it transcribes the viral RNA into DNA. The AIDS virus makes about 10 times as many errors as do other well-studied RNA viruses.

One study was done by Bradley D. Preston and Lawrence A. Loeb at the University of Washington working with Bernard J. Poiesz at the State University of New York in Syracuse. The other was done by John D. Roberts, Katarzyna Bebenek and Thomas A. Kunkel, all at the National Institute of Environmental Health Sciences at Research Triangle Park, N.C.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

August 2, 1988

STATEMENT BY THE PRESIDENT

Acquired Immunodeficiency Syndrome (AIDS), caused by the Human Immunodeficiency Virus (HIV), has moved through our society with tragic human consequences. It is a public health threat that has touched the lives of Americans with alarming speed and frightening consequences. It demands knowledge and attention by the best experts in our society. I am today ordering a number of actions to focus the efforts of the Government and private sector on this horrible human problem. These directives will assure compassion toward those with the HIV infection, provide dignity and kindness in treatment and medical care, and require that we inform and educate our citizens to prevent further spread of the disease.

We are today adopting a 10-point action plan to advance the battle against AIDS and HIV consistent with the recommendations of the Presidential Commission on AIDS. It is a wide-ranging plan that calls on the action and cooperation of all levels of our society. As a first step, I am today directing that every Federal agency adopt a policy based on Office of Personnel Management (OPM) guidelines on how to treat HIV infected persons in the workplace. I ask American businesses, unions and schools to examine and consider adopting education and personnel policies based on the OPM and Centers for Disease Control guidelines.

I am directing the Attorney General to provide me with an expeditious review of how the Federal government should provide direction and leadership in encouraging non-discrimination for HIV-infected individuals.

We will also proceed to improve laboratory safety, accelerate drug approvals, evaluate the health care financing system and pursue a multi-focused international initiative among other steps. I have asked Dr. Macdonald to monitor our response to the Commission's recommendations and report to me in September.

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

August 2, 1988

IMPLEMENTING RECOMMENDATIONS OF THE PRESIDENTIAL COMMISSION
ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

Fact Sheet

President Reagan today directed all Federal agencies to protect HIV-infected persons against discrimination in the Federal workplace. He instructed agencies to adopt a policy based on Office of Personnel Management (OPM) guidelines developed in March. They state: "... HIV-infected employees should be allowed to continue working as long as they are able to maintain acceptable performance and do not pose a safety or health threat to themselves or others in the workplace."

President Reagan's directive to Federal agencies is part of a 10-point plan he put in place today that will advance the battle against Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) infection. The plan calls for actions to assure compassion towards those with HIV infection, to allow for their care with dignity and kindness, and to inform and educate citizens to prevent further spread of the disease.

The plan is based on recommendations of the Presidential Commission on the Human Immunodeficiency Virus Epidemic. The President received the commission's report on June 27, 1988, from the chairman, Admiral James D. Watkins, and praised it as an impressive effort that significantly increases our understanding of AIDS.

After reviewing the report, the President asked Dr. Donald Ian Macdonald, his Special Assistant and Director of the Drug Abuse Policy Office, to evaluate the commission's 20 summary recommendations and 597 recommendations and develop a course of action that addresses the most pressing problems posed by HIV infection. The plan announced today results from Dr. Macdonald's evaluation and recommendations.

As part of his review, Dr. Macdonald agreed with the commission's recommendation that attention be focused on the threat from HIV infection rather than on AIDS, the most advanced stage of the infection. An estimated 1 million to 1.5 million Americans are infected with HIV. Since 1981, there have been 68,000 cases of AIDS.

Comprehensive Review

The President's plan was developed through a review process that involved consultation with executive branch agencies, the Office of Management and Budget, White House staff and a cross-section of private groups and individuals, including the National Academy of Sciences. That group recently released an AIDS report with conclusions similar to those of the commission.

The review determined that 40 percent of the commission's recommendations with a Federal component have already been completed, are underway or are planned. Another 30 percent are under consideration as part of the FY 1990 agency budget plans.

--MORE--

The 10-Point Plan

Under the action plan, the President:

1. Directs the Department of Health and Human Services (HHS) to develop a series of consensus conferences with representatives from all levels of government and the private sector to intensify public health measures to reduce the spread of HIV infection. The President instructs HHS to increase the number of community based education programs directed to those at increased risk of HIV infection.
2. Requires the Food and Drug Administration (FDA) to improve laboratory quality and blood screening tests immediately and within 45 days begin notification of transfusion recipients. In addition, FDA should encourage self-donated blood before surgery.
3. Emphasizes his concern about drug abuse and its relation to HIV infection and continues his call for bipartisan efforts to enact his anti-drug proposals.
4. Begins action in and out of Government that will accelerate development, approval and distribution of vaccines and drugs.
5. Reaffirms his commitment to provide adequate resources (dollars, staff, office and laboratory space) to combat the HIV epidemic and directs the Office of Management and Budget to make certain there are no impediments to efficient use of these resources.
6. Asks Congress to accelerate enactment of his FY 1989 HIV appropriations request and adopt the FY 1990 budget request for HIV activities as early as possible after the budget is submitted. The President will seek a special HIV emergency fund for unanticipated problems and opportunities in the FY 1990 budget request.
7. Instructs the Secretary of HHS to evaluate the current system of health care financing; and directs HHS to conduct specific studies of ways to promote out-of-hospital care; encourage states to establish insurance risk pools for medically uninsurable persons; and increase the public health response to HIV infected infants, children, adolescents and low income disabled individuals.
8. Directs the Secretary of State to develop a multi-focused international initiative to combat HIV, particularly in less-developed countries; increase U.S. commitment to international technical assistance; and seek development of a three-year plan for international efforts against HIV infection.
9. Requires the Public Health Service to update the 1986 Public Health Service plan for combatting HIV infection. The President has asked Dr. Macdonald to provide him with status reports in September and December on progress to implement the commission's recommendations.
10. Calls on all sectors of society to respond equitably and compassionately to those with HIV infection and to their families. In addition to directing all Federal agencies to adopt a policy based on OPM guidelines, the President requests that American businesses, unions and schools examine and consider adopting education and personnel policies based on the OPM and Centers for Disease Control guidelines.

In addition, the President referred to the Attorney General for expeditious review and response the commission's recommendations as to how the Federal Government should provide direction and leadership to encourage non-discrimination for HIV infected persons.

Accomplishments in Combatting HIV

Over the past seven years, this Administration has committed more than \$5.3 billion to biomedical research, drug trials, prevention education, treatment, financial assistance programs, and other measures to protect public health against HIV. State and local governments and our nation's charitable institutions have also spent generously. The President has commissioned two major reports on the epidemic: the Surgeon General's Report on AIDS and the Report of the Presidential Commission on the HIV Epidemic. Over the past seven years, real advances have been made:

- o Discovery of HIV, the virus that causes AIDS.
- o Determination of HIV incidence, prevalence and disease transmission.
- o Development of a screening test which has virtually eliminated virus transmission through the blood supply.
- o Establishment of a HIV prevention program in every state.
- o Establishment of clearinghouses in the Department of Health and Human Services and the Department of Justice for distribution of information on HIV infection.
- o Distribution of Understanding AIDS, an educational booklet, to 105 million American households.
- o Development of recommendations and guidelines to protect the public against infection in the workplace, schools and the community at large.
- o Clearance in record time of one significant drug therapy (AZT) and substantial progress on a number of others.
- o Production of two HIV vaccines now being tested in human volunteers.
- o Support of international AIDS efforts and funding for the World Health Organization's Global Programme on AIDS.

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COMMISSION RECOMMENDATIONS RELATING TO THE 10-POINT PLAN

The following recommendations of the President's Commission on the HIV Epidemic relate in whole or in part to:

Point 1: Chapter 1: 2-4, 7-11, 13-15, 20, 25; Chapter 3: 40, 42-45; Chapter 5: 13-16, 18-20; Chapter 6: 1-20, 28, 33, 37, 38, 40, 41; Chapter 7: 1-3, 5, 6, 18-33, 40; Chapter 8: 13, 36, 46, 53, 54, 56-57, 60, 62-64, 69, 74, 75, 79, 84, 88-93; Chapter 9: 26, 36-42, 44-51, 56, 63-71, 73-76, 100-103. TOTAL: 129.

Point 2: Chapter 4: 68 and Chapter 6: 21-39. TOTAL: 19.

Point 3: Chapter 8: 1-51; Chapter 9: 83-84. TOTAL: 52.

Point 4: Chapter 4: 1-6, 23, 29, 32-37, 42-64, 68, 73, 75-100, 102; and Chapter 11: 041. TOTAL 67.

Point 5: Chapter 1: 12; Chapter 4: 7-14, 17-22, 24-27, 38, 65-67, 70; Chapter 5: 1-3, 9-12, 34; Chapter 8: 4, 23, 58, 70; Chapter 11: 37-40, 44. TOTAL: 41.

Point 6: For the December report, HHS will submit a document identifying all FY 1989 and FY 1990 resources devoted to each of the Commission recommendations to which the Department has no disagreement.

Point 7: Chapter 1: 12; Chapter 2: 1, 4-5, 7-9, 12-14, 16, 18; Chapter 3: 4-6; 8-13; 15-25, 27, 32; Chapter 6: 27, 31, 36; Chapter 8: 65-68, 83; Chapter 10: 1-25. TOTAL: 68.

Point 8: Chapter 11: 1-15, 17-34, 36-38, 41-42, 45-47. TOTAL: 41.

Point 9: For the December report, HHS will submit a report on how the recommendations of the Presidential Commission relate to those of the PHS Charlottesville Report.

Point 10: Chapter 1: 1; Chapter 2: 1-2, 6-7; Chapter 3: 2, 7, 28, 35, 48-50; Chapter 6: 1, 7, 11-12, 17; Chapter 7: 30, 32-33; Chapter 8: 52, 54, 71-78, 81-82, 85, 87; Chapter 9: 1-2, 4-37, 39-40, 47, 76-77, 80-82, 86-88, 90, 92, 95-97, 104-105; Chapter 11: 8. TOTAL 89.

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THE WHITE HOUSE

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Drug Abuse Policy Office

FOR IMMEDIATE RELEASE

(DATE)

SUMMARY OF ACCOMPLISHMENTS IN COMBATTINGTHE HUMAN IMMUNODEFICIENCY VIRUS (HIV)*on the human
immunodeficiency
virus (HIV) which
causes AIDS*

~~Not until 1982 did researchers in France and the United States isolate and identify the human immunodeficiency virus (HIV).~~ The urgency and breadth of the nation's ~~HIV~~ research efforts is without precedent in the history of the Federal government's response to an infectious disease crisis. In the 7 years since the first reports of AIDS cases, the virus has been identified; the ways in which it is spread have been pinpointed; an AIDS antibody screening test has been developed and is being used to protect blood supplies; the first steps toward development of a protective vaccine have been taken; and promising drugs to fight the HIV and its manifestations are being synthesized and tested.

And, in order to promote even greater understanding, the President commissioned two major reports on the epidemic: the Surgeon General's Report on AIDS and the Report of the Presidential Commission on the HIV.

with all
The HIV epidemic will be an ~~international threat~~ for years to come. Knowledge is a critical weapon against HIV -- knowledge about the virus and how it is transmitted, and knowledge of how to protect one's health. It is critical also that knowledge lead to individual responsibility. Toward that end, it is the responsibility of each individual to learn about HIV and to treat those infected with HIV with respect and compassion. And it is the responsibility of infected individuals not to infect others.

In the absence of a curative drug or preventive vaccine,
The President established a 18-point action plan to advance the U.S. battle against AIDS and HIV. The plan, based on recommendations of the Presidential Commission on the HIV Epidemic, calls for actions to assure compassion towards those with HIV infection, to allow for their care with dignity and kindness, and to inform and educate citizens to prevent further spread of the disease. The President further instructed the Federal government to take the lead in protecting HIV-infected persons against discrimination in the Federal workplace.

Accomplishments in Combatting HIV

HIV will continue to pose a great public health threat to the world community -- it is estimated that ~~65,000 people will die because of HIV in the year 1992 alone.~~ However, extensive efforts by Government and the private sector as well as the international community are underway in the fight against AIDS and HIV infection, and great strides have been made.

the total of AIDS cases will reach 300,000 by the end of 1988 and 3 million over the next 5 years.

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- o As the first cases of AIDS were identified, nationwide surveillance activities were initiated to monitor the spread of the disease. Disease surveillance began early in the epidemic, before the HIV had been identified or isolated, and before it was known that there could be a lengthy period of infection prior to illness.
- o There has been unprecedented progress in identifying and describing how HIV is structured and how it works. The Federal government continues to probe the inner workings of the immune system and its function during HIV infection to find ways to halt the progress of the virus. Continued research is also being pursued to expand our knowledge of the factors and causes of progression to clinical disease.

Public Health Measures

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In 1982, scientists determined that AIDS could be transmitted through transfusion of contaminated blood or blood products. Some two years later, HIV was identified as the agent that causes AIDS. This discovery allowed scientists to develop screening tests to detect antibodies to HIV in blood. This breakthrough provided the opportunity to essentially eliminate one form of HIV transmission, that is, through blood transfusions or blood products.

- o Since the approval of these screening tests, all donated blood and plasma throughout the U.S. is screened for HIV.
- o Individuals whose blood is found to be infected with HIV are referred for appropriate medical treatment and counseling.
- o The U.S. blood supply is now among the safest in the world - since 1985, only 13 new cases of HIV infection have been associated with the transfusion of blood.
- o Although the risk of transmission of HIV by transfusion has been almost eliminated, the Federal government continues to initiate activities to further reduce the remaining risk.
- o A series of consensus conferences are being held to intensify public/private sector collaboration of public health measures to reduce the spread of AIDS.

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Approximately 30 percent of all AIDS cases are associated with intravenous (IV) drug use. HIV infected drug users are a source of infection not only to other IV drug users through needle sharing, but also to their sexual partners and their unborn children. Currently, most heterosexual HIV infections are indirectly related to people who are IV drug users. Over 70 percent of the HIV infection in newborns is related to the use of intravenous drugs by the mother or her sexual partner.

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- o Research aimed improving the treatment for IV drug abuse and the most effective approaches for changing this behavior has been expanded.
- o A data base is being developed on which research can be built to improve information about the extent and nature of IV drug use.
- o Additional research is being conducted on the effects of all drugs, particularly illicit drugs, on the immune and nervous systems, and how treatment for drug abuse affect AIDS disease progression.

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Public Health Issues Education and Public Information

The Reagan Administration has placed a high priority on programs to strengthen the level of understanding in the general public about AIDS, HIV infection and effective prevention measures. The education programs are geared towards increasing the prevention-specific knowledge in the general public so as to reduce misinformation, allay unfounded fears, and increase levels of support for AIDS/HIV prevention and control efforts.

- o In 1982, a toll-free national AIDS hotline was established.
- o An HIV prevention program has been established in every State.
- o An educational brochure, Understanding AIDS, was distributed in the spring of 1988 to every household in the United States.
- o OPM has established an AIDS clearinghouse to make information on AIDS and HIV available to all Federal agencies seeking assistance. The clearinghouse contains, among other things, education and training materials, results of periodic surveys regarding extent and status of AIDS policies and programs, and specific AIDS education activities.
- o The Federal government increased funding for community-based organization involved with AIDS education and prevention -- from _____ in 1982 to _____ in 1989.
- o Public policy and prevention efforts are now based on understanding the extent and distribution of HIV in the population and on the rate at which new infections occur.

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International Cooperation

The U.S. has committed itself internationally to lead the effort to control the spread of HIV infection and find a cure. Working with the World Health Organization, the Department of State has developed a three-year plan for international efforts against HIV infection. The strategy includes: enhanced coordination to control the spread of HIV and further research; support for multi- and bilateral programs to reduce the spread of infection; and strengthened research and research cooperation to control the spread of infection and treat those already infected.

- o _____ countries [All countries with which the U.S. is working] have implemented HIV public information campaigns, including education programs targeted at reducing high risk behavior.
- o Blood transfusion screening programs has been implemented in _____ countries and most are now working to ensure that their national blood supply is free from HIV infection.
- o Simple and rapid HIV diagnostics are being tested for use in developing countries.
- o Incidence and prevalence studies are being conducted to assess the scope of the world's HIV epidemic.

Antidiscrimination and Confidentiality

In response to the President's request, the Attorney General reviewed Federal anti-discrimination laws in this area and issued a legal opinion clarifying the coverage of the Rehabilitation Act. The opinion clarifies that the act protects HIV-infected individuals in Federal employment and programs and activities receiving Federal funds (i.e. schools, hospitals). It also concludes that if the infection is a direct threat to the health or safety of others or renders an individual unable to perform the duties of his or her job, an employer is not required to retain or hire that person.

- o The 22 largest Federal agencies (96 percent of the Federal workforce), have instituted AIDS antidiscrimination guideline, per the OPM Guidelines.
- o These 22 Federal agencies have established Employee Assistance Programs which have been expanded to include counseling and referral services for AIDS-related issues.
- o OPM sent a letter to each of the Fortune 1000 companies telling them of the President's 10-point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines." Positive response has been received from a number of companies thanking OPM for the mailing and announcing plans to implement the guidelines.

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- o The Federal government is pursuing a closer linkage between drug abuse treatment services and the primary health care services -- particularly because people with AIDS require special health and social services.
- o Outreach programs have been expanded to reach those drug users who are not currently in treatment.

Resources

State and local governments and our nation's charitable institutions have spent generously to fight the HIV epidemic. Since 1982, the Reagan Administration has committed more than \$5.4 billion to various measure to protect public health against HIV -- biomedical research, drug trials, prevention, education, treatment, financial assistance programs.

- o A consolidated office building is being constructed on the NIH campus to remove the administrative obstacles and to provide additional laboratory and office space for AID/HIV research.
- o Additional FTEs for HHS have been approve to assure that adequate human resources are available for HIV efforts.

- o [QPM is addressing the issue of recruitment and retention of science personnel.]

[insert chart]

This issue is still a problem for HHS

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Treatment

Success in treating HIV infection will depend on the discovery and testing of new drugs and treatments. The overall goal of the Federal government in therapeutics is to aid in these discoveries by developing and testing compounds, providing an extensive clinical trials network in which to test the efficacy of these compounds, and providing the regulatory framework for getting new drugs into the marketplace rapidly. Both the Federal government and the private sector are very active in preclinical drug development, clinical trials testing, and regulatory approval processes.

- o A comprehensive program has been established which fully supports all phases of drug discovery.
- o In 1987, Azidothymidine (AZT) was approved in record time and prolongs the life of some HIV infected individuals.
- o A massive drug screening program has been established to evaluate potential therapies from all possible sources.
- o The Federal government has made a cooperative arrangement with other research institutions and pharmaceutical companies to explore the range of drugs to treat infections that occur in or kill AIDS patients, such as Pneumocystis Carinii (PCP). *pneumonia*
- o A large clinical trials network has been established at medical centers across the country to evaluate various drugs and treatment regimens in populations of HIV-infected individuals.
- o The Federal government, in collaboration with the pharmaceutical industry, is conducting extensive clinical trials to judge therapies efficacy in humans.
- o The FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has approved a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o The Federal government is expanding and improving treatment for IV drug users. Demonstration projects have been initiated to help identify and understand the behavior of IV drug abusers so that more effective treatment and prevention programs can be designed.
- o The methadone regulations and practices are being revised so that its use can be expanded to cause a reduction in IV use of opiates.

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

DEC 9 1988

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DEC 13 1988

Donald Ian Macdonald, MD
Deputy Assistant to the President
and Director, Drug Abuse Policy Office
220 Old Executive Office Building
Washington, D.C. 20503

Dear Dr. Macdonald:

I am pleased to comment on our actions implementing the two charges assigned to OMB by the President on August 5th. Specific resource levels for Human Immunodeficiency Virus (HIV) have not been determined, because we are still developing the President's FY90 Budget. We will, of course, work with Congress to facilitate swift appropriations action regarding HIV.

While I cannot identify an exact amount for the President's HIV request, I can say our approach to HIV includes a double digit increase above FY89 for Public Health Service (PHS) HIV funding, and FTE allocations above HHS' proposed allocations. Additional funding would be available outside of PHS, through Medicaid, Social Security, the Veterans Administration, DOD, Medicare, and other agencies.

The lease-purchase acquisition of CDC laboratory and office space is underway, as authorized by the FY89 Labor/HHS Appropriations Act. We also expect the President's FY90 Budget to repropose language sent to Congress on September 26th that would allow NIH to construct a consolidated office building as recommended by the President's HIV Commission. Finally, we are also encouraging HHS to identify and eliminate impediments to efficient use of HIV resources.

I hope this information will assist you in preparing your report. Please let me know if I may be of further assistance.

Sincerely,

Joseph B. Wright, Jr.
Director

TAB D

THE WHITE HOUSE

WASHINGTON

6 October 1988

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D. 

SUBJECT: Progress Report: 10-Point Action Plan to Fight the Human Immunodeficiency Virus Epidemic

I am pleased to report that substantial progress has been made during the past six weeks on your 10-point action plan to fight the Human Immunodeficiency Virus (HIV) epidemic.

Background On August 2, you approved a 10-point action plan to advance the battle against HIV infection and AIDS consistent with the recommendations of your Presidential Commission. As a result of your August 5 directive to selected Cabinet agencies a significant number of activities have been initiated or expanded.

Discussion In response to your request, the Attorney General has reviewed Federal anti-discrimination laws in this area and today issued a legal opinion clarifying the coverage of the Rehabilitation Act. The opinion clarifies that the act protects HIV-infected individuals in Federal employment and programs and activities receiving Federal funds (i.e. schools, hospitals). It also concludes that if the infection is a direct threat to the health or safety of others or renders an individual unable to perform the duties of his or her job, an employer is not required to retain or hire that person.

Details of our progress are attached (Tab A). Highlights:

- A U.S. Health Summit on HIV infection (November 28-29) will be the first in a series of ten consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- To promote fairness and compassion, the 22 largest Federal agencies will have the OPM guidelines in place by December.
- FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, expects to announce soon a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- On September 26, you requested Congress grant authority to the NIH to begin construction of a consolidated office building devoted exclusively to HIV research.

In December, I will provide you with another progress report.

THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Progress Report

October 6, 1988

1. Develop a series of consensus conferences with representatives from all levels of government and the private sector to intensify public health measures to reduce the spread of HIV infection. Increase the number of community-based education programs directed to those at increased risk of HIV infection.

Status

Consensus Conferences In response to your letter to Secretary Bowen, HHS will convene a series of ten conferences over the next year to intensify public/private sector collaboration on a variety of HIV-related public health problems.

- A "U.S. Health Summit" will kick off the series in Washington, D.C., on November 28-29, 1988. ISSUES: counseling, testing, partner notification, reporting of HIV infection, and health care worker safety.
- Five regional "mini-summits" will be held from January to May in New York City, Chicago, San Francisco, Dallas and Atlanta.
- Four conferences will address specific issues you raised in your directive to HHS:
 - "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety and liability.
 - "Federal-State Strategies" (Planning for February 1989 with the National Governor's Association meeting). ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.
 - "Legal Issues" (tentative - May 1989). ISSUES: restrictive measures and criminal statutes directed to HIV-infected persons who knowingly persist in behaviors that transmit the infection and other legal issues.
 - "Reporting HIV Infection" (tentative - Atlanta, June 1989).

In addition, a number of conferences previously scheduled for FY 1989 have been reprogrammed to address issues identified by you and your HIV Commission, such as HIV infection in racial/ethnic minority populations; workplace standards for bloodborne diseases; planning and management of health care services for HIV-infected patients; drug abuse and AIDS; services for adolescents and youth at risk of HIV infection; and safety of health care workers.

Community-Based Education Programs Funding for local HIV prevention programs will be increased by 44 percent -- from \$15 million to \$21.6 million in FY 1989. In October, competitive awards will be made for HIV prevention activities and will go to 15 to 20 areas with high prevalence of HIV infection.

2. **Implement actions within 45 days that address: (a) prompt notification of transfusion recipients who are at increased risk of HIV infection; (b) steps to improve HIV laboratory quality and HIV screening tests; and, (c) ways to encourage the use of autologous transfusions in appropriate circumstances.**

Status

Notification of Transfusion Recipients Notification of transfusion recipients through "look-back" programs are underway. These programs will be strengthened through: (a) regulations making current voluntary programs mandatory (draft due mid-1989); (b) requirements that the blood industry and hospitals notify physicians when potentially contaminated blood units may have been released and "look-back" should be initiated (draft to be developed October 1988); and, (c) the American Medical Association (AMA) has begun, at the request of FDA, conducting education programs for transfusion recipients including notification, testing and counseling. By the end of 1988, special out-reach efforts, conducted by HHS as well as the American Hospital Association (AHA) and the AMA, will begin to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available).

Improving Laboratory Quality HHS is initiating an integrated strategy to improve laboratory testing accuracy, including: (a) regulations for proficiency testing and development of standards for laboratory quality (standards due January 1989); (b) doubled inspections and surveillance of blood bank facilities will begin in October; (c) FDA is conducting enhanced training for investigators who inspect blood banks; and, (d) based on the findings of inspections, enhanced training programs are being conducted for blood establishment staff under FDA regulations/standards. In addition, NIH is conducting research to develop and evaluate new tests to detect HIV infection.

Self-Donated (Autologous) Transfusions HHS will be conducting a major educational effort, "The National Blood Resources Education Program," to promote a safe supply of blood and the more effective use of blood and blood products. This program will include a public education campaign (radio, television and print public service announcements) to promote autologous donation prior to elective surgery as a means of increasing the blood supply and assuring safety. The FDA is preparing information for health professionals (for release in Winter 1989) and, in August, began consultations with representatives of the AMA and the AHA to further encourage appropriate use of autologous transfusions.

In addition, HHS will increase research on techniques, such as red blood cell sterilization, which show promise for eradicating HIV and other viruses from the blood.

3. **The President emphasizes his concern about drug abuse and its relation to HIV infection and continues his call for bipartisan efforts to enact his anti-drug proposals.**

Status

Drug and HIV/AIDS Legislation Most of your recent proposals for both HIV/AIDS and anti-drug efforts exist in pending legislation, but their status is uncertain at this point. On September 23, 1988, the House passed an anti-drug bill which contains many desirable features. There is reason for concern that the Senate will not take action on an anti-drug bill before the October recess.

Several important HIV-related issues:

- **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.
- **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on congressional action. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. One of the new HHS consensus conferences will address the issue of personnel. To alleviate the facilities problem, HHS is pursuing with DOD the use of unused or under-used DOD and other federal facilities.
- **High-Risk Populations** HHS and DOJ are developing demonstration projects which target populations at high risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. HHS and DOJ are providing technical assistance to major metropolitan areas working with high-risk youth. In FY 1989, NIDA will begin model demonstration projects for IV drug users at risk for HIV/AIDS.

4. Begins action in and out of Government that will accelerate development, approval and distribution of vaccines and drugs.

Status

Accelerate Approval Process FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, is developing a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS. Key elements of the plan include:

- Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby shortening the approval time.
- Use of Investigational New Drugs for treatment will be permitted prior to full marketing approval.
- New standards established for use of drugs to treat life-threatening illnesses by incorporating an assessment of the risks of the disease against the identified benefits and risks of the products.
- Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

Incentives for Drug Development HHS appointed a working group which held its first meeting on August 3 in response to your request for assessment of private initiatives for the development and marketing of HIV products. As you requested, they will include recommendations on such issues as granting of marketing rights, waivers of royalty or patent licensing rights, and examination of appropriate Federal role, if any, in encouragement of reasonable pricing for HIV-related products which are developed in part with Federal grants. The working group report is anticipated before the December deadline.

Liability Issue HHS is investigating the parameters of liability risk and the perception of liability risk which may inhibit rapid research and development of some HIV-related products, particularly vaccines. HHS will consult with private groups, including the Keystone Group and the Institute of Medicine, and will collaborate with representatives from the Department of Justice and the Department of Defense. Findings will be available by December 5.

5. Reaffirms his commitment to provide adequate resources (dollars, staff, office and laboratory space) to combat the HIV epidemic, and directs the Office of Management and Budget to make certain there are no impediments to efficient use of these resources.

Status

Space Needs On September 26, you requested that Congress grant authority to the NIH to initiate construction of a consolidated office building on the NIH campus (Bethesda, MD). Your HIV Commission recommended construction of a consolidated office building to remove "one of the most serious research administrative obstacles ... encountered." Also, the Centers for Disease Control's construction to provide additional laboratory and office space is planned for FY 1989.

Resource Needs Because of the urgent need, additional FTEs for HHS have been approved for FY 1989. OMB will continue to work with the Secretary to assure that adequate resources are available for HIV efforts. Dollars and resources for HIV infection will receive priority consideration in preparation of the FY 1990 budget.

Unresolved Issues The recruitment and retention of science personnel are being addressed by OPM, and a more complete answer may be available for the December report.

6. Asks Congress to accelerate enactment of his FY 1989 HIV appropriations request and adopt the FY 1990 budget request for HIV activities as early as possible after the budget is submitted. The President will seek a special HIV emergency fund for unanticipated problems and opportunities in the FY 1990 budget request.

Status

Presidential Action On August 5, you sent a letter to the Congress announcing your 10-point plan and asking Congress to expeditiously enact both the FY 1989 and FY 1990 appropriations requested for HIV activities. Much of your FY 1989 HIV appropriations request was contained in the Labor, Health and Human Services and Education Bill which you signed on September 20 -- included was a \$1.29 billion appropriation to combat HIV infection (a 1.2 percent decrease from your budget request).

HUMAN IMMUNODEFICIENCY VIRUS (HIV) FUNDING Government-wide Crosscut (Obligations in \$ millions)

	FY82	FY83	FY84	FY85	FY86	FY87	FY88*	FY89*
Public Health Service (Research & Prevention)	6	29	61	109	234	502	956	1287
Medicaid (Federal share) ...	0	10	30	70	130	200	330	490
Medicare	0	0	0	5	5	10	20	30
Social Security								
DI	0	0	5	10	25	40	70	110
SSI	0	0	1	3	8	15	18	28
Veterans Admin	2	5	6	10	23	54	69	98
(Res, Prev, & Treatment)								
Defense Department	0	0	0	0	79	74	52	52
(Res, Prev, & Treatment)								
AID	0	0	0	0	0	0	30	40
(Prevention)								
Bureau of Prisons	0	0	0	0	1	1	1	2
(Prev & Treatment)								
State Department	0	0	0	0	0	1	2	1
(Prevention)								
Labor Department	0	0	0	0	0	1	1	1
(Prevention)								
Education Department	0	0	0	0	0	0	1	0
(Prevention)								
TOTAL	8	44	104	207	504	898	1549	2139

* Estimate

Detail may not add to total due to rounding.

7. Instructs the Secretary of HHS to evaluate the current system of health care financing, and directs HHS to conduct specific studies of ways to promote out-of-hospital care; encourage states to establish insurance risk pools for medically uninsurable persons; and increase the public health response to HIV infected infants, children, adolescents and low income disabled individuals.

Status

Evaluation of Health Care Financing In response to your directive, HHS has begun an evaluation of access to health care with a focus on financing and insurance -- by December 1, this will include consultation with outside experts. Considerations will include the under-insured and uninsured, experiences of low-income disabled individuals, and disability coverage through the Social Security Administration and/or Medicaid.

Alternatives to Acute Care HHS is encouraging states and other organizations to study the efficacy of care and to provide more cost-effective care through:

- the home and community-based services waiver program;
- solicitation of research and demonstration projects to study the effectiveness of out-of-hospital and case-managed care;
- evaluation of patterns of utilization and costs in AIDS Service demonstration grant projects (due late summer 1989); and
- evaluation of regional AIDS education and training centers (due late summer 1989).

Risk Pools HHS plans to promote risk pools through the consensus conference approach, in cooperation with the Winter 1989 meeting of the National Governors Association. HHS is also considering the use of "seed money" to encourage states to establish such pools.

Infants, Children and Adolescents The HHS Secretary's Task Force on Pediatric HIV Infection Report recommends specific studies regarding infants, children and adolescents. This report is currently being reviewed by the Department, and a more complete submission will be available for the December report.

8. Directs the Secretary of State to develop a multi-focused international initiative to combat HIV, particularly in less-developed countries; increase U.S. commitment to international technical assistance; and seek development of a three-year plan for international efforts against HIV infection.

Status

Draft Plan A three-year plan outline has been drafted by the Department of State, with the U.S. Agency for International Development (A.I.D.). Final development of the plan will be coordinated with other Federal agencies through the State Department's Interagency Committee on AIDS and HHS's Federal Coordinating Committee on AIDS, and will focus on four broad areas:

- multilateral and bilateral activities for the prevention and control of HIV infection;
- international aspects of the development of therapeutic agents and vaccines;
- foreign policy implications of AIDS; and,
- budgetary implications.

The plan should be available for review by mid-November with the final report submitted by mid-December.

Financial Support A.I.D. funds for international assistance for HIV prevention programs will increase from \$30 million in FY 1988 to \$40 million in FY 1989.

9. Requires the PHS to update the 1986 Public Health Service plan for combatting HIV infection.

Status

The Public Health Service will submit a Department-wide HIV Implementation Plan in December which will identify major goals to be accomplished during FY 1989. This plan will be developed from your 10-point action plan, the report of your HIV Commission, and the October 1988 report of the June 1988 PHS AIDS Prevention and Control Conference. Issues, goals and objectives will be divided into ten broad categories:

- epidemiology and surveillance;
- clinical manifestations and pathogenesis;
- prevention, information, education, and behavior change;
- patient care/health care needs, including financing;
- blood and blood products;
- intravenous drug abuse;
- neuroscience and behavior;
- therapeutics;
- vaccines; and
- other departmental activities.

A computerized tracking and monitoring system for HHS activities in combatting HIV infection, including implementation of your action plan and the Commission's recommendations, will be established.

10. Calls on all sectors of society to respond equitably and compassionately to those with HIV infection and to their families. In addition to directing all Federal agencies to adopt a policy based on OPM guidelines, the President requests that American businesses, unions and schools examine and consider adopting education and personnel policies based on the OPM and CDC guidelines.

Status

Agencies Comply A telephone survey of the largest 22 Federal agencies (96 percent of the Federal workforce), initiated in July, was followed in August with a supplemental survey.

- All 22 agencies are putting AIDS policy guidelines in place and now offer counseling and referral services for AIDS-related issues through their Employee Assistance Programs or medical services facilities. By December, all will have initiated formal training/education programs on AIDS-related issues for employees, supervisors and managers. Seven agencies have directly issued AIDS policies. Fourteen others are presently drafting policies/guidelines to be issued by the end of October. One agency will issue policy guidance no later than December.

OPM held a conference on September 14, 1988, in Washington, D.C. on "AIDS in the Workplace."

OPM AIDS Clearinghouse Established To make AIDS information available to agencies seeking assistance, OPM has established a clearinghouse which contains your action plan, copies of all agency policy statements, education and training materials, results of periodic surveys regarding extent and status of AIDS policies and programs, and specific AIDS educational activities.

Private Sector Responding On August 17, 1988, the Director of OPM sent a letter to each of the Fortune 1000 companies telling them of your 10-point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines." Positive response has been received from a number of companies thanking OPM for the mailing and announcing plans to implement the guidelines.

ITEMS PROMISED IN OCTOBER FOR DECEMBER REPORT

4. **Begins action in and out of Government that will accelerate development, approval and distribution of vaccines and drugs.**

Incentives for Drug Development HHS appointed a working group which held its first meeting on August 3 in response to your request for assessment of private initiatives for the development and marketing of HIV products. As you requested, they will include recommendations on such issues as granting of marketing rights, waivers of royalty or patent licensing rights, and examination of appropriate Federal role, if any, in encouragement of reasonable pricing for HIV-related products which are developed in part with Federal grants. The working group report is anticipated before the **December** deadline.

Liability Issue HHS is investigating the parameters of liability risk and the perception of liability risk which may inhibit rapid research and development of some HIV-related products, particularly vaccines. HHS will consult with private groups, including the Keystone Group and the Institute of Medicine, and will collaborate with representatives from the Department of Justice and the Department of Defense. Findings will be available by **December 5**.

5. **Reaffirms his commitment to provide adequate resources (dollars, staff, office and laboratory space) to combat the HIV epidemic, and directs the Office of Management and Budget to make certain there are no impediments to efficient use of these resources.**

Unresolved Issues The recruitment and retention of science personnel are being addressed by OPM, and a more complete answer may be available for the **December** report.

7. **Instructs the Secretary of HHS to evaluate the current system of health care financing, and directs HHS to conduct specific studies of ways to promote out-of-hospital care; encourage states to establish insurance risk pools for medically uninsurable persons; and increase the public health response to HIV infected infants, children, adolescents and low income disabled individuals.**

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7. (Continued)

Infants, Children and Adolescents The HHS Secretary's Task Force on Pediatric HIV Infection Report recommends specific studies regarding infants, children and adolescents. This report is currently being reviewed by the Department, and a more complete submission will be available for the **December** report.

- 8. Directs the Secretary of State to develop a multi-focused international initiative to combat HIV, particularly in less-developed countries; increase U.S. commitment to international technical assistance; and seek development of a three-year plan for international efforts against HIV infection.**

The plan should be available for review by mid-November with the final report submitted by mid-**December**.

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1. Rpt on Health Summit (shared responsibility)
↳ firm-up dates

NIMBI

Community-based (competitive awards)

2. Blood bank

3. follow-up on drug business

Tom Vernon
St Health Dir
Colorado

4. (2 Rpts)

5. Resources
OPM Rpt.

6. ~~done~~ budget

7. ~~do~~ review
Pediatric Rpt
Nursing Commission (due 12/15)

8. State Dept.

9. PHS

10. OPM
DOJ } should there be legs? } Rpt w/ AG
if so, what? } Model laws

Report for S.2889

As finally approved by the House and Senate (Enrolled), AT THE SECOND
SESSION

With reference to Item(s): 115

KEY: << ... >> indicates struck-through text in printed version
{ { ... } } indicates bold parenthesis (usually numbered Senate amendments)
[[...]] indicates bold brackets in printed version

Item 115: Subtitle D--National Commission on Acquired Immune Deficiency
Syndrome

Subtitle D--National Commission on Acquired Immune
Deficiency Syndrome

SEC. 241. SHORT TITLE.

This subtitle may be cited as the "National Commission on Acquired Immune
Deficiency Syndrome Act".

SEC. 242. ESTABLISHMENT.

There is established a commission to be known as the "National Commission on
Acquired Immune Deficiency Syndrome" (hereinafter in this Act referred to as
the "Commission").

SEC. 243. DUTIES OF COMMISSION.

(a) General Purpose of the Commission.--The Commission shall carry out
activities for the purpose of promoting the development of a national
consensus on policy concerning acquired immune deficiency syndrome
(hereinafter in this subtitle referred to as "AIDS") and of studying and
making recommendations for a consistent national policy concerning AIDS.

(b) Succession.--The Commission shall succeed the Presidential Commission on
the Human Immunodeficiency Virus Epidemic, established by Executive Order
12601, dated June 24, 1987.

(c) Functions.--The Commission shall perform the following functions:

(1) Monitor the implementation of the recommendations of the
Presidential Commission on the Human Immunodeficiency Virus Epidemic,
modifying those recommendations as the Commission considers appropriate.

(2) Evaluate the adequacy of, and make recommendations regarding, the
financing of health care and research needs relating to AIDS, including
the allocation of resources to various Federal agencies and State and
local governments and the roles for and activities of private and public
financing.

(3) Evaluate the adequacy of, and make recommendations regarding, the
dissemination of information that is essential to the prevention of the
spread of AIDS, and that recognizes the special needs of minorities and
the important role of the family, educational institutions, religion, and
community organizations in education and prevention efforts.

(4) Address any necessary behavioral changes needed to combat AIDS,
taking into consideration the multiple moral, ethical, and legal concerns
involved, and make recommendations regarding testing and counseling
concerning AIDS, particularly with respect to maintaining confidentiality.

(5) Evaluate the adequacy of, and make recommendations regarding,
Federal and State laws on civil rights relating to AIDS.

(6) Evaluate the adequacy of, and make recommendations, regarding the capability of the Federal Government to make and implement policy concerning AIDS (and, to the extent feasible to do so, other diseases, known and unknown, in the future), including research and treatment, the availability of clinical trials, education and the financing thereof, and including specifically--

(A) the streamlining of rules, regulations, and administrative procedures relating to the approval by the Food and Drug Administration of new drugs and medical devices, including procedures for the release of experimental drugs; and

(B) the advancement of administrative consideration by the Health Care Financing Administration relating to reimbursement for new drugs and medical devices approved by the Food and Drug Administration.

(7) Evaluate the adequacy of, and make recommendations regarding, international coordination and cooperation concerning data collection, treatment modalities, and research concerning AIDS.

SEC. 244. MEMBERSHIP.

(a) Number and Appointment.--

(1) Appointment.--The Commission shall be composed of 15 members as follows:

(A) Five members shall be appointed by the President--

(i) three of whom shall be--

- (I) the Secretary of Health and Human Services;
- (II) the Administrator of Veterans' Affairs; and
- (III) the Secretary of Defense;

who shall be nonvoting members, except that, in the case of a tie vote by the Commission, the Secretary of Health and Human Services shall be a voting member; and

(ii) two of whom shall be selected from the general public on the basis of such individuals being specially qualified to serve on the Commission by reason of their education, training, or experience.

(B) Five members shall be appointed by the Speaker of the House of Representatives on the joint recommendation of the Majority and Minority Leaders of the House of Representatives.

(C) Five members shall be appointed by the President pro tempore of the Senate on the joint recommendation of the Majority and Minority Leaders of the Senate.

(2) Congressional committee recommendations.--In making appointments under subparagraphs (B) and (C) of paragraph (1), the Majority and Minority Leaders of the House of Representatives and the Senate shall duly consider the recommendations of the Chairmen and Ranking Minority Members of committees with jurisdiction over laws contained in chapter 17 of title 38, United States Code (relating to veterans' health care), title XIX of the Social Security Act (42 U.S.C. 1901 et seq.) (relating to Medicaid), and the Public Health Service Act (42 U.S.C. 201 et seq.) (relating to the Public Health Service).

(3) Requirements of appointments.--The Majority and Minority Leaders of the Senate and the House of Representatives shall--

(A) select individuals who are specially qualified to serve on the Commission by reason of their education, training, or experience; and

(B) engage in consultations for the purpose of ensuring that the expertise of the 10 members appointed by the Speaker of the House of Representatives and the President pro tempore of the Senate shall provide as much of a balance as possible and, to the greatest extent possible, cover the fields of medicine, science, law, ethics, health-care economics, and health-care and social services.

(4) Term of members.--Members of the Commission (other than members appointed under paragraph (1)(A)(i)) shall serve for the life of the Commission.

(5) Vacancy.--A vacancy on the Commission shall be filled in the manner

in which the original appointment was made.

(b) Chairman.--Not later than 15 days after the members of the Commission are appointed, such members shall select a Chairman from among the members of the Commission.

(c) Quorum.--Seven members of the Commission shall constitute a quorum, but a lesser number may be authorized by the commission to conduct hearings.

(d) Meetings.--The Commission shall hold its first meetings on a date specified by the Chairman, but such date shall not be earlier than September 1, 1988, and not be later than 60 days after the date of the enactment of this Act, or September 30, 1988, whichever is later. After the initial meetings, the Commission shall meet at the call of the Chairman or a majority of its members, but shall meet at least three times each year during the life of the Commission.

(e) Pay.--Members of the Commission who are officers or employees or elected officials of a government entity shall receive no additional compensation by reason of their service on the Commission.

(f) Per Diem.--While away from their homes or regular places of business in the performance of duties for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under sections 5702 and 5703 of title 5, United States Code.

(g) Deadline for Appointment.--Not earlier than July 11, 1988, and not later than 45 days after the date of the enactment of this Act, or August 1, 1988, whichever is later, the members of the Commission shall be appointed.

SEC. 245. REPORTS.

(a) Interim Reports.--

(1) In general.--Not later than 1 year after the date on which the Commission is fully constituted under section 244(a), the Commission shall prepare and submit to the President and to the appropriate committees of Congress a comprehensive report on the activities of the Commission to that date.

(2) Contents.--The report submitted under paragraph (1) shall include such findings, and such recommendations for legislation and administrative action, as the Commission considers appropriate based on its activities to that date.

(3) Other reports.--The Commission shall transmit such other reports as it considers appropriate.

(b) Final Report.--

(1) In general.--Not later than 2 years after the date on which the Commission is fully constituted under section 244(a), the Commission shall prepare and submit a final report to the President and to the appropriate committees of Congress.

(2) Contents.--The final report submitted under paragraph (1) shall contain a detailed statement of the activities of the Commission and of the findings and conclusions of the Commission, including such recommendations for legislation and administrative action as the Commission considers appropriate.

SEC. 246. EXECUTIVE DIRECTOR AND STAFF.

(a) Executive Director.--

(1) Appointment.--The Commission shall have an Executive Director who shall be appointed by the Chairman, with the approval of the Commission, not later than 30 days after the Chairman is selected.

(2) Compensation.--The Executive Director shall be compensated at a rate not to exceed the maximum rate of basic pay payable under GS-18 of the General Schedule as contained in title 5, United States Code.

(b) Staff.--With the approval of the Commission, the Executive Director may appoint and fix the compensation of such additional personnel as the Executive Director considers necessary to carry out the duties of the Commission.

(c) Applicability of Civil Service Laws.--The Executive Director and the additional personnel of the Commission appointed under subsection (b) may be

appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and may be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(d) Consultants.--Subject to such rules as may be prescribed by the Commission, the Executive Director may procure temporary or intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals not to exceed \$200 per day.

(e) Detailed Personnel and Support Services.--Upon the request of the Commission for the detail of personnel, or for administrative and support services, to assist the Commission in carrying out its duties under this Act, the Secretary of Health and Human Services and the Administrator of Veterans' Affairs, either jointly or separately, may on a reimbursable basis (1) detail to the Commission personnel of the Department of Health and Human Services or the Veterans' Administration, respectively, or (2) provide to the Commission administrative and support services. The Secretary and the Administrator shall consult for the purpose of determining and implementing an appropriate method for jointly or separately detailing such personnel and providing such services.

SEC. 247. POWERS OF COMMISSION.

(a) Hearings.--For the purpose of carrying out this Act, the Commission may conduct such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission considers appropriate. The Commission may administer oaths or affirmations to witnesses appearing before the Commission.

(b) Delegation.--Any member or employee of the Commission may, if authorized by the Commission, take any action that the Commission is authorized to take under this Act.

(c) Access to Information.--The Commission may secure directly from any executive department or agency such information as may be necessary to enable the Commission to carry out this Act, except to the extent that the department or agency is expressly prohibited by law from furnishing such information. On the request of the Chairman of the Commission, the head of such department or agency shall furnish nonprohibited information to the Commission.

(d) Mails.--The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

SEC. 248. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated for fiscal year 1989 \$2,000,000, and such sums as may be necessary in any subsequent fiscal year, to carry out the purposes of this Act. Amounts appropriated pursuant to such authorization shall remain available until expended.

SEC. 249. TERMINATION.

The Commission shall cease to exist 30 days after the date on which its final report is submitted under section 245(b). The President may extend the life of the Commission for a period of not to exceed 2 years.

Multiple versions of S.2889 found - which do you desire:

- 1: * As passed by the Senate, October 13, 1988
- 2: * As passed by the

THE WHITE HOUSE

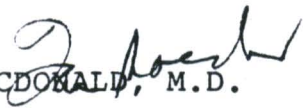
WASHINGTON

July 28, 1988

ACTION

MEMORANDUM FOR THE PRESIDENT

FROM:

DONALD IAN MACDONALD, M.D. 

SUBJECT:

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

Issue: Whether to approve an action plan to respond to the HIV Commission report.

Background: During the past seven years, you have led an ever-widening effort to combat the effects of HIV infection and Acquired Immunodeficiency Syndrome (AIDS) through biomedical research, drug and vaccine trials, education, and measures to protect the public health. In June 1987 you established a one-year Presidential commission to investigate the spread of HIV and "recommend measures that Federal, state, and local officials can take." Four weeks ago, you received the final report of the commission from its Chairman, Admiral James D. Watkins, and asked me to prepare "a course of action that takes us forward" against HIV infection. The commission's comprehensive report contains 597 overall recommendations directed at all levels of government and the private sector. In many cases the report has implications reaching beyond efforts to combat AIDS and HIV infection.

During the past 30 days, I have consulted with Executive Branch agencies, the Office of Management and Budget (OMB), White House staff, and a cross-section of private groups and individuals, including the National Academy of Sciences which recently released an AIDS report with conclusions similar to those of the commission.

Discussion: Government and private agencies have continued to work throughout the year the commission has been active. Fully 40 percent of the 360 commission recommendations with federal components are already completed, underway, or planned. An additional 30 percent are under consideration as part of FY 90 agency budget plans.

The commission has identified 20 priority recommendations.

- o I agree with their top recommendation that attention be focused on the threat from HIV infection (estimate: 1 to 1.5 million infected Americans) rather than on AIDS, the most advanced stage of the infection (about 65,000 cases since 1981).
- o Action is underway on 5 other commission recommendations which urge increased emphasis on counseling and testing, partner notification, and prevention and treatment of IV drug abuse.
- o An additional 12 of the commission's top 20 recommendations will be advanced if you approve this plan. They are in the areas of personal responsibility, safety of the blood supply, ensuring adequate resources and flexibility of effort, education, health care financing, boarder babies, youth, international cooperation and discrimination.
- o One of the top 20 recommendations which calls for more nurses should be deferred pending a Nursing Commission report to the Secretary of Health and Human Services in December. Another recommendation which calls for extension of the National Health Services Corps should be rejected because I believe it will not solve the problem it addresses and because the Administration has previously opposed such action.

HIV infection and AIDS have created an unprecedented crisis that will have tremendous social and economic costs. The myriad problems must be a shared responsibility of federal, state, local, and private health agencies and of private citizens, businesses, and foundations. The Federal government cannot solve these problems alone.

Difficult decisions about education, prevention, diagnosis, intervention, treatment, and research will be managed best when public health principles, epidemiological models, and knowledge are applied with compassion and skill. At the same time, issues of individual rights and legitimate state interests must not be ignored.

TEN-POINT ACTION PLAN

Your approval of this ten-point plan will take the Nation forward in our fight against HIV infection. The proposed actions reflect a combination of my consultations and those commission recommendations with which I agree.

1. Implementation of Traditional Public Health Measures. The report endorses a number of public health measures that you have already recommended and which need to be implemented at state, local, and private levels. These include increased counseling and testing, reporting of HIV infection, and partner notification. Education must include emphasis on the importance of personal values and behavior and we must especially increase our efforts to reach persons at highest risk, including those in minority communities. Federal leadership should address the adoption of criminal statutes dealing with HIV-infected individuals who knowingly persist in behaviors that will transmit their infection. Another key issue is the serious problem of local community resistance to neighborhood facilities for treating AIDS patients, drug abusers, and boarder babies.

I **recommend** that you: urge federal, state and local agencies, private citizens, businesses, and foundations to work together to more fully implement public health measures to reduce the spread of HIV infection; direct an increase in the number of community-based educational programs directed to persons at highest risk of HIV infection, including women and members of minority populations; urge that all HIV educational programs, especially those directed to youth, place greater emphasis on your Principles on AIDS Education.

2. Anti-Drug Programs. The commission, and virtually everyone with whom I consulted, stressed the explosive threat to society from HIV transmission by intravenous drug users. Expansion of drug treatment capacity is needed, but it must grow over a period of years because there are limits to how fast the treatment community can expand. We need to continue our research efforts to learn better what works in drug prevention and treatment.

I **recommend** that you continue to communicate publicly your concern about drug abuse and its relation to HIV infection and continue to call for bi-partisan effort to enact your anti-drug proposals.

3. Ensuring A Safe Blood Supply. The progress made to safeguard our Nation's blood supply has been remarkable, but the commission believes that additional measures are necessary. They raised issues of laboratory quality, better screening tests, greater use of self-donated blood, direct notification of past transfusion recipients, and a restructuring of the Food and Drug Administration's Blood Products Advisory Committee.

I **recommend** that you: call for immediate action to improve laboratory quality and screening tests; call for appropriate steps to promptly notify those most at risk of HIV infection from blood transfusion; and urge greater use of self-donated blood.

4. Eliminating Barriers to Development of Vaccines and Drugs. Because of genuine concern about HIV infection and knowledge of the many scientific miracles produced in our lifetime, public expectations seem overly-optimistic as to how quickly government, the research community, and the pharmaceutical industry can reasonably be expected to develop drug therapies and a vaccine for AIDS and HIV infection.

I **recommend** that you call for immediate action inside and outside of government to further accelerate the process for development, evaluation, approval, and distribution of HIV vaccines, drugs, and devices; call upon the pharmaceutical industry to increase their already considerable efforts to develop products to combat HIV; and call for an assessment of private incentives for development and marketing of HIV products, including an evaluation of the need, if any, to have federal authority with which to offer increased incentives in exchange for royalties, licenses, or pricing concessions. This assessment should take into consideration solutions proposed in the February 1986 report of the Federal Tort Policy Working Group.

5. Ensuring Adequate and Effective Use of Resources. The commission has serious concerns about management of federal resources, especially about whether a long-range perspective is being applied.

I **recommend** that you reaffirm your commitment to ensuring that the Federal government's HIV-related activities receive appropriate resource support (dollars, FTEs, and office and laboratory space) and that, consistent with your other management improvement initiatives, no impediments to efficient use of these resources exist (including any problems with grant, contract, and hiring procedures) to the extent consistent with good administrative and fiscal controls. The Administration should pursue a vigorous and creative solution to the numerous issues raised by the commission.

6. Accelerating FY 90 Appropriations. Delay in the congressional appropriations process slows planning and implementation of our HIV efforts.

I **recommend** that you call upon Congress to accelerate enactment of your FY 89 HIV appropriations request and adopt your FY 90 budget request for HIV activities as quickly in the coming year as possible. A special HIV emergency fund for unanticipated problems and opportunities should be incorporated in the FY 90 budget request.

7. Health Care Financing Issues. The commission found health care financing issues to be among the most difficult they confronted.

I **recommend** that you endorse the concept expressed in the commission's recommendation 10-13 that "the Secretary of Health and Human Services...should evaluate our current system of health care financing"

I also **recommend** that you call for specific studies of ways to: better promote out-of-hospital and case-managed care; encourage states to establish insurance risk pools for medically uninsurable persons; and increase the responsiveness of the public health and health services systems to HIV-infected infants, children, and adolescents, and to low-income disabled individuals.

8. International Initiative. The United States must continue to do its part to stem the international epidemic of HIV infection. The commission recommended increased international funding and better planning and coordination.

I **recommend** that you endorse a multi-focused initiative involving encouragement and assistance to international HIV efforts, with emphasis on less-developed countries; a heightened U.S. commitment to international technical assistance within established technology transfer laws; and development of a three-year plan for international efforts against HIV infection.

9. Sustained Federal Leadership. Because there is no cure in sight, most if not all of the 1 to 1.5 million who are infected with the HIV virus will die and will remain infectious to others until their death. There will be huge personal, social, and economic costs which will extend well into the future.

I **recommend** that you request an update of the 1986 Public Health Service (PHS) plan for combatting HIV infection, reflecting elements of the commission report and the recent PHS Charlottesville planning conference; and monitor progress on the Executive Branch's response to the Presidential commission report. Status reports can be given to the Nation in September and December, with the second report containing specific recommendations for your successor.

10. Compassionate and Fair Treatment of HIV-Infected Individuals. Several dozen commission recommendations deal with fair and compassionate treatment of HIV-infected individuals through school and workplace guidelines, anti-discrimination laws, and confidentiality of medical records. The commission report repeatedly stresses the virtual non-transmissibility of AIDS and HIV infection in casual settings, as well as the need for enhanced public education about how HIV is, and is not, transmitted. It is also relevant to note that HIV testing is an important diagnostic and preventive tool which will be less widely used if there is fear that positive results will be disclosed publicly and result in adverse consequences.

I **recommend** that you endorse the commission's call for all sectors of society to respond equitably and compassionately to those who are HIV-infected and to their families. I **recommend** that you direct every Federal agency to adopt a policy based on the recently issued Office of Personnel Management (OPM) guidelines. I further **recommend** that you call upon American businesses, unions, and schools to examine the OPM and Centers for Disease Control guidelines and suggest their use as a model with appropriate modifications.

RECOMMENDATION: I recommend that you approve implementation of the proposed ten point action plan.

DECISION

Approve_____ Disapprove_____ Approve as modified_____

In regard to the Federal government's role in non-discrimination, I want to raise an additional issue which has potentially far-reaching implications and could carry us in a policy direction that is uncharted. Both the courts and Congress are struggling with issues surrounding expansion of non-discrimination policy. These are complicated policy questions that will require us to balance competing values and need thoughtful legal review.

RECOMMENDATION: I recommend that you refer these issues to the Attorney General for expeditious review and response.

DECISION

Approve_____ Disapprove_____ Approve as modified_____

If you approve this action plan, appropriate directives will be prepared for your signature.

Attachment

HIGHLIGHTS OF ACCOMPLISHMENTS IN COMBATTING
AIDS AND HIV INFECTION----1981 TO 1988

Acquired Immunodeficiency Syndrome (AIDS) existed, but was unknown, for a number of years prior to its discovery in 1981. Since that time, the Federal Government, in cooperation with state and local organizations, researchers, public health workers and health care professionals, has embarked on an ever-widening effort to combat this public health threat. During your Administration more than \$5.3 billion has been committed to fight Human Immunodeficiency Virus (HIV) infection: through biomedical research, drug trials, prevention education, health care delivery and financial assistance programs, and measures to protect the public health. Hundreds of millions of dollars more have been expended by state and local governments and our nation's many charitable institutions. The President has commissioned two major reports on the epidemic: the Surgeon General's Report on AIDS and the Report of the Presidential Commission on the HIV Epidemic.

There have been many successes over the past 7 years, among them:

- o discovery of the causative agent known as HIV;
- o improved knowledge of HIV incidence, prevalence, and disease transmission;
- o implementation of nationwide blood screening which has virtually eliminated virus transmission through the blood supply;
- o establishment, with federal funding and technical assistance, of a comprehensive HIV prevention program in every state;
- o nationwide availability of testing and counseling for individuals who think they may be infected;
- o establishment through the National Institute of Justice of a national clearinghouse for AIDS information as it pertains to law enforcement agencies;
- o an educational mailer to all 105 million American households;
- o Federal leadership in developing recommendations and guidelines on protecting the public against infection in the workplace, schools, and the community at large.
- o market availability of one significant drug therapy and substantial progress on a number of others, including ongoing clinical trials with thousands of persons with HIV-infection;
- o approval to test two experimental HIV vaccines in human volunteers;
- o significant United States involvement and support for international AIDS efforts, including funding for the World Health Organization's Global Program on AIDS.

Points for Consideration

The audience is State Health Commissioners, gubernatorially appointed State AIDS Coordinators, representatives of State Medical Societies and the National Medical Associations, and Health Officers representing cities and counties with substantial programs directed toward reducing the spread of HIV infection.

How the President's 10 Point Action Plan was Put Together

- o Federal agency directors were sent a copy of the Commission Report and asked to identify each of the 597 recommendations within their purview and report on the status of each.
- o Dr. Macdonald met with more than 50 individuals representing private sector and voluntary organizations with an interest in AIDS and HIV infection. These individuals were also asked to comment on recommendations that effected their organization.
- o This review showed that 357 of the recommendations fell within the Federal purview for implementation. Our September follow up showed that 51 percent of these are either completed, ongoing, or planned. The rest of the 240 recommendations fell primarily to the private sector for implementation. And of these 77 were dependent upon the States for implementation. Another 15 require assistance from the States for implementation.
- o Of course, there is some overlap in areas where the Federal sector shares responsibility because it provides funding and technical assistance to State and local governments. But the policy choices--whether or not to implement--clearly belong to the State and local governments.
- o In developing the 10 point action plan, consideration was given to those recommendations that needed implementation and capturing them within broad categories.
- o The recommendation on consensus conferences was meant to deal with a series of recommendations--about 129--scattered throughout the Commission report that dealt with a broad range of public health measures.

How the Conference Relates to Point One

- o The President's charge to HHS was to develop a series of consensus conferences with representatives from all levels of government and the private sector to intensify public health measures to reduce the spread of HIV infection.
- o Dr. Windom deserves praise for convening this conference.

- o It was planned before the President issued his 10 point action plan.
- o But Dr. Windom's farsightedness in envisioning a mechanism for bringing together those responsible for planning and managing HIV related activities and programs in State and local governments gave us a forum that he so graciously adapted to fit the President's directive.
- o I am pleased that this conference is the kickoff for a series of 5 additional regional conferences for State and local officials on public health control measures.

Specific Commission Recommendations for Consideration

- o As the group breaks up into into its work groups for discussion, they might consider the following points:
 - Should States requiring reporting of HIV infection?
 - If reporting of HIV infection is implemented should it be--as the Commission recommended--without identifiers? If so, can it be done so that results are useful (i.e. can duplicated reporting of the same person tested at different sites be prevented?)
 - Will this information better enable us to assess and monitor the HIV epidemic?
 - Do States need laws to permit hospitals to notify health care workers, who in the process of providing health care have been exposed to the blood and body fluid of an HIV infected person?
 - Could State departments of health coordinate the prevention and education activities of local health departments, community-based service organizations, and professional medical and health care associations to prevent needless duplication of services or lack of services in key areas?
 - What steps do States need to take to shore up their confidentiality provisions and antidiscrimination protections for HIV-infected individuals.
 - What about partner notification services?
 - And then there is the issue of public health quarantine provisions - Are these ever appropriate to control AIDS and HIV infection?
 - Should States consider enacting medically needy provisions under their Medicaid programs?

RATIONALE FOR CONSENSUS CONFERENCES

The Presidential Commission on the HIV epidemic addressed a broad range of topics. While the responsibility for their implementation is primarily Federal, forty percent of the recommendations are non-Federal. Many of these are the responsibility of State and local health departments.

The President feels that these topics should be addressed by those responsible for implementing them. The purpose of the consensus conferences, then, is for State and local health departments to discuss the relative merit of the recommendations and how best to implement them.

The topics addressed in the recommendations with State responsibility include:

1. Incidence and Prevalence

Reporting of HIV infection (1-3)

2. Health Care Providers

- o Educational requirements linked to licensing of health care providers (3-33)
- o Notification of health care providers of their exposure to HIV infection (3-44)

3. The Public Health System

- o Responsibility of state in providing full HIV prevention services (5-13)
- o Formation of state advisory committees (5-14)
- o Role of state departments of health in coordinating HIV prevention activities (5-15)

4

4. Prevention

- o Statutes ensuring confidentiality (6-1)
- o Provision of adequate and convenient counseling and testing facilities (6-4)
- o Provision of partner notification services (6-13)
- o Revision of public health statutes (6-17)
- o Isolation of HIV-infected persons (6-18)
- o Quality assurance in testing facilities (6-38)

5. Education

- o HIV infection in minority communities (7-21)
- o Support to community-based organizations (7-25)
- o Promotion of HIV education in schools (7-31)

6. Societal Issues

- o Increase in drug treatment facilities (8-5)
- o Quality assurance in drug treatment facilities (8-14)
- o Street outreach teams (8-39)
- o Increased funding for local enforcement efforts to combat drug abuse (8-47)
- o Strengthen drug abuse laws (8-48)
- o Special HIV unit for comprehensive care program for biological and foster families with children with HIV infection (8-60)

7. Legal and ethical issues

- o Laws to prohibit discrimination (9-9)
- o Education campaigns to counteract discrimination (9-10)
- o Development of long term plans to anticipate the need for community-based health care facilities (9-26)
- o Duty to warn (9-40)
- o Adoption of criminal statutes (9-46)
- o Enhanced sentencing for in cases where sexual offenders commit sexual crimes knowing they are HIV-infected (9-68)
- o Testing in correctional facilities (9-73)

8. Financing health care

Medically needy provisions under Medicaid programs (10-21)

REPORT OF THE PRESIDENTIAL COMMISSION ON THE HIV EPIDEMIO
RECOMMENDATIONS WITH STATE SECONDARY RESPONSIBILITY

REC #

01-001
01-004
01-005
01-006
01-007
01-008
01-009
01-011
01-013
01-014
01-022
01-025
05-017
08-094
10-010

Count: 15

REPORT OF THE PRESIDENTIAL COMMISSION ON THE HIV EPIDEMIC
RECOMMENDATIONS WITH STATE PRIMARY RESPONSIBILITY

REC #

01-003
01-010
01-015
03-033
03-044
03-045
05-013
05-014
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07-036
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08-016
08-017
08-029
08-039
08-043

REPORT OF THE PRESIDENTIAL COMMISSION ON THE HIV EPIDEMIC
RECOMMENDATIONS WITH STATE PRIMARY RESPONSIBILITY

6

REC #

08-047
08-048
08-049
08-050
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09-009
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09-026
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09-050
09-051
09-068
09-076
09-077
09-103
10-021

Count: 77

8

PANEL A; CONTROL PRINCIPLES**Monday, 1:30 p.m.**

The panel on control principles will address issues relative to controlling the spread of HIV infection in certain occupational environments, particularly among health-care workers. Other occupations which could also be addressed are emergency-care workers, laboratory workers, morticians, correctional institution staff, and other occupations where the workforce may have an increased risk of occupational exposure to HIV. The panel will explore universal precautions, protective equipment, the work environment, and information and education programs directed to workers at increased risk of exposure to HIV. Are Federal guidelines and proposed regulations adequate? How should State and local entities develop their own workplace policies for employees with occupational risk of infection? How should state and local entities promulgate these policies in their communities? What kind of information/education programs are available, or should be available, for workers in these occupations? Are there other issues to be addressed or barriers to implementing effective control programs?

PANEL B. OUTREACH TO RISK GROUPS**Monday, 1:30 - 2:45 P.M.**

This panel will examine the need to respond to the unique pattern of spread of HIV infection. The transmission routes are better known and control measures have been established in many public and private sector efforts. Several of the risk groups are particularly difficult to reach or have not responded well to the efforts to date.

This panel will examine innovative outreach programs. Important questions about their effectiveness to date should be asked. What barriers did they overcome and which ones still exist? Were there some false starts or outright failures which have taught us important lessons? Are there appropriate definitions of responsibilities among the public and private sectors at this point? How does the multiple risk factor population affect ones outreach efforts? Are there specific recommendations that can be addressed to the Federal government for leadership actions?

9

PANEL C: EDUCATION/BEHAVIOR CHANGE**Monday, 1:30 P.M.**

The panel on education and behavior change will address the effectiveness of media campaigns, national vs. local educational campaigns and whether behavior change can be effected by information and education alone. It will explore the types of campaigns being used to reach various sectors of the population stressing what works and what doesn't work. How do you measure behavior change? Are education and information programs being evaluated for effectiveness? How? What education programs are being used in the schools. What are the policies in your particular area effecting education in the schools. What is being done to educate health-care providers? Other target groups (judicial, prison guards, etc.) How can the Federal Government and the PHS improve their role? Are there barriers to implementing the recommendations set forth in the Presidential Commission Report on the HIV Epidemic and the President's 10-Point Plan?

Panel D. MANAGEMENT ISSUES IN HIV EPIDEMIC CONTROL PROGRAMS
Tuesday, 9:00 - 10:15 A.M.

This panel will address the resource management issues involved with providing services to HIV infected persons. It takes a look at the entire system of health care provision. Integration and coordination are of particular interest; the lack of these and the barriers which prevent them occurring should be identified: mission, funding, skills, and others. How well have we achieved anything approaching a continuum of care? How can the system components be networked better? Is the framework present? How does one integrate support, family, and other non-medical service components? Are there some other questions that need to be raised about collaboration and networking?

PANEL E: TESTING ISSUES: COUNSELING, REPORTING HIV INFECTION AND PARTNER NOTIFICATION**Tuesday, 8:30 A.M.**

This panel will discuss the very sensitive issues regarding reporting HIV infection, counseling and partner notification. It will examine the issues of mandatory vs. voluntary and/or routine testing, and the value of data obtained from anonymous, blinded and name associated testing. It will discuss strategies for eliciting information from patients to determine if they should be tested. Another testing issue to be considered is the value of testing in different populations and the applications for thees data. What are the effects of confidentiality or lack thereof? How do you handle fear of discrimination?

THE WHITE HOUSE

WASHINGTON

TELECOPY MESSAGE

DRUG ABUSE POLICY OFFICE
ROOM 220
WASHINGTON, D.C. 20500

FAX: (202) 456-2246
PHONE: (202) 456-6554

TO: Sally Macdonald
ORGANIZATION: Rep. Bilirakis's Office
PHONE #: 225-5755
FAX #: 225-4085

DATE: 11/22/88
TIME: ~~4:00~~ p.m. 5:20

FROM: Terry Bell
SUBJECT: Please include in package to Dr. Mac

☒ PER OUR CONVERSATION.

☐ AS REQUESTED.

☐ FOR YOUR INFORMATION.

☐ FOR COMMENT.

☐ OTHER _____

REMARKS: ~~In case Jim's note doesn't fax well, it says: Mac: I'd like to
speak with you over the weekend re this. Jim Manning (203) 250-8376~~

ITEMS PROMISED IN OCTOBER FOR DECEMBER REPORT

4. **Begins action in and out of Government that will accelerate development, approval and distribution of vaccines and drugs.**

Incentives for Drug Development HHS appointed a working group which held its first meeting on August 3 in response to your request for assessment of private initiatives for the development and marketing of HIV products. As you requested, they will include recommendations on such issues as granting of marketing rights, waivers of royalty or patent licensing rights, and examination of appropriate Federal role, if any, in encouragement of reasonable pricing for HIV-related products which are developed in part with Federal grants. The working group report is anticipated before the **December** deadline.

Liability Issue HHS is investigating the parameters of liability risk and the perception of liability risk which may inhibit rapid research and development of some HIV-related products, particularly vaccines. HHS will consult with private groups, including the Keystone Group and the Institute of Medicine, and will collaborate with representatives from the Department of Justice and the Department of Defense. Findings will be available by **December 5**.

5. **Reaffirms his commitment to provide adequate resources (dollars, staff, office and laboratory space) to combat the HIV epidemic, and directs the Office of Management and Budget to make certain there are no impediments to efficient use of these resources.**

Unresolved Issues The recruitment and retention of science personnel are being addressed by OPM, and a more complete answer may be available for the **December** report.

7. **Instructs the Secretary of HHS to evaluate the current system of health care financing, and directs HHS to conduct specific studies of ways to promote out-of-hospital care; encourage states to establish insurance risk pools for medically uninsurable persons; and increase the public health response to HIV infected infants, children, adolescents and low income disabled individuals.**

Evaluation of Health Care Financing In response to your directive, HHS has begun an evaluation of access to health care with a focus on financing and insurance -- by **December 1**, this will include consultation with outside experts. Considerations will include the under-insured and uninsured, experiences of low-income disabled individuals, and disability coverage through the Social Security Administration and/or Medicaid.

7. (Continued)

Infants, Children and Adolescents The HHS Secretary's Task Force on Pediatric HIV Infection Report recommends specific studies regarding infants, children and adolescents. This report is currently being reviewed by the Department, and a more complete submission will be available for the **December** report.

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The plan should be available for review by mid-November with the final report submitted by mid-**December**.

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The Public Health Service will submit a Department-wide HIV Implementation Plan in **December** which will identify major goals to be accomplished during FY 1989. This plan will be developed from your 10-point action plan, the report of your HIV Commission, and the October 1988 report of the June 1988 PHS AIDS Prevention and Control Conference.

- 10. Calls on all sectors of society to respond equitably and compassionately to those with HIV infection and to their families. In addition to directing all Federal agencies to adopt a policy based on OPM guidelines, the President requests that American businesses, unions and schools examine and consider adopting education and personnel policies based on the OPM and CDC guidelines.**

Agencies Comply A telephone survey of the largest 22 Federal agencies (96 percent of the Federal workforce), initiated in July, was followed in August with a supplemental survey.

- o All 22 agencies are putting AIDS policy guidelines in place and now offer counseling and referral services for AIDS-related issues through their Employee Assistance Programs or medical services facilities. By **December**, all will have initiated formal training/education programs on AIDS-related issues for employees, supervisors and managers. Seven agencies have directly issued AIDS policies. Fourteen others are presently drafting policies/guidelines to be issued by the end of October. One agency will issue policy guidance no later than **December**.

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FROM YOUR JULY 28 MEMO TO THE PRESIDENT (10-POINT PLAN)

9. Sustained Federal Leadership. Because there is no cure in sight, most if not all of the 1 to 1.5 million who are infected with the HIV virus will die and will remain infectious to others until their death. There will be huge personal, social, and economic costs which will extend well into the future.

I **recommend** that you request an update of the 1986 PHS plan for combatting HIV infection, reflecting elements of the commission report and the recent PHS Charlottesville planning conference; and monitor progress on the Executive Branch's response to the Presidential commission report. Status reports can be given to the Nation in September and **December, with the second report containing specific recommendations for your successor.**