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ACTION

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

SUBJECT: Progress on 10-Point Action Plan to Fight AIDS/HIV

Our Knowledge of the Human Immunodeficiency Virus (HIV) and our response to the epidemic have come further faster than with any disease in history. However, the death toll continues to rise. The predicted consequences of this disease will place increasing demands on our nation's health and science resources.

Status In June, you asked me to review the report of your Commission on the HIV Epidemic (The Watkins' Report). In this, my third and final report, I am pleased to state that most of the 354 Commission recommendations within Federal purview have been completed or will be implemented with FY 1989 funds. Additionally, Federal leadership will continue to stimulate action on most of the 243 recommendations that fall outside Federal jurisdiction.

Progress Progress on your 10-point plan since my September report (Tab C) is addressed at Tab B. Highlights ~~of the progress~~ include:

- o Legislation you signed in November included the largest increase for drug abuse treatment to date.
- o FDA has implemented a process which will speed approval of therapies to treat life-threatening illness such as AIDS.
- o HHS has taken steps to promote private sector participation in research and development of HIV-related products.
- o The Public Health Service has set in place a plan to implement many of the specific recommendations of your Commission.
- o The Department of State has begun ~~implementation of a three-year plan to enhance international prevention efforts.~~

effort
Unresolved Issues and Recommendations Your 10-point action plan directed implementation or further study of most of Commission recommendations. Some deferred issues have been resolved; a number will require attention from the next Administration. My recommendations for disposition of the unresolved issues are:

- o Management of HIV Issues Points 5 and 6 of your 10-point plan addressed most of the Commission's recommendations aimed at improving adequacy and coordination of Federal management and resource allocation. A proposal on ~~the~~ unresolved organizational issues is included at Tab B. *(A)* I recommend that completion of action on this issue be addressed by the upcoming Administration.

- o Confidentiality Many public health officials believe that lack of adequate and consistent privacy protection for HIV-infected individuals is inhibiting the attack on this major epidemic. An option for legislative action is discussed at Tab B. This issue requires further study by the Bush Administration.
- o Discrimination Discrimination remains an issue of legal, economic and political concern. Since my last report to you, the Attorney General has ruled that asymptomatic carriers of HIV infection are protected under the Federal Rehabilitation Act if they are linked to agencies which receive Federal funds. In addition, States have been strengthening their protections; however significant gaps remain. The Department of Justice is reviewing options for additional Federal action.
- o Nursing Shortage Planning is necessary for expansion of our health care system which, by 1992, will be caring for 172,000 people with AIDS. The shortage of nurses has already affected the ability of our medical system to care for sick people in general. The Secretary of HHS ~~has a plan to address~~ recommendations he received in December from the Nursing Commission he appointed. I recommend that HHS continue to take the lead on this issue.
- o Financing of Health Care Per your request, HHS has begun a one year study of the health care financing system; the report will be available in September 1989. I recommend that the next Administration continue to monitor this important study.
- o National Commission on AIDS The Health Omnibus Programs Extension Act of 1988 (P.L.100-607) establishes a two-year National Commission to promote development of a consensus on AIDS policy, make recommendations regarding a consistent policy and monitor implementation of your HIV Commission's report. Congress plans to defer appointment of their Commissioners until the next Session. I recommend that the Presidential appointees to this Commission be named by the new Administration.

RECOMMENDATION The AIDS/HIV crisis will continue through the next Administration. Presidential leadership has been the key element in the extensive gains thus far. We are making every effort to capitalize on the foundation laid by your Administration in stopping the spread of the HIV disease.

I recommend that the full record of the AIDS/HIV effort, along with an explanation of the unresolved issues, be passed on to the new President and his health advisors so that they will have no loss of momentum in dealing with this health crisis.

_____ approve

_____ disapprove

ATTACHMENT B

Explanation of Transition Contacts

To facilitate an orderly transition, the Transition's information-gathering and review process is divided into two phases.

The first phase is the Transition Office Contact ("TOC") phase. The TOCs are a group of people designated to make the initial contacts with a Department or agency. TOCs are primarily arranged according to department and area of specialization. For example, the TOC group responsible for the Department of Agriculture is also responsible for the Farm Credit Administration. For efficiency's sake, a TOC leader is designated to coordinate transition efforts.

Keeping with the requirements of law, the Transition sends a TOC member's name, along with a disclosure of funding document and a signed copy of the transition standards of conduct, to the White House, and then to the General Services Administration. The White House in turn notifies the particular Department or agency of the identity of the person or persons authorized to serve as TOCs.

It should be noted that TOCs have not been designated for all agencies and Departments and that a person can serve on more than one TOC team.

After a person is named to a TOC team, he/she begins to gather and analyze the information provided by the particular department (in books and briefings) and then prepares material to be used in the second phase of the Transition process by the Secretary-designee.

That second phase is called the Transition Team phase. Transition Teams are more senior and ideally are headed by the Secretary-designee for the particular department. The Transition Team's role is twofold: to continue the information-gathering process, as well as to facilitate hands-on administration of the department after the Inauguration and Senate confirmation. The Transition Teams are subject to the same reporting requirements as the TOCs.

Finally, there is a group of approximately 40 individuals at the President-elect's transition office who are not TOC or Team members but who because of their particular responsibilities may need to discuss a range of issues with appropriate staff at various departments and agencies. These individuals are listed in Attachment A of this memorandum.

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THE WHITE HOUSE
WASHINGTON

December 9, 1988

MEMORANDUM FOR CABINET AND AGENCY HEADS

FROM: KENNETH M. DUBERSTEIN *K. Duberstein*
SUBJECT: Identification of Members of the President-elect's
Staff Authorized to Communicate with Departments
and Agencies

The Office of the President-elect has selected certain of its employees and volunteers to assume responsibilities (such as for Presidential personnel decisions, for Congressional affairs, and for providing legal and policy advice to the President-elect) which require that they contact appropriate staff at the Departments and agencies from time to time to discuss a range of issues. The names of those employees and volunteers appear on the attached list.

In accordance with the President's Directive of November 18, 1988 and the Policy Statement Concerning Information Disclosure to Transition Personnel forwarded earlier, I am verifying that the individuals whose names appear on the attached list have been authorized to communicate with all Departments and agencies. I am also confirming that those individuals have provided statements concerning their most recent employment and sources of funding and copies of their written agreements to comply with the President-elect's standards of conduct.

Please understand that these individuals are not designated transition office contacts for your Department and agency, but are legitimate members of the President-elect's transition staff who should be provided with access to public information as defined in the Policy Statement Concerning Information Disclosure. Unless I inform you otherwise and provide you with copies of their Source of Funding Statements and Transition Standards of Conduct Agreements, these individuals are not to be provided with access to non-public information.

Thank you for your assistance in this matter.

ATTACHMENT A: Certain Members of the Staff of the Office of the President-elect Authorized to Communicate with Departments and Agencies.

ATTACHMENT B: Explanation of Transition Contacts

ATTACHMENT A

Certain Members of the Staff of the Office of the President-elect Authorized to Communicate with Departments and Agencies

Co-Director's Office

Fred Bush	Mary Lukens
George Bush, Jr.	Kathleen Shanahan
Tom Collamore	John Sununu
Michael Farren	Diane Terpeluk
Craig Fuller	Bob Grady
Robert Teeter	

Public Liaison Office

Dave Demarest	Bobbie Kilberg
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Press Office

David Prosperi	Sheila Tate
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Office of the Vice President-elect

Fred Fielding	Daniel F. Evans, Jr.
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Transition Policy Office

Richard D. English	Martha Johnston
Austen Furse	Lehman Li
John Gardner	Jim Pinkerton
Lloyd Green	Peter Scott
Otto Wolff	Kate Moore
Marshall Breger	

Personnel Office

David Hansen	Ross Starek
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Legal Counsel's Office

Boyden Gray	John Schmitz
William Barr	Wendell Willkie
Richard Hauser	Sherrie Marshall

Chief of Staff Designee's Office

Ed Rogers

Congressional Affairs Office

Gary Andris	Steve Britt
Martha Johnston	Janet Mullins
Tom Scully	Mary Tinsley

December 23, 1988

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.
SUBJECT: Progress on 10-Point Action Plan on HIV/AIDS

Our knowledge of the Human Immunodeficiency Virus (HIV) and our response to the epidemic have come further faster than with any disease in history. However, the death toll continues to rise. The predicted consequences of this disease will place increasing demands on the Nation's health and science resources.

Status In June, you asked me to review the report of your Commission on the HIV Epidemic (The Watkins' Report). In this, my third and final report, I am pleased to state that most of the 354 Commission recommendations within Federal purview have been completed or will be implemented with FY 1989 funds. Additionally, Federal leadership will continue to stimulate action on most of the 243 recommendations that fall outside Federal jurisdiction.

Progress Progress since September on your 10-point plan is addressed at Tab A. Highlights include:

- o Legislation you signed in November includes the largest increase for drug abuse treatment to date.
- o Your 1990 budget contains a double-digit funding increase for HIV/AIDS activities of the Public Health Service and additional funding for other programs (e.g., medicaid).
- o The Food and Drug Administration has implemented a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o The Public Health Service has set in place a plan to implement many of the specific recommendations of your Commission.
- o The Department of State has begun a three-year plan to enhance international prevention activities.

Unresolved Issues and Recommendations Your 10-point action plan directs immediate implementation or further study of most of the Commission recommendations. Some deferred issues have been resolved; a number will require attention from the next Administration. My recommendations for disposition of the unresolved issues are:

- o Management of HIV Issues Points 5 and 6 of your 10-point plan address the Commission's recommendations on improving adequacy and coordination of Federal management and resource allocation. I am proposing to increase the influence of public health officials (Tab B). I recommend that this issue be addressed by the upcoming Administration.
- o Confidentiality Many public health officials believe that lack of adequate and consistent privacy protection for HIV-infected individuals is inhibiting the medical efforts. An option considered for legislative action is discussed at Tab C and should be considered by the Bush Administration.
- o Discrimination Discrimination remains an issue of legal, economic, and political concern. Since my last report to you, the Attorney General has ruled that asymptomatic carriers of HIV infection are protected under the Federal Rehabilitation Act if they are linked to agencies which receive Federal funds. In addition, states have been strengthening their protections; however significant gaps remain. The Department of Justice is reviewing options for additional Federal action.
- o Nursing Shortage Planning is necessary for expansion of our health care system which, by 1992, will be caring for 172,000 people with AIDS. The shortage of nurses is already affecting our general medical system. The Secretary of HHS is considering recommendations from his Nursing Commission. I recommend that HHS continue to take the lead on this issue.
- o Financing of Health Care Per your request, HHS has begun a one-year study of the health care financing system; the report is due in September 1989. I recommend that the next Administration continue to monitor this important study.
- o National Commission on AIDS The Health Omnibus Programs Extension Act of 1988 (P.L.100-607) establishes a two-year National Commission to make recommendations on AIDS policy and to monitor policy implementation. Congress plans to defer appointment of their commissioners until the next session. I recommend that the Presidential appointees to this Commission be named by the new Administration.

CONCLUSION The HIV/AIDS crisis will continue during through the next Administration. We are making every effort to capitalize on the foundation laid under your leadership in stopping the spread of HIV disease.

I plan to transmit a summary of the the HIV/AIDS effort, along with an explanation of the unresolved issues, to Vice President Bush and his advisors. The nation must not lose momentum in dealing with this health crisis.

(TAB B)

~~We are proposing~~
I am proposing to

o Management of HIV Issues Points 5 and 6 of your 10-point plan address the Commission's recommendations on improving adequacy and coordination of Federal management and resource allocation. ~~An organizational proposal to increase the influence of public health officials is at Tab A. I recommend that completion of action on this issue be addressed by the upcoming Administration.~~

o Confidentiality Many public health officials believe that lack of adequate and consistent privacy protection for HIV-infected individuals is inhibiting the ~~attack on this major epidemic~~. An option for legislative action is discussed at Tab A. ~~This issue requires further study by the Bush Administration.~~ *medical efforts* *discuss* *and should be considered*

o Discrimination Discrimination remains an issue of legal, economic, and political concern. Since my last report to you, the Attorney General has ruled that asymptomatic carriers of HIV infection are protected under the Federal Rehabilitation Act if they are linked to agencies which receive Federal funds. In addition, states have been strengthening their protections; however significant gaps remain. The Department of Justice is reviewing options for additional Federal action.

o Nursing Shortage Planning is necessary for expansion of our health care system which, by 1992, will be caring for 172,000 people with AIDS. The shortage of nurses is already affecting ~~the ability of our general medical system to care for sick people~~. The Secretary of HHS is considering recommendations ~~he received this month from the Nursing Commission, he appointed~~. I recommend that HHS continue to take the lead on this issue. *his*

o Financing of Health Care Per your request, HHS has begun a one-year study of the health care financing system; the report ~~will be available~~ in September 1989. I recommend that the next Administration continue to monitor this important study. *is due*

o National Commission on AIDS The Health Omnibus Programs Extension Act of 1988 (P.L.100-607) establishes a two-year National Commission to ~~study and~~ make recommendations on AIDS policy and to monitor policy implementation. Congress plans to defer appointment of their commissioners until the next session. I recommend that the Presidential appointees to this ~~important and highly visible~~ Commission be named by the new Administration.

CONCLUSION The HIV/AIDS crisis will continue ~~and in many ways worsen~~ *DURING* through the next Administration. We are making every effort to capitalize on the foundation laid by your Administration in stopping the spread of HIV disease. *under your leadership*

I plan to transmit a summary of the ~~history and accomplishments of~~ the HIV/AIDS effort, along with an explanation of the unresolved issues, to Vice President Bush and his advisors. ~~in the hope that the nation will not lose momentum in dealing with this health crisis.~~ *must*

either delete phrase or change through "during"

TABS A - options
B - Summary of Progress
C - Previous Report (September 1988)

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INFORMATION

DRAFT 12/14/88

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

In this my third and final

sketch

(the Watkins' report)

(B)

In June you asked me to review the report of your Commission on the Human Immunodeficiency Virus Epidemic (HIV) and make recommendations for its implementation. ^{HIV} ~~In this third and final report, I am pleased to report that much progress has been made.~~ A number of important issues, however, are still unresolved, and I herewith make additional recommendations to you for transmission to the next administration.

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~~Accomplishments and Status Since June 1988~~ The majority (62 percent) of the 354 Commission recommendations that fall within the Federal purview have already been completed or will be implemented with FY 1989 funds. Additionally, Federal leadership has been provided to stimulate implementation of many of the 243 recommendations that fall largely outside Federal jurisdiction.

Details of the Federal response to your 10-Point Action Plan are at Tab A. Highlights:

- o FDA has implemented a process which will speed approval of therapies to treat life-threatening illness such as AIDS.
- o Legislation you signed in November put in place the largest increase for drug abuse treatment ever.
- o The Public Health Service has set in place a plan that includes many of the more specific recommendations of your Commission.
- o The Department of State has begun implementation of a three-year plan to enhance international efforts to control the spread of HIV infection.
- o HHS has taken a number of steps to promote private sector participation in research and development of HIV-related products.

DRAFT

DRAFT -- 12/19/88 (11:00am)

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

Our understanding of the Human Immunodeficiency Virus (HIV) and our response to the epidemic have come further faster than with any disease in history. Despite all our efforts, however, the death toll continues to rise and the predicted consequences of this "killer disease" will put an increasingly severe strain on future health and science resources.

In June you asked me to review the report of your Commission on the HIV Epidemic (the Watkins' Report) and make recommendations for its implementation.

Status In this my third and final report, I am pleased to report that the majority of the 354 Commission recommendations that fall within the Federal purview have already been completed or will be implemented with FY 1989 funds. Additionally, Federal leadership has been provided to stimulate implementation of most of the 243 recommendations that fall outside Federal jurisdiction.

Progress Progress on your 10-point plan since my September report (Tab C) is addressed at Tab B. Highlights of that progress are:

- o Legislation you signed in November put in place the largest increase for drug abuse treatment ever.
- o FDA has implemented a process which will speed approval of therapies to treat life-threatening illness such as AIDS.
- o HHS has taken a number of steps to promote private sector participation in research and development of HIV-related products.
- o The Public Health Service has set in place a plan that includes many of the more specific recommendations of your Commission.
- o The Department of State has begun implementation of a three-year plan to enhance international efforts to control the spread of HIV infection.

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Unresolved Issues and Recommendations Your 10-point action plan directed implementation or further study of most of the recommendations of the HIV Commission. Some of the deferred issues have been resolved, but a number will require attention from the next Administration. These unresolved issues and my recommendations for their disposition are as follows:

- o Management of HIV Issues Points 5 and 6 of your 10-point plan addressed many, but not all, of the Commission's recommendations which were aimed at improving the adequacy and coordination of Federal management and resource allocation. A proposal on the unresolved portion of this issue is included at Tab B. I recommend that further action on this issue be left to the next Administration.
- o Confidentiality Many Federal and non-Federal public health officials believe that lack of adequate and consistent privacy protection for HIV-infected individuals is inhibiting the attack on this major epidemic. An option for action is discussed at Tab B. This issue needs further study and, I believe, is best left for the next Administration.
- o Discrimination Discrimination remains an issue of legal, economic and political concern. Since my last report to you, the Attorney General has ruled that asymptomatic carriers of HIV infection are protected under the Federal Rehabilitation Act if they are linked to agencies which receive Federal funds. This act covers a broad range of situations and States have been strengthening their protections, however significant gaps in protection remain. The Department of Justice is presently reviewing options for additional Federal action.
- o Nursing Shortage We must plan for expansion of our health care system which, by 1992, will be caring for 172,000 people with AIDS. A critical issue is the shortage of nurses which is already affected the ability of our medical system to care for sick people in general. The Secretary of HHS has set in motion a plan for assessment and implementation of recommendations he received in December from the Nursing Commission he appointed. I recommend that we await guidance from HHS on this issue.
- o Financing of Health Care Per your request, HHS has begun a one year study of the health care financing system; the report will be available in September 1989. I recommend that the next Administration continue to monitor this important study.
- o National Commission on AIDS The Health Omnibus Programs Extension of 1988 (P.L.100-607) establishes a two-year National Commission to promote the development of a consensus on AIDS policy, make recommendations regarding a consistent policy and monitor the implementation of the recommendations of your HIV Commission. Congress plans to defer appointment of their Commissioners until the next Session. I recommend that the Presidential appointees to this Commission be named by the next Administration.

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TAB A

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DRAFT -- 12/19/88

Organizational Issues Raised by the Presidential Commission on the HIV Epidemic

Issue The HIV Commission focused heavily on resource and management issues, such as: overall budget levels; adequate personnel, space and equipment; grant and contracting policies; and communication between government agencies. Your 10-point plan responded to many of the direct and immediate needs, however, a number of larger organizational considerations were appropriately deferred for consideration by the next Administration.

The Department of Health and Human Services bears the bulk of the responsibility for the Federal response to the HIV epidemic and receives most of the HIV budget. Understandably, many of the management and organizational questions are targeted at HHS and raise issues of micro-management and unresponsiveness to requests from science and health officials. Improvements in these areas should be possible without eliminating or by-passing the important oversight and management functions of the current system. It is my belief that changes should be made at HHS to facilitate more direct input from public health officials to the Secretary, OMB and the White House.

Recommendation I recommend to the next Administration an examination of ways to strengthen the lead agency position of HHS, including revision of its current structure, so that line health officials carry a more senior status in the Department.

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**Federal Privacy Legislation Regarding
Health Records of HIV Infected Individuals**

Issue The HIV Commission recommended Federal law to assure privacy and confidentiality of medical information obtained during testing, counseling and treatment encounters. Such assurances are particularly important to people with illnesses such as AIDS which are surrounded with stigma. Without adequate assurances it is believed that many HIV-infected individuals will not come forward for testing and early counseling and treatment. A balance must be reached, however, between privacy/confidentiality and a genuine public health "need to know."

Concerns exist about casual or inadvertent disclosure to a landlord, employer, or neighbor which could result in discrimination, loss of job, denial of services, ostracism, etc. and about legally-compelled disclosure in private litigation or in governmental proceedings may result in undesired consequences for the individual.

Background The 100th Congress considered HIV confidentiality legislation similar to that recommended by the Commission. None was enacted, but Congress did direct the Secretary of HHS to study existing State laws governing confidentiality of HIV-related information (due May 1989).

In general, the key legal enactments on use and disclosure of medical information are State laws. An increasing number of States have strengthened their confidentiality protections, some specifically for HIV-related data. The strength and breadth of these protections vary widely, however.

Existing Federal confidentiality law for drug and alcohol abuse patient information sets a precedent for Federal action in stigmatized public health conditions. Federal action on confidentiality of HIV-related records would provide reassurance that should encourage more people to be tested. Further, such a law would provide uniformity across the United States and would protect the integrity of HIV records.

Recommendation If the HHS survey of States confidentiality laws does not show substantial progress by States in offering better protection for HIV-related records, Federal or model legislation should be promoted.

TAB B

DRAFT 12/19/88 (11:00am)

THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

DRAFT

Second Progress Report

December , 1988

DRAFT

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.**

Point 1 responds to 129 recommendations of the HIV Commission.

- o Consensus Conferences Key state and local public health officials met November 28-29 at the HHS "Health Summit" to discuss the next steps to reduce the spread of HIV infection. Issues discussed included outreach programs to get IV drug users in treatment, management of public health agencies, testing issues such as counseling, reporting and partner notification, and health care worker safety and education. This was the first in a series of ten conferences which HHS will sponsor throughout 1989.
- o Issue Many State and local officials expressed reservations in implementing stronger public health measures in the absence of stronger privacy and anti-discrimination protections for HIV infected persons. The Health Summit recommended that the Federal government take the lead on this issue. The importance of confidentiality of health information and recommendations for its resolution are addressed in Tab A.

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.**

Point 2 responds to 19 recommendations of the Presidential HIV Commission.

- o U.S. blood supply is among the safest in the world, however its safety must continually be monitored and improved.
- o HHS has begun drafting regulations to mandate notification of transfusion recipients through "look back" programs.
- o Within the next few months, FDA will send to all blood establishments a document consolidating all of the HIV and blood specific recommendations.
- o The Social Security Administration is establishing (date ???) a Blood Donor Locator Service to aid notification and identification of HIV infected donors.
- o FDA has begun its enhanced inspection program to improve laboratory quality of HIV antibody testing.

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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.**

Point 3 responds to 50 recommendations of the HIV Commission.

- o Your goal of a drug-free America has been aided by passage of the Omnibus Drug Act of 1988, however strong efforts must continue and be updated by the next Administration.
- o The "drug bill" contained the single largest expansion of funding for drug abuse treatment and authorized the following activities which are being implemented:
 - Prevention and Treatment of Intravenous (IV) Drug Abuse Funds will go to States for development, implementation and operation of IV drug abuse treatment programs, training of drug abuse counselors, and outreach activities to bring persons into treatment.
 - Expansion of Demonstration Programs 3-year demonstration projects will be funded to: (1) study efficacy of providing drug treatment and vocational training in exchange for public service; (2) conduct outreach activities to IV drug users to prevent the spread of HIV, and (3) provide drug treatment services to pregnant and postpartum women, and their infants.

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

Point 4 responds to 67 recommendations of the HIV Commission.

- o Accelerate Approval Process Since the September report, FDA has implemented procedures to speed up the development, evaluation, and marketing of products for AIDS.
- o Incentives for Drug Development HHS is exploring 2 ways to improve Federal incentives to the private sector for developing HIV-related products:
 - a legislative proposal to assure that the important research and development (R&D) incentives under the Orphan Drug Act (i.e. market exclusivity, R&D, tax deductions) will be available after the number of AIDS patients exceeds the 200,000 ceiling applied by the act; and
 - negotiation of equitable pricing assurances in cooperative R&D agreements when exclusive licenses are granted to industrial partners for HIV-related products.
- o Liability Issues HHS has found no indication that promising research has been delayed or foregone in the public or private sector because of fears about liability. HHS has, however, identified a series of options for continued attention to possible liability problems.

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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.**

Point 5 responds to 41 recommendations of the HIV Commission.

- o Construction of NIH and CDC the office/laboratory facilities will begin in FY 1989.
- o Unresolved Issue The recruitment and retention of science personnel remains a problem for HHS. Several sources, including the Commission on Executive, Legislative and Judicial Salaries, have recommended salary increases to make the Federal government more competitive.

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.**

- o FY 1990 funding for HIV will include a double digit increase for PHS and additional funding will be available from other sources (i.e. Medicaid, Social Security, the Veterans Administration, DOD, Medicare). In addition, FTE allocations have been made above HHS' requested level.

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.**

Point 7 responds to 68 recommendations of the HIV Commission.

- o An estimated 172,000 people with AIDS will be alive in 1992. The HIV epidemic is also spreading rapidly in populations unable to pay for their medical care. Ensuring availability of an adequate number of health care workers and the financial burden of medical care (\$5 to \$13 billion in 1992) are issues which will need much consideration.
- o Risk Pools The Secretary of HHS is sending an advisory letter to State Governors and legislative leaders (January 1989) to encourage replication of risk pools for the medically uninsurable. The letter also suggests sources of technical information and assistance.
- o Infants, Children and Adolescents Within the next year, HHS will implement many of the recommended actions of the Secretary's Task Force on Pediatric HIV Infection Report to respond to the needs of infants, children and adolescents.

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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.**

Point 8 responds to 41 recommendations of the HIV Commission.

- o The following achievements are anticipated in the next 3 years from the State Department's international plan:
 - The 70 countries with which the U.S. is working will have implemented HIV public information campaigns;
 - All of these countries will have implemented, and most will have evaluated, educational programs aimed at the reduction of high risk behavior;
 - All of these countries will have implemented blood transfusion screening programs for HIV;
 - New HIV diagnostics appropriate for use in developing countries will have been field tested and will be in common use;
 - Vaccine field trial sites will have been established;
 - Better estimates of the number of HIV infected individuals in developing countries will have been completed.

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

- o PHS has completed a strategy for the Nation's response to AIDS. The strategy includes goals and objectives for the major topics raised by your HIV commission. The goals will cross referenced with the recommendations of your Commission on the HIV Epidemic. PHS will track progress on the goals beginning in January 1989.

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.**

Point 10 responds to 89 recommendations of the HIV Commission.

- o Attention to antidiscrimination is needed to ensure that all sectors of society respond equitably and compassionately to those with HIV infection. A discussion of the related issue of privacy/confidentiality is included at Tab A.

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TAB

C

A COPY OF THE SEPTEMBER
PROGRESS 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

Three-Year Plan The following achievements are anticipated:

- o All (70 ?) countries with which the U.S. is working will have implemented HIV public information campaigns;
- o All of these countries will also have implemented, and most will have evaluated, targeted educational programs aimed at the reduction of high risk behavior;
- o All of these countries will have implemented blood transfusion screening programs for HIV;
- o New HIV diagnostics appropriate for developing countries will have been field tested and will be in common use;
- o Vaccine field trial sites will have been established;
- o A mathematical model to better estimate the number of HIV infected individuals in developing countries will have been completed.

Financial Support In FY 1989, Congress appropriated \$25.5 million for the World Health Organization's Global Programme on AIDS (GPA). This increases the U.S. share of the GPA FY89 budget to 72 percent.

Unresolved Issues

Implementation of the plan will be a continuing effort.

DRAFT -- 12/16/88

INFORMATION

MEMORANDUM FOR THE PRESIDENT

DRAFT

FROM: DONALD IAN MACDONALD, M.D.

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

In this third and final report on progress made in fighting the Human Immunodeficiency Virus (HIV) epidemic, I am pleased to report that much progress has been made.

Status The majority (64 percent) of the 354 Commission recommendations that fall within the Federal purview have already been completed or will be implemented with FY 1989 funds. Additionally, Federal leadership has been provided to stimulate implementation of many of the 243 recommendations that fall largely outside Federal jurisdiction.

Several general areas will require additional attention over the years to come and these, with recommendations, are outlined in Tab A. A number of issues within your 10-point plan are unresolved or incomplete and I have noted those along with details of the Federal response to your 10-Point Action Plan are at Tab B. Finally, I have provided additional recommendations for you for possible transmission to the incoming Administration.
(TAB C)

Highlights of Accomplishments in the 10-Point Plan:

- o FDA has implemented a process which will speed approval of therapies to treat life-threatening illness such as AIDS.
- o Legislation you signed in November put in place the largest increase for drug abuse treatment ever.
- o The Public Health Service has set in place a plan that includes many of the more specific recommendations of your Commission.
- o The Department of State has begun implementation of a three-year plan to enhance international efforts to control the spread of HIV infection.
- o HHS has taken a number of steps to promote private sector participation in research and development of HIV-related products.

DRAFT

Tab A

DRAFT

ATTACHMENT A

Unresolved Issues and Recommendations A process has been set in motion to deal with the unresolved issues. The principal issues involved and my recommendations are, briefly, as follows:

- o Management of HIV Issues There are larger organizational issues to consider to alleviate the Government's perceived inability to respond effectively and expeditiously to health emergencies. A proposal on this issue is included at Tab B. I recommend that further action on this issue be left to the next Administration.
- o Confidentiality Many State and local officials have expressed reservations in implementing stronger public health measures in the absence of stronger privacy and anti-discrimination protections for HIV infected persons. An option for action is discussed at Tab B. This issue needs further study and, I believe, is best left for the next Administration.
- o Discrimination Discrimination against HIV-infected individuals is still of concern. The Federal Rehabilitation Act covers a broad range of situations and States have been strengthening their protections, however gaps in protection remain. The Department of Justice is reviewing options for additional Federal action.
- o Adequacy of Health Care Workers It is estimated that there may be 172,000 people with AIDS alive in 1992 who will need medical care. This increased burden on our health care system could have a significant impact on the ability of our medical system to care for sick people in general. The Secretary of HHS is assessing the situation and will be making recommendations. I recommend that we defer to HHS on resolution of this issue.
- o Financing of Health Care HHS has begun a one year study of the health care financing system; the report will be available in September 1989. I recommend we leave this issue to HHS for resolution but that the next Administration continue to monitor the study.
- o National Commission on AIDS The Health Omnibus Programs Extension of 1988 (P.L.100-607) establishes a two-year National Commission to promote the development of a consensus on AIDS policy, make recommendations regarding a consistent policy and monitor the implementation of the recommendations of your HIV Commission. Congress plans to defer appointment of their Commissioners until the next Session. I recommend that the three Presidential appointees to this Commission be named by the next Administration.

DRAFT

Tab B

DRAFT 12/16/88

THE PRESIDENT'S 10-POINT ACTION PLAN
AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Second Progress Report

December , 1988

DRAFT

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.**

- o Consensus Conferences Key state and local public health officials gathered November 28-29 at the HHS "Health Summit" to discuss the next steps in addressing public health measures to reduce the spread of HIV infection. Measures addressed included reaching the IV drug users, management of public health control programs, testing issues such as counseling, reporting and partner notification, and health care worker safety and education. This was the first in a series of ten conferences which HHS will sponsor throughout 1989.

New Issue Many State and local officials have expressed reservations in implementing stronger public health measures in the absence of stronger privacy and anti-discrimination protections for HIV infected persons. The Health Summit recommended that the Federal government take the lead on this issue. The importance of privacy/confidentiality of health information and recommendations for its resolution are addressed in Tab B.

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.**

- o HHS has begun drafting proposed regulations for making mandatory efforts for notification of transfusion recipients through "look back" programs.
- o Within the next few months, FDA will send to all blood establishments a document consolidating all of the HIV and blood specific recommendations.
- o The Social Security Administration will establish a Blood Donor Locator Service to facilitate notification and identification of HIV infected donors.
- o FDA has begun its enhanced inspection program to improve laboratory quality of HIV antibody testing.

Uncompleted Issue The U.S. blood supply is among the safest in the world, however its safety must continually be monitored and improved.

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DRAFT

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.

- o The Omnibus Drug Initiative Act of 1988 (P.L.100-680) expanded funding for drug abuse treatment and authorized the following activities which are being implemented:
 - Prevention and Treatment of Intravenous (IV) Drug Abuse States use of funds for development, implementation and operation of IV drug abuse treatment programs, training of drug abuse counselors, and outreach activities to bring persons into treatment.
 - Expansion of Demonstration Programs 3-year demonstration projects authorized to: (1) determine long-term efficacy of programs providing drug abuse treatment and vocational training in exchange for public service; (2) conduct outreach activities to IV drug users to prevent transmission of HIV, and (3) provide drug abuse treatment services to pregnant women, postpartum women, and their infants.

Uncompleted Issue Your goal of a drug-free America has facilitated progress in this area but efforts must remain vigilant and will need further consideration by the next Administration.

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

- o Accelerate Approval Process Since the September report, FDA has implemented procedures which will facilitate the development, evaluation, and marketing of products for AIDS.
- o Incentives for Drug Development HHS is exploring 2 ways to improve Federal incentives to the private sector for developing HIV-related products: a legislative proposal to amend the Orphan Drug Act so that those incentives provided regardless of the number of AIDS patients (Act places a ceiling of 200,000); and PHS negotiating equitable pricing assurances in cooperative research and development agreements when exclusive licenses are granted to industry for HIV-related products.
- o Liability Issues HHS has found no indication that promising research has been delayed or foregone in the public or private sector because of fears about liability. HHS has, however, identified a series of options for addressing problems of liability, should they arise.

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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 Issue The recruitment and retention of science personnel remains a problem for HHS. Several sources have recommended salary increases to make the Federal government more competitive. Further efforts are needed to attract such personnel.

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.**

- o FY 1990 funding for HIV will include a double digit increase for PHS and additional funding will be available from other sources (i.e. Medicaid, Social Security, the Veterans Administration, DOD, Medicare). In addition, FTE allocations have been made above HHS'proposed level.

Unresolved Issues HHS has been unable to bargain effectively with OMB on the HIV budget to ensure expeditious funding by Congress. Possible ways to facilitate this are suggested at Tab B.

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.**

- o Risk Pools The Secretary of HHS is sending an advisory letter to State Governors and legislative leaders (January 1989) to encourage replication of risk pools for the medically uninsurable. The letter also suggests sources of technical information and assistance.
- o Infants, Children and Adolescents Within the next year, HHS will implement many of the recommended actions of the Secretary's Task Force on Pediatric HIV Infection Report to respond to the needs of infants, children and adolescents.

Unresolved Issues Current trends suggest that 172,000 people with AIDS will be alive in 1992 and that the epidemic is spreading rapidly in populations unable to pay for their medical care. Ensuring availability of an adequate number of health care workers and the burden payment of medical care are issues which will need much consideration.

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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.**
 - o The following achievements are anticipated in the next 3 years from the State Department's international plan:
 - The 70 countries with which the U.S. is working will have implemented HIV public information campaigns;
 - All of these countries will have implemented, and most will have evaluated, educational programs aimed at the reduction of high risk behavior;
 - All of these countries will have implemented blood transfusion screening programs for HIV;
 - New HIV diagnostics appropriate for use in developing countries will have been field tested and will be in common use;
 - Vaccine field trial sites will have been established;
 - Better estimates of the number of HIV infected individuals in developing countries will have been completed.

9. **Requires the PHS to update the 1986 Public Health Service plan for combatting HIV infection.**
 - o PHS has completed a strategy for the Nation's response to AIDS. The strategy includes goals and objectives for the major topics raised by your HIV commission. The goals will cross referenced with the recommendations of your Commission on the HIV Epidemic. PHS will track progress on the goals beginning in January 1989.

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.**

Unresolved Issue Further attention to antidiscrimination is needed to ensure that all sectors of society respond equitably and compassionately to those with HIV infection. A more thorough discussion of this issue is included at Tab B.

DRAFT

Table

DRAFT

**Organizational Issues Raised by the
Presidential Commission on the HIV Epidemic**

Issue The Federal Government has been frequently criticized for not responding thoroughly and expeditiously to public health crisis. The HIV Commission, for example, identified the problem in terms of resource and management issues, such as: overall budget levels; adequate personnel, space and equipment; grant and contracting policies; and communication between government agencies. The President's 10-point plan has responded to many of the direct and immediate needs, however, the larger organizational considerations have been left for the President and the President-elect to consider in a more studied fashion.

The Department of Health and Human Services bears the bulk of the responsibility for the Federal response to the HIV epidemic and receives the most of the HIV budget. Therefore, many of the management and organization questions should be targetted at HHS and answered in terms what improvements are necessary to strengthen the Nation's response to the HIV epidemic.

The public health functions of HHS need to be more visible and more capable of commanding attention from both the public and the resource and management agencies. Dramatic improvements in this area may not be possible without more direct reporting from line health officials to the Secretary, OMB and the White House. More direct authority could be granted without impuning the integrity of the system and retain the day-to-day decision-making authority of the Department.

Recommendation I recommend this be defered to the incoming Administration and that they examine ways of strengthening the lead agency position of HHS, including revising its current structure so that line health officials carry a more senior status in the Department.

DRAFT

**Federal Privacy Legislation Regarding
Health Records of HIV Infected Individuals**

Issue Privacy/confidentiality of information is important, especially in stigmatized situations. In public health emergencies, however, a balance must be reached between privacy and a genuine "need to know." This is of particular significance with HIV-infected individuals because of the critical nature of the disease and since the beginning of the epidemic, the confidentiality of personally-identifiable records about AIDS patients and HIV-positive individuals has been of major concern.

The issue, however, is not the behavior but the disease. We do not want to stigmatize individuals infected with HIV, regardless of their behavior. The concern is that casual or inadvertent disclosure to a landlord, employer, or neighbor could result in discrimination, loss of job, denial of services, ostracism, etc. and that legally-compelled disclosure in private litigation or in governmental proceedings may result in undesired consequences for the individual.

Background The 100th Congress considered HIV confidentiality legislation similar to that recommended by the Commission, but none was enacted. Congress did, however, direct the Secretary of HHS to study existing State laws governing confidentiality of HIV-related information (due May 1989).

In general, the key legal enactments on use and disclosure of medical information are State laws. An increasing number of States have strengthened their confidentiality protections, some specifically for HIV-related data. The strength and breadth of these protections vary widely, however.

There is precedent for Federal action in certain public health cases; the existing Federal confidentiality law for drug and alcohol abuse patient information is such a case. Federal action on confidentiality of HIV-related records would provide the reassurance needed by those concerned and might encourage more people to be tested. Further, such a law would provide uniformity across the United States and would protect the integrity of HIV records.

Recommendation If the HHS survey of States confidentiality laws does not show substantial progress by States in offering better protection for HIV-related records, Federal legislation should be promoted.

- o Management of HIV Issues Points 5 and 6 of your 10-point plan address the Commission's recommendations on improving adequacy and coordination of Federal management and resource allocation. I am proposing to increase the influence of public health officials (Tab B). I recommend that this issue be addressed by the upcoming Administration.
- o Confidentiality Many public health officials believe that lack of adequate and consistent privacy protection for HIV-infected individuals is inhibiting the medical efforts. An option considered for legislative action is discussed at Tab C and should be considered by the Bush Administration.
- o Discrimination Discrimination remains an issue of legal, economic, and political concern. Since my last report to you, the Attorney General has ruled that asymptomatic carriers of HIV infection are protected under the Federal Rehabilitation Act if they are linked to agencies which receive Federal funds. In addition, states have been strengthening their protections; however significant gaps remain. The Department of Justice is reviewing options for additional Federal action.
- o Nursing Shortage Planning is necessary for expansion of our health care system which, by 1992, will be caring for 172,000 people with AIDS. The shortage of nurses is already affecting our general medical system. The Secretary of HHS is considering recommendations from his Nursing Commission. I recommend that HHS continue to take the lead on this issue.
- o Financing of Health Care Per your request, HHS has begun a one-year study of the health care financing system; the report is due in September 1989. I recommend that the next Administration continue to monitor this important study.
- o National Commission on AIDS The Health Omnibus Programs Extension Act of 1988 (P.L. 100-607) establishes a two-year National Commission to make recommendations on AIDS policy and to monitor policy implementation. Congress plans to defer appointment of their commissioners until the next session. I recommend that the Presidential appointees to this Commission be named by the new Administration.

CONCLUSION The HIV/AIDS crisis will continue during through the next Administration. We are making every effort to capitalize on the foundation laid under your leadership in stopping the spread of HIV disease.

I plan to transmit a summary of the the HIV/AIDS effort, along with an explanation of the unresolved issues, to Vice President Bush and his advisors. The Nation must not lose momentum in dealing with this health crisis.

THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Second Progress Report

December 23, 1988

TAB A

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.**

Point 1 responds to 129 recommendations of the HIV Commission.

- o Consensus Conferences Key state and local public health officials met November 28-29 at the HHS "Health Summit" to discuss the next steps to reduce the spread of HIV infection. Issues discussed included outreach programs to get IV drug users in treatment, management of public health agencies, testing issues such as counseling, reporting and partner notification, and health care worker safety and education. This was the first in a series of ten conferences which HHS will sponsor throughout 1989.
- o Issue Many State and local officials expressed reservations in implementing stronger public health measures in the absence of stronger privacy and anti-discrimination protections for HIV infected persons. The Health Summit recommended that the Federal government take the lead on this issue. The importance of confidentiality of health information and recommendations for its resolution are addressed at Tab C.

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.**

Point 2 responds to 19 recommendations of the Presidential HIV Commission.

- o U.S. blood supply is among the safest in the world, however its safety must continually be monitored and improved.
- o HHS has begun drafting regulations to mandate notification of transfusion recipients through "look back" programs.
- o Within the next few months, FDA will send to all blood establishments a document consolidating all of the HIV and blood specific recommendations.
- o The Social Security Administration is establishing a Blood Donor Locator Service to aid notification and identification of HIV infected donors.
- o FDA has begun its enhanced inspection program to improve laboratory quality of HIV antibody testing.

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.**

Point 3 responds to 50 recommendations of the HIV Commission.

- o Your goal of a drug-free America has been aided by passage of the Omnibus Drug Act of 1988, however strong efforts must continue and be updated by the next Administration.
- o The "drug bill" contained the single largest expansion of funding for drug abuse treatment and authorized the following activities which are being implemented:
 - Prevention and Treatment of Intravenous (IV) Drug Abuse Funds will go to States for development, implementation and operation of IV drug abuse treatment programs, training of drug abuse counselors, and outreach activities to bring persons into treatment.
 - Expansion of Demonstration Programs 3-year demonstration projects will be funded to: (1) study efficacy of providing drug treatment and vocational training in exchange for public service; (2) conduct outreach activities to IV drug users to prevent the spread of HIV, and (3) provide drug treatment services to pregnant and postpartum women, and their infants.

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

Point 4 responds to 67 recommendations of the HIV Commission.

- o Accelerate Approval Process Since the September report, FDA has implemented procedures to speed up the development, evaluation, and marketing of products for AIDS.
- o Incentives for Drug Development HHS is exploring 2 ways to improve Federal incentives to the private sector for developing HIV-related products:
 - a legislative proposal to assure that the important research and development (R&D) incentives under the Orphan Drug Act (i.e. market exclusivity, R&D, tax deductions) will be available after the number of AIDS patients exceeds the 200,000 ceiling applied by the act; and
 - negotiation of equitable pricing assurances in cooperative R&D agreements when exclusive licenses are granted to industrial partners for HIV-related products.
- o Liability Issues HHS has found no indication that promising research has been delayed or foregone in the public or private sector because of fears about liability. HHS has, however, identified a series of options for continued attention to possible liability problems.

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.**

Point 5 responds to 41 recommendations of the HIV Commission.

- o Construction of NIH and CDC the office/laboratory facilities will begin in FY 1989.
- o Unresolved Issue The recruitment and retention of science personnel remains a problem for HHS. Several sources, including the Commission on Executive, Legislative and Judicial Salaries, have recommended salary increases to make the Federal government more competitive.

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.**

- o FY 1990 funding for HIV will include a double digit increase for PHS and additional funding will be available from other sources (i.e. Medicaid, Social Security, the Veterans Administration, DOD, Medicare). In addition, FTE allocations have been made above HHS' requested level.

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.**

Point 7 responds to 68 recommendations of the HIV Commission.

- o An estimated 172,000 people with AIDS will be alive in 1992. The HIV epidemic is also spreading rapidly in populations unable to pay for their medical care. Ensuring availability of an adequate number of health care workers and the financial burden of medical care (\$5 to \$13 billion in 1992) are issues which will need much consideration.
- o Risk Pools The Secretary of HHS is sending an advisory letter to State Governors and legislative leaders (January 1989) to encourage replication of risk pools for the medically uninsurable. The letter also suggests sources of technical information and assistance.
- o Infants, Children and Adolescents Within the next year, HHS will implement many of the recommended actions of the Secretary's Task Force on Pediatric HIV Infection Report to respond to the needs of infants, children and adolescents.

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.**

Point 8 responds to 41 recommendations of the HIV Commission.

- o The following achievements are anticipated in the next 3 years from the State Department's international plan:
 - The 70 countries with which the U.S. is working will have implemented HIV public information campaigns;
 - All of these countries will have implemented, and most will have evaluated, educational programs aimed at the reduction of high risk behavior;
 - All of these countries will have implemented blood transfusion screening programs for HIV;
 - New HIV diagnostics appropriate for use in developing countries will have been field tested and will be in common use;
 - Vaccine field trial sites will have been established;
 - Better estimates of the number of HIV infected individuals in developing countries will have been completed.

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

- o PHS has completed a strategy for the Nation's response to AIDS. The strategy includes goals and objectives for the major topics raised by your HIV commission. The goals will cross referenced with the recommendations of your Commission on the HIV Epidemic. PHS will track progress on the goals beginning in January 1989.

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.**

Point 10 responds to 89 recommendations of the HIV Commission.

- o Attention to anti-discrimination is needed to ensure that all sectors of society respond equitably and compassionately to those with HIV infection. A discussion of the related issue of privacy/confidentiality is included at Tab C.

**Organizational Issues Raised by the
Presidential Commission on the HIV Epidemic**

Issue The HIV Commission focused heavily on resource and management issues, such as: overall budget levels; adequate personnel, space and equipment; grant and contracting policies; and communication between government agencies. Your 10-point plan responded to many of the direct and immediate needs, however, a number of larger organizational considerations were appropriately deferred for consideration by the next Administration.

The Department of Health and Human Services bears the primary responsibility for the Federal response to the HIV epidemic and receives most of the HIV budget. Understandably, many of the management and organizational questions are targeted at HHS and raise issues of micro-management and unresponsiveness to requests from science and health officials. Improvements in these areas should be possible without eliminating or by-passing the important oversight and management functions of the current system.

Recommendation I recommend that the next Administration examine ways to strengthen the lead agency position of HHS. Revision of the HHS structure could include bringing HCFA/PHS under a senior health official. Also, changes should be made at HHS to facilitate more direct input from public health officials to the Secretary, OMB and the White House.

Federal Privacy Legislation Regarding Health Records of HIV Infected Individuals

Issue The HIV Commission recommended Federal law to assure privacy and confidentiality of medical information obtained during testing, counseling and treatment encounters. Such assurances are particularly important to people with illnesses such as AIDS which are surrounded with stigma. With adequate assurances I believe that HIV-infected individuals will come forward for testing and early counseling and treatment. A balance must be reached, however, between privacy/confidentiality and a genuine public health "need to know."

Concerns exist about casual or inadvertent disclosure to a landlord, employer, or neighbor which could result in discrimination, loss of job, denial of services, ostracism, etc. and about legally-compelled disclosure in private litigation or in governmental proceedings may result in undesired consequences for the individual.

Background The 100th Congress considered HIV confidentiality legislation similar to that recommended by the Commission. None was enacted, but Congress did direct the Secretary of HHS to study existing State laws governing confidentiality of HIV-related information (due May 1989).

In general, the key legal enactments on use and disclosure of medical information are State laws. An increasing number of States have strengthened their confidentiality protections, some specifically for HIV-related data. The strength and breadth of these protections vary widely, however.

Existing Federal confidentiality law for drug and alcohol abuse patient information sets a precedent for Federal action in stigmatized public health conditions. Federal action on confidentiality of HIV-related records would provide reassurance that should encourage more people to be tested. Further, such a law would provide uniformity across the United States and would protect the integrity of HIV records.

Recommendation If the HHS survey of State confidentiality laws does not show substantial progress by States in offering better protection for HIV-related records, Federal or model legislation should be promoted.

WHITE HOUSE STAFFING MEMORANDUM

DATE: 12/23/88 ACTION/CONCURRENCE/COMMENT DUE BY: C.O.B. 12/27/88

SUBJECT: PROGRESS ON 10-POINT ACTION PLAN ON HIV/AIDS

	ACTION FYI			ACTION FYI	
VICE PRESIDENT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	KRANOWITZ	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DUBERSTEIN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	MASENG	<input checked="" type="checkbox"/>	<input type="checkbox"/>
POWELL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RANGE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
WRIGHT - OMB	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RISQUE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
OGLESBY	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RYAN	<input type="checkbox"/>	<input type="checkbox"/>
CRIPPEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SPRINKEL	<input type="checkbox"/>	<input type="checkbox"/>
CULVAHOUSE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	TUCK	<input type="checkbox"/>	<input type="checkbox"/>
DAWSON	<input type="checkbox"/>	<input checked="" type="checkbox"/>	TUTTLE	<input type="checkbox"/>	<input type="checkbox"/>
DONATELLI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MACDONALD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
FITZWATER	<input type="checkbox"/>	<input checked="" type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HOBBS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HOOLEY	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

Please provide any comments/recommendations directly to my office by close of business on Tuesday, 12/27. Thanks.

RESPONSE:

THE WHITE HOUSE

WASHINGTON

December 23, 1988

100-11-113-10

MEMORANDUM FOR THE PRESIDENT

FROM:

DONALD IAN MACDONALD, M.D.

SUBJECT:

Progress on 10-Point Action Plan on HIV/AIDS

Our knowledge of the Human Immunodeficiency Virus (HIV) and our response to the epidemic have come further faster than with any disease in history. However, the death toll continues to rise. The predicted consequences of this disease will place increasing demands on the Nation's health and science resources.

Status In June, you asked me to review the report of your Commission on the HIV Epidemic (The Watkins' Report). In this, my third and final report, I am pleased to state that most of the 354 Commission recommendations within Federal purview have been completed or will be implemented with FY 1989 funds. Additionally, Federal leadership will continue to stimulate action on most of the 243 recommendations that fall outside Federal jurisdiction.

Progress Progress since September on your 10-point plan is addressed at Tab A. Highlights include:

- o Legislation you signed in November includes the largest increase for drug abuse treatment to date.
- o Your 1990 budget contains a double-digit funding increase for HIV/AIDS activities of the Public Health Service and additional funding for other programs (e.g., Medicaid).
- o The Food and Drug Administration has implemented a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o The Public Health Service has set in place a plan to implement many of the specific recommendations of your Commission.
- o The Department of State has begun a three-year plan to enhance international prevention activities.

Unresolved Issues and Recommendation Your 10-point action plan directs immediate implementation or further study of most of the Commission recommendations. Some deferred issues have been resolved; a number will require attention from the next Administration. My recommendations for disposition of the major unresolved issues are:

- o Management of HIV Issues Points 5 and 6 of your 10-point plan address the Commission's recommendations on improving adequacy and coordination of Federal management and resource allocation. I am proposing to increase the influence of public health officials (Tab B). I recommend that this issue be addressed by the upcoming Administration.
- o Confidentiality Many public health officials believe that lack of adequate and consistent privacy protection for HIV-infected individuals is inhibiting the medical efforts. An option considered for legislative action is discussed at Tab C and should be considered by the Bush Administration.
- o Discrimination Discrimination remains an issue of legal, economic, and political concern. Since my last report to you, the Attorney General has ruled that asymptomatic carriers of HIV infection are protected under the Federal Rehabilitation Act if they are linked to agencies which receive Federal funds. In addition, states have been strengthening their protections; however significant gaps remain. The Department of Justice is reviewing options for additional Federal action.
- o Nursing Shortage Planning is necessary for expansion of our health care system which, by 1992, will be caring for 172,000 people with AIDS. The shortage of nurses is already affecting our general medical system. The Secretary of HHS is considering recommendations from his Nursing Commission. I recommend that HHS continue to take the lead on this issue.
- o Financing of Health Care Per your request, HHS has begun a one-year study of the health care financing system; the report is due in September 1989. I recommend that the next Administration continue to monitor this important study.
- o National Commission on AIDS The Health Omnibus Programs Extension Act of 1988 (P.L. 100-607) establishes a two-year National Commission to make recommendations on AIDS policy and to monitor policy implementation. Congress plans to defer appointment of their commissioners until the next session. I recommend that the Presidential appointees to this Commission be named by the new Administration.

CONCLUSION The HIV/AIDS crisis will continue during through the next Administration. We are making every effort to capitalize on the foundation laid under your leadership in stopping the spread of HIV disease.

I plan to transmit a summary of the the HIV/AIDS effort, along with an explanation of the unresolved issues, to Vice President Bush and his advisors. The Nation must not lose momentum in dealing with this health crisis.

THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Second Progress Report

December 23, 1988

TAB A

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.**

Point 1 responds to 129 recommendations of the HIV Commission.

- o Consensus Conferences Key state and local public health officials met November 28-29 at the HHS "Health Summit" to discuss the next steps to reduce the spread of HIV infection. Issues discussed included outreach programs to get IV drug users in treatment, management of public health agencies, testing issues such as counseling, reporting and partner notification, and health care worker safety and education. This was the first in a series of ten conferences which HHS will sponsor throughout 1989.
- o Issue Many State and local officials expressed reservations in implementing stronger public health measures in the absence of stronger privacy and anti-discrimination protections for HIV infected persons. The Health Summit recommended that the Federal government take the lead on this issue. The importance of confidentiality of health information and recommendations for its resolution are addressed at Tab C.

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.**

Point 2 responds to 19 recommendations of the Presidential HIV Commission.

- o U.S. blood supply is among the safest in the world, however its safety must continually be monitored and improved.
- o HHS has begun drafting regulations to mandate notification of transfusion recipients through "look back" programs.
- o Within the next few months, FDA will send to all blood establishments a document consolidating all of the HIV and blood specific recommendations.
- o The Social Security Administration is establishing a Blood Donor Locator Service to aid notification and identification of HIV infected donors.
- o FDA has begun its enhanced inspection program to improve laboratory quality of HIV antibody testing.

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.**

Point 3 responds to 50 recommendations of the HIV Commission.

- o Your goal of a drug-free America has been aided by passage of the Omnibus Drug Act of 1988, however strong efforts must continue and be updated by the next Administration.
- o The "drug bill" contained the single largest expansion of funding for drug abuse treatment and authorized the following activities which are being implemented:
 - Prevention and Treatment of Intravenous (IV) Drug Abuse Funds will go to States for development, implementation and operation of IV drug abuse treatment programs, training of drug abuse counselors, and outreach activities to bring persons into treatment.
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. **Begins action in and out of Government that will accelerate development, approval and distribution of vaccines and drugs.**

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- o Accelerate Approval Process Since the September report, FDA has implemented procedures to speed up the development, evaluation, and marketing of products for AIDS.
- o Incentives for Drug Development HHS is exploring 2 ways to improve Federal incentives to the private sector for developing HIV-related products:
 - a legislative proposal to assure that the important research and development (R&D) incentives under the Orphan Drug Act (i.e. market exclusivity, R&D, tax deductions) will be available after the number of AIDS patients exceeds the 200,000 ceiling applied by the act; and
 - negotiation of equitable pricing assurances in cooperative R&D agreements when exclusive licenses are granted to industrial partners for HIV-related products.
- o Liability Issues HHS has found no indication that promising research has been delayed or foregone in the public or private sector because of fears about liability. HHS has, however, identified a series of options for continued attention to possible liability problems.

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.**

Point 5 responds to 41 recommendations of the HIV Commission.

- o Construction of NIH and CDC the office/laboratory facilities will begin in FY 1989.
- o Unresolved Issue The recruitment and retention of science personnel remains a problem for HHS. Several sources, including the Commission on Executive, Legislative and Judicial Salaries, have recommended salary increases to make the Federal government more competitive.

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.**

- o FY 1990 funding for HIV will include a double digit increase for PHS and additional funding will be available from other sources (i.e. Medicaid, Social Security, the Veterans Administration, DOD, Medicare). In addition, FTE allocations have been made above HHS' requested level.

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.**

Point 7 responds to 68 recommendations of the HIV Commission.

- o An estimated 172,000 people with AIDS will be alive in 1992. The HIV epidemic is also spreading rapidly in populations unable to pay for their medical care. Ensuring availability of an adequate number of health care workers and the financial burden of medical care (\$5 to \$13 billion in 1992) are issues which will need much consideration.
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- o Infants, Children and Adolescents Within the next year, HHS will implement many of the recommended actions of the Secretary's Task Force on Pediatric HIV Infection Report to respond to the needs of infants, children and adolescents.

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.**

Point 8 responds to 41 recommendations of the HIV Commission.

- o The following achievements are anticipated in the next 3 years from the State Department's international plan:
 - The 70 countries with which the U.S. is working will have implemented HIV public information campaigns;
 - All of these countries will have implemented, and most will have evaluated, educational programs aimed at the reduction of high risk behavior;
 - All of these countries will have implemented blood transfusion screening programs for HIV;
 - New HIV diagnostics appropriate for use in developing countries will have been field tested and will be in common use;
 - Vaccine field trial sites will have been established;
 - Better estimates of the number of HIV infected individuals in developing countries will have been completed.

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

- o PHS has completed a strategy for the Nation's response to AIDS. The strategy includes goals and objectives for the major topics raised by your HIV commission. The goals will cross referenced with the recommendations of your Commission on the HIV Epidemic. PHS will track progress on the goals beginning in January 1989.

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.**

Point 10 responds to 89 recommendations of the HIV Commission.

- o Attention to anti-discrimination is needed to ensure that all sectors of society respond equitably and compassionately to those with HIV infection. A discussion of the related issue of privacy/confidentiality is included at Tab C.

**Organizational Issues Raised by the
Presidential Commission on the HIV Epidemic**

Issue The HIV Commission focused heavily on resource and management issues, such as: overall budget levels; adequate personnel, space and equipment; grant and contracting policies; and communication between government agencies. Your 10-point plan responded to many of the direct and immediate needs, however, a number of larger organizational considerations were appropriately deferred for consideration by the next Administration.

The Department of Health and Human Services bears the primary responsibility for the Federal response to the HIV epidemic and receives most of the HIV budget. Understandably, many of the management and organizational questions are targeted at HHS and raise issues of micro-management and unresponsiveness to requests from science and health officials. Improvements in these areas should be possible without eliminating or by-passing the important oversight and management functions of the current system.

Recommendation I recommend that the next Administration examine ways to strengthen the lead agency position of HHS. Revision of the HHS structure could include bringing HCFA/PHS under a senior health official. Also, changes should be made at HHS to facilitate more direct input from public health officials to the Secretary, OMB and the White House.

Federal Privacy Legislation Regarding Health Records of HIV Infected Individuals

Issue The HIV Commission recommended Federal law to assure privacy and confidentiality of medical information obtained during testing, counseling and treatment encounters. Such assurances are particularly important to people with illnesses such as AIDS which are surrounded with stigma. With adequate assurances I believe that HIV-infected individuals will come forward for testing and early counseling and treatment. A balance must be reached, however, between privacy/confidentiality and a genuine public health "need to know."

Concerns exist about casual or inadvertent disclosure to a landlord, employer, or neighbor which could result in discrimination, loss of job, denial of services, ostracism, etc. and about legally-compelled disclosure in private litigation or in governmental proceedings may result in undesired consequences for the individual.

Background The 100th Congress considered HIV confidentiality legislation similar to that recommended by the Commission. None was enacted, but Congress did direct the Secretary of HHS to study existing State laws governing confidentiality of HIV-related information (due May 1989).

In general, the key legal enactments on use and disclosure of medical information are State laws. An increasing number of States have strengthened their confidentiality protections, some specifically for HIV-related data. The strength and breadth of these protections vary widely, however.

Existing Federal confidentiality law for drug and alcohol abuse patient information sets a precedent for Federal action in stigmatized public health conditions. Federal action on confidentiality of HIV-related records would provide reassurance that should encourage more people to be tested. Further, such a law would provide uniformity across the United States and would protect the integrity of HIV records.

Recommendation If the HHS survey of State confidentiality laws does not show substantial progress by States in offering better protection for HIV-related records, Federal or model legislation should be promoted.

THE WHITE HOUSE

WASHINGTON

December 23, 1988

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MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D. *Donald Ian Macdonald*

SUBJECT: Progress on 10-Point Action Plan on HIV/AIDS

Our knowledge of the Human Immunodeficiency Virus (HIV) and our response to the epidemic have come further faster than with any disease in history. However, the death toll continues to rise. The predicted consequences of this disease will place increasing demands on the Nation's health and science resources.

Status In June, you asked me to review the report of your Commission on the HIV Epidemic (The Watkins' Report). In this, my third and final report, I am pleased to state that most of the 354 Commission recommendations within Federal purview have been completed or will be implemented with FY 1989 funds. Additionally, Federal leadership will continue to stimulate action on most of the 243 recommendations that fall outside Federal jurisdiction.

Progress Progress since September on your 10-point plan is addressed at Tab A. Highlights include:

- o Legislation you signed in November includes the largest increase for drug abuse treatment to date.
- o Your 1990 budget contains a double-digit funding increase for HIV/AIDS activities of the Public Health Service and additional funding for other programs (e.g., Medicaid).
- o The Food and Drug Administration has implemented a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o The Public Health Service has set in place a plan to implement many of the specific recommendations of your Commission.
- o The Department of State has begun a three-year plan to enhance international prevention activities.

Unresolved Issues and Recommendation Your 10-point action plan directs immediate implementation or further study of most of the Commission recommendations. Some deferred issues have been resolved; a number will require attention from the next Administration. My recommendations for disposition of the major unresolved issues are:

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Second Progress Report

December 23, 1988

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- o Nursing Shortage Planning is necessary for expansion of our health care system which, by 1992, will be caring for 172,000 people with AIDS. The shortage of nurses is already affecting our general medical system. The Secretary of HHS is considering recommendations from his Nursing Commission. I recommend that HHS continue to take the lead on this issue.
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- o Your goal of a drug-free America has been aided by passage of the Omnibus Drug Act of 1988, however strong efforts must continue and be updated by the next Administration.
- o The "drug bill" contained the single largest expansion of funding for drug abuse treatment and authorized the following activities which are being implemented:
 - Prevention and Treatment of Intravenous (IV) Drug Abuse Funds will go to States for development, implementation and operation of IV drug abuse treatment programs, training of drug abuse counselors, and outreach activities to bring persons into treatment.
 - Expansion of Demonstration Programs 3-year demonstration projects will be funded to: (1) study efficacy of providing drug treatment and vocational training in exchange for public service; (2) conduct outreach activities to IV drug users to prevent the spread of HIV, and (3) provide drug treatment services to pregnant and postpartum women, and their infants.

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

Point 4 responds to 67 recommendations of the HIV Commission.

- o Accelerate Approval Process Since the September report, FDA has implemented procedures to speed up the development, evaluation, and marketing of products for AIDS.
- o Incentives for Drug Development HHS is exploring 2 ways to improve Federal incentives to the private sector for developing HIV-related products:
 - a legislative proposal to assure that the important research and development (R&D) incentives under the Orphan Drug Act (i.e. market exclusivity, R&D, tax deductions) will be available after the number of AIDS patients exceeds the 200,000 ceiling applied by the act; and
 - negotiation of equitable pricing assurances in cooperative R&D agreements when exclusive licenses are granted to industrial partners for HIV-related products.
- o Liability Issues HHS has found no indication that promising research has been delayed or foregone in the public or private sector because of fears about liability. HHS has, however, identified a series of options for continued attention to possible liability problems.

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.**

Point 5 responds to 41 recommendations of the HIV Commission.

- o Construction of NIH and CDC the office/laboratory facilities will begin in FY 1989.
- o Unresolved Issue The recruitment and retention of science personnel remains a problem for HHS. Several sources, including the Commission on Executive, Legislative and Judicial Salaries, have recommended salary increases to make the Federal government more competitive.

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.**

- o FY 1990 funding for HIV will include a double digit increase for PHS and additional funding will be available from other sources (i.e. Medicaid, Social Security, the Veterans Administration, DOD, Medicare). In addition, FTE allocations have been made above HHS' requested level.

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.**

Point 7 responds to 68 recommendations of the HIV Commission.

- o An estimated 172,000 people with AIDS will be alive in 1992. The HIV epidemic is also spreading rapidly in populations unable to pay for their medical care. Ensuring availability of an adequate number of health care workers and the financial burden of medical care (\$5 to \$13 billion in 1992) are issues which will need much consideration.
- o Risk Pools The Secretary of HHS is sending an advisory letter to State Governors and legislative leaders (January 1989) to encourage replication of risk pools for the medically uninsurable. The letter also suggests sources of technical information and assistance.
- o Infants, Children and Adolescents Within the next year, HHS will implement many of the recommended actions of the Secretary's Task Force on Pediatric HIV Infection Report to respond to the needs of infants, children and adolescents.

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.**

Point 8 responds to 41 recommendations of the HIV Commission.

- o The following achievements are anticipated in the next 3 years from the State Department's international plan:
 - The 70 countries with which the U.S. is working will have implemented HIV public information campaigns;
 - All of these countries will have implemented, and most will have evaluated, educational programs aimed at the reduction of high risk behavior;
 - All of these countries will have implemented blood transfusion screening programs for HIV;
 - New HIV diagnostics appropriate for use in developing countries will have been field tested and will be in common use;
 - Vaccine field trial sites will have been established;
 - Better estimates of the number of HIV infected individuals in developing countries will have been completed.

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

- o PHS has completed a strategy for the Nation's response to AIDS. The strategy includes goals and objectives for the major topics raised by your HIV commission. The goals will cross referenced with the recommendations of your Commission on the HIV Epidemic. PHS will track progress on the goals beginning in January 1989.

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.**

Point 10 responds to 89 recommendations of the HIV Commission.

- o Attention to anti-discrimination is needed to ensure that all sectors of society respond equitably and compassionately to those with HIV infection. A discussion of the related issue of privacy/confidentiality is included at Tab C.

**Organizational Issues Raised by the
Presidential Commission on the HIV Epidemic**

Issue The HIV Commission focused heavily on resource and management issues, such as: overall budget levels; adequate personnel, space and equipment; grant and contracting policies; and communication between government agencies. Your 10-point plan responded to many of the direct and immediate needs, however, a number of larger organizational considerations were appropriately deferred for consideration by the next Administration.

The Department of Health and Human Services bears the bulk of the responsibility for the Federal response to the HIV epidemic and receives most of the HIV budget. Understandably, many of the management and organizational questions are targeted at HHS and raise issues of micro-management and unresponsiveness to requests from science and health officials. Improvements in these areas should be possible without eliminating or by-passing the important oversight and management functions of the current system.

Recommendation I recommend that the next Administration examine ways to strengthen the lead agency position of HHS. Revision of the HHS structure should include bringing HCFA/PHS under a senior health official. Also, changes should be made at HHS to facilitate more direct input from public health officials to the Secretary, OMB and the White House.