

Ronald Reagan Presidential Library  
Digital Library Collections

---

This is a PDF of a folder from our textual collections.

---

**Collection:** Daoulas, Sue: Files

**Folder Title:** [September Progress Report – 10 Point  
Action Plan to Fight the Human Immunodeficiency Virus  
(HIV) Epidemic] (4)

**Box:** 3

---

To see more digitized collections visit:

<https://reaganlibrary.gov/archives/digital-library>

To see all Ronald Reagan Presidential Library inventories visit:

<https://reaganlibrary.gov/document-collection>

Contact a reference archivist at: [reagan.library@nara.gov](mailto:reagan.library@nara.gov)

Citation Guidelines: <https://reaganlibrary.gov/citing>

National Archives Catalogue: <https://catalog.archives.gov/>

9/26/88 Sue  
4:00pm D

(date)

INFORMATION

DRAFT

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

SUBJECT: September Progress Report: 10-Point Action Plan to Fight the Human Immunodeficiency Virus<sup>(HIV)</sup> Epidemic

I am pleased to report ~~that~~<sup>skel</sup> progress<sup>skel</sup> during the past ~~six~~ weeks on your 10-point action plan to fight the human immunodeficiency virus (HIV) epidemic, ~~has been remarkable.~~<sup>skel</sup>

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

Discussion Details of the progress on each of the ten points are attached (Tab A); highlights include:

- o A U.S. Health Summit on HIV infection will be held on November 28-29. This will be the first in a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- o A number of steps have been undertaken to further ensure the safety of our blood supply: an education program to encourage persons about to undergo elective surgery to pre-donate their own blood; increased inspections and proficiency testing of laboratories; and, expansion of current efforts to notify transfusion recipients at risk for HIV infection.
- o In response to your directive <sup>will have</sup> to promote fairness and compassion, ~~22~~<sup>22</sup> of the largest Federal agencies (96 percent of the Federal workforce) ~~are putting the~~ OPM guidelines in place, <sup>by December</sup>
- o Over half of the Presidential HIV Commission's recommendations for the Federal Government have been or <sup>will have</sup> soon will be implemented (up from 42 percent in July). <sup>An additional</sup> ~~are~~ planned for 1990
- o Unresolved Issue We have <sup>not</sup> yet ~~to~~ receive a response from the Attorney General on ~~the~~ discrimination law<sup>s</sup> -- ~~this~~ most sensitive and important issue ~~of your action plan~~. A response is expected by \_\_\_\_\_.

~~Although HIV infection remains a serious public health problem, never before in history has so much progress been made so quickly. In December I will provide you with another progress report on implementation of your 10-point plan.~~

DRAFT

1990  
July 1990  
w.b. / [unclear]  
to [unclear]

293



# 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.

## Status

Consensus Conferences In response to your letter to Secretary Bowen, HHS will convene a series of ten conferences over the next year to intensify public/private sector collaboration on a variety of HIV-related public health problems. A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989, with public and private state health officials. ISSUES: counseling, testing and partner notification, reporting of HIV infection, and health care worker safety.

- o Five regional mini-summits on the "Summit" issues will be held between January and May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

Four conferences will address specific issues you raised in your directive to HHS:

- o "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety and liability.
- o "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.
- o "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit the infection and other legal issues.
- o "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

Community Based Education Programs Funding for local HIV prevention programs will be increased by 44 percent -- from \$15 million to \$21.6 million in FY 1989.

Competitive awards for HIV prevention activities will be made in October to 15 to 20 areas with high prevalence of HIV infection.

# DRAFT

9/26



# DRAFT

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.

will be

Status

(draft due by mid-1989)

Notification of Transfusion Recipients Notification of transfusion recipients through "look-back" programs are underway. These programs have been strengthened through: (a) regulations making current voluntary programs mandatory; (b) requiring the blood industry and hospitals to notify physicians that potentially contaminated blood units may have been released and "look-back" should be initiated; and, (c) education programs for transfusion recipients including notification, testing and counselling. Within three months, special out-reach efforts will begin to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available).

By the end of 1988

Improving Laboratory Quality HHS is initiating an integrated strategy to improve laboratory testing accuracy, including: (a) proficiency testing requirements and development of standards for laboratory quality; (b) doubled inspections and surveillance of blood bank facilities; (c) enhanced training of FDA investigators who inspect blood banks; and, (d) training programs for blood establishment staff. In addition, NIH is conducting research to develop and evaluate new tests to detect HIV infection.

Draft (conclude) Jan 1989

Self-Donated (Autologous) Transfusions HHS will be conducting a major educational effort, "the National Blood Resources Education Program," to promote a safe supply of blood and the more effective use of blood and blood products. This program will include a public education campaign (radio, television and print PSAs) to promote autologous donation prior to elective surgery as a means of increasing the blood supply and assuring safety. The FDA ~~is preparing an article for the FDA Drug Bulletin to present information to health professionals on the appropriate use of autologous transfusions.~~ ~~have scheduled meetings with representatives of the~~

In addition, HHS ~~intends to~~ <sup>will</sup> increase research on techniques, such as red blood cell sterilization, which show promise for eradicating HIV and other viruses in blood.

is preparing information for health professionals

# DRAFT

to NIH

\*\* Specific details will be added 9/27/88.

and will be meeting

with representatives of the American Medical Association and the American Hospital Association to further encourage appropriate use of autologous transfusions.

to the American Hospital Association and the American Medical Association to further encourage appropriate use of 9/26



# 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.

Status

*The Congress has cut*  
~~Drug and HIV/AIDS Legislation: (Unfortunately) almost \$13 million has been cut from your FY 1989 budget request.~~ Most of your ~~more~~ recent proposals for both HIV/AIDS and anti-drug efforts exist in pending legislation, but their status is uncertain at this point. On September 23, 1988, the House passed anti-drug legislation which contains: evaluation of "what works" in treatment; targeting block grants through HHS to States for specific population groups, i.e. pregnant women; and, programs aimed at high risk youth. The Senate has yet to take action but is expected to successfully negotiate an anti-drug and a HIV/AIDS bill before the October recess.

Several important HIV-related issues which remain unresolved:

- the availability of additional funds for drug treatment hinges on Congress action on your request budget*
- o **Increased Drug Treatment Capacity** ~~There may or may not be additional funds for drug treatment and Although money is important,~~ it is not the only constraint to increased treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS, however administration of these grants is dependent upon increased funding for treatment.
  - o **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.
  - o **High-Risk Populations** HHS is developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. The Office of Juvenile Justice Drug Prevention at Justice and the Office of Substance Abuse Prevention at HHS are providing technical assistance to major metropolitan areas working with high-risk youth.

*However, money*

# DRAFT

9/26

# DRAFT

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

### Status

Accelerate Approval Process <sup>revised?</sup> [As directed by the Vice President and the Presidential Task Force on Regulatory Relief, FDA is expected to release on \_\_\_\_\_ the details of a process to speed approval of therapies to treat life-threatening illnesses such as AIDS.] The key elements of the plan include:

- o Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.
- o Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).
- o Appropriate drugs will be made available for patient use through Treatment Investigational New Drug status as a bridge between completion of the expedited testing process and marketing approval.
- o Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.
- o Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

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

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

# DRAFT

9/26



# DRAFT

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

## Status

Space Needs OMB will soon recommend to you that a budget amendment be sent to Congress seeking authority for the NIH to initiate construction of a consolidated office building on the NIH campus in Bethesda. Your HIV Commission recommended construction of a consolidated office building to remove "one of the most serious research administrative obstacles ... encountered." In addition, Congress is expected to approve a lease-purchase acquisition for the Centers for Disease Control to provide additional laboratory and office space.

Resource Needs Because of the <sup>urgent</sup> urgency need, \_\_\_\_\_ additional FTEs have been approved for HHS for FY 1989. OMB will continue to work with the Secretary to assure that adequate resources are available for HIV efforts. HHS Secretary Bowen has the authority to transfer FTEs and HIV funds among HHS agencies. OMB will address dollar resources and FTEs for HIV infection ~~as it prepares~~ <sup>in preparing</sup> your FY 1990 budget.

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

# DRAFT

9/26

# DRAFT

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.

*you* Status  
Presidential Action Much of the FY 1989 HIV appropriations request has been enacted and signed. On August 5, you sent a letter to the Congress announcing his 10-point plan and asked Congress to expeditiously enact both the FY 1989 and FY 1990 appropriations request for HIV activities. The Labor, Health and Human Services and Education Bill was signed on September 20, and included \$1.29 billion -- a 1.2 percent decrease from your budget request.

Status of FY 1990 Request HHS submitted its FY 1990 budget request to OMB on September 1, which includes an AIDS emergency fund ~~request~~ to meet unanticipated problems or opportunities. ~~The request will go to Congress with the President's budget in February 1989.~~

FEDERAL AIDS SPENDING  
 By Year and Department  
 (in millions of dollars)

	1982	1983	1984	1985	1986	1987	1988	1989
<b>Health &amp; Human Services</b>								
<b>Public Health Service</b>								
NIH	3.4	21.7	44.1	63.7	134.7	260.9	467.8	607.0
CDC	2.1	6.2	13.8	33.3	62.1	136.0	304.9	382.3
ADAMHA	0.0	0.5	2.8	2.6	12.2	47.5	112.3	175.5
HRSA	0.0	0.0	0.0	0.0	15.3	41.9	37.0	45.4
FDA	0.2	0.4	0.8	9.0	9.5	15.8	24.8	65.4
OASH	0.0	0.0	0.0	0.0	0.0	0.2	3.7	13.4
IHS	0.0	0.0	0.0	0.0	0.0	0.1	0.6	0.8
<b>SUB-TOTAL PHS</b>	<b>5.6</b>	<b>28.7</b>	<b>61.5</b>	<b>108.6</b>	<b>233.8</b>	<b>502.5</b>	<b>951.0</b>	<b>1289.8</b>
<b>Hlth Care Finc. Admin.</b>								
Medicaid (Fed Share)	0.0	10.0	30.0	70.0	130.0	200.0	330.0	490.0
Medicare	0.0	0.0	0.0	5.0	5.0	10.0	15.0	30.0
<b>SUB-TOTAL HCFA</b>	<b>0.0</b>	<b>10.0</b>	<b>30.0</b>	<b>75.0</b>	<b>135.0</b>	<b>210.0</b>	<b>345.0</b>	<b>520.0</b>
<b>Social Security Admin.</b>								
Disability Income	0.0	0.0	5.0	10.0	25.0	40.0	70.0	110.0
Supp. Security Income	0.0	0.0	1.0	3.0	8.0	11.0	18.0	28.0
<b>SUB-TOTAL SSA</b>	<b>0.0</b>	<b>0.0</b>	<b>6.0</b>	<b>13.0</b>	<b>33.0</b>	<b>51.0</b>	<b>88.0</b>	<b>138.0</b>
<b>Human Development Serv.</b>								
	0.0	0.0	0.0	0.0	0.0	0.0	5.7	5.2
<b>SUB-TOTAL HHS</b>	<b>5.6</b>	<b>38.7</b>	<b>97.5</b>	<b>196.6</b>	<b>401.8</b>	<b>763.5</b>	<b>1389.7</b>	<b>1947.8</b>
<b>Veterans Admin.</b>								
	2.0	5.0	6.1	10.1	22.9	52.6	82.9	99.3
<b>Dept. of Defense</b>								
	0.0	0.0	0.0	0.0	79.0	74.0	52.0	52.0
<b>Dept. of Justice</b>								
	0.0	0.0	0.0	0.0	1.0	3.0	6.0	6.0
<b>Dept. of Labor</b>								
	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
<b>Dept. of State</b>								
	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
<b>Dept. of Education</b>								
	0.0	0.0	0.0	0.0	0.0	0.0	1.2	0.0
<b>Dept. of Agriculture</b>								
	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3
<b>SUB-TOTAL NON HHS</b>	<b>2.0</b>	<b>5.0</b>	<b>6.1</b>	<b>10.1</b>	<b>102.9</b>	<b>131.6</b>	<b>144.3</b>	<b>159.6</b>
<b>* * * GRAND TOTAL</b>	<b>7.6</b>	<b>43.7</b>	<b>103.6</b>	<b>206.7</b>	<b>504.7</b>	<b>895.0</b>	<b>1534.0</b>	<b>2107.4</b>

Detail may not add to total due to rounding.

DRAFT

9/26



# DRAFT

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

## Status

Evaluation of Health Care Financing In response to your directive, HHS, in consultation with outside experts, has begun an evaluation of access to health care with a focus on financing and insurance, ~~is especially for~~ <sup>including</sup> the underinsured and uninsured, experiences of low-income disabled individuals, and disability coverage through the Social Security Administration and/or Medicaid.

Alternatives to Acute Care HHS is encouraging states and other organizations to study the efficacy of care and to provide more cost effective care ~~for persons who would otherwise be at risk for institutionalization~~ through:

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

Risk Pools HHS has proposed to OMB that the Administration support enactment of S.1634 which would encourage states to establish risk pools, would establish very limited Federal requirements (needing modification), and would provide \$30 million in "seed money" spread over 3 years. HHS plans to promote risk pools through the consensus conference approach and through interaction with outside organizations such as the National Governors Association.

Infants, Children and Adolescents The HHS Secretary's Task Force on Pediatric HIV Infection Report recommends specific studies regarding ~~infants, children and adolescents~~ <sup>BEING</sup>. This report is currently ~~under review with~~ <sup>BEING</sup> the Department and a more complete submission will be available for the December report.

# DRAFT

# DRAFT

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

## Status

Draft Plan The outline for a 3-year plan has been drafted by the Department of State, with the U.S. Agency for International Development (A.I.D.). The development of the plan ~~from the outline~~ will be coordinated with other Federal agencies through the HHS's Federal Coordinating Committee on AIDS, but focusses on four broad areas:

- o multilateral and bilateral activities for the prevention and control of HIV infection;
- o development of new methods of treatment and a vaccine;
- o foreign policy implications of AIDS; and,
- o budgetary implications.

The plan should be available for review by mid-October and the final report completed by mid-December.

Financial Support A.I.D. will increase its financial support for international assistance for HIV prevention programs from \$30 million in FY 1988 to \$35-40 million in FY 1989.

# DRAFT



# DRAFT

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

### Status

The Public Health Service will submit a HIV Implementation Plan in December which will identify the major goals to be carried out during FY 1989. This plan will be developed from the report of your HIV Commission and the October 1988 report of the second PHS AIDS Prevention and Control Conference, held by the Assistant Secretary for Health in June 1988. A computerized tracking and monitoring system for HHS activities in combatting HIV infection, including implementation of the Commission's recommendations will be established.

Issues, goals and objectives will be divided into nine (9) broad categories:

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

# DRAFT

9/26

# DRAFT

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

## Status

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

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

~~o All 22 agencies~~

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

OPM AIDS Clearinghouse Established OPM has established a clearinghouse to make AIDS information available to agencies seeking assistance. Items included in the clearinghouse are: the President's action plan; copies of all agency policy statements; education and training materials; results of periodic surveys regarding extent of AIDS policies and programs; and AIDS education programs.

Private Sector Responding On August 17, 1988 the Director of OPM sent a letter to each of the Fortune 1000 companies telling them of the President's ten point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines."

Discrimination Laws We have <sup>not</sup> yet ~~to~~ receive a response from the Attorney General on this most sensitive and important issue, discrimination. A response is expected by \_\_\_\_\_.

# DRAFT

9/26



9/26/88  
4:00pm

(date)

INFORMATION

DRAFT

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

I am pleased to report that progress during the past six weeks on your 10-point action plan to fight the human immunodeficiency virus (HIV) epidemic has been remarkable.

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

Discussion Details of the progress on each of the ten points are attached (Tab A); highlights include:

- o A U.S. Health Summit on HIV infection will be held on November 28-29. This will be the first in a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS. *te*
- o A number of steps have been undertaken to further ensure the safety of our blood supply: an education program to encourage persons about to undergo elective surgery to pre-donate their own blood; increased inspections and proficiency testing of laboratories; and, expansion of current efforts to notify transfusion recipients at risk for HIV infection.
- o In response to your directive to promote fairness and compassion, 22 of the largest Federal agencies (96 percent of the Federal workforce) are putting the OPM guidelines in place.
- o Over half of the Presidential HIV Commission's recommendations for the Federal Government have been or soon will be implemented (up from 42 percent in July).
- o Unresolved Issue We have yet to receive a response from the Attorney General on ~~the~~ discrimination laws-- this most sensitive and important issue of your action plan. A response is expected by \_\_\_\_\_.

Although HIV infection remains a serious public health problem, never before in history has so much progress been made so quickly. In December I will provide you with another progress report on implementation of your 10-point plan.

DRAFT

# 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.

## Status

Consensus Conferences In response to your letter to Secretary Bowen, HHS will convene a series of ten conferences over the next year to intensify public/private sector collaboration on a variety of HIV-related public health problems. A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989, with public and private state health officials. ISSUES: counseling, testing and partner notification, reporting of HIV infection, and health care worker safety.

- o Five regional mini-summits on the "Summit" issues will be held between January and May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

Four conferences will address specific issues you raised in your directive to HHS:

- o "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety and liability.
- o "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.
- o "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit the infection and other legal issues.
- o "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

Community Based Education Programs Funding for local HIV prevention programs will be increased by 44 percent -- from \$15 million to \$21.6 million in FY 1989.

Competitive awards for HIV prevention activities will be made in October to 15 to 20 areas with high prevalence of HIV infection.

# DRAFT

9/26



# DRAFT

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

## Status

Notification of Transfusion Recipients Notification of transfusion recipients through "look-back" programs are underway. These programs have been strengthened through: (a) regulations making current voluntary programs mandatory; (b) requiring the blood industry and hospitals to notify physicians that potentially contaminated blood units may have been released and "look-back" should be initiated; and, (c) education programs for transfusion recipients including notification, testing and counselling. Within three months, special out-reach efforts will begin to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available).

Improving Laboratory Quality HHS is initiating an integrated strategy to improve laboratory testing accuracy, including: (a) proficiency testing requirements and development of standards for laboratory quality; (b) doubled inspections and surveillance of blood bank facilities; (c) enhanced training of FDA investigators who inspect blood banks; and, (d) training programs for blood establishment staff. In addition, NIH is conducting research to develop and evaluate new tests to detect HIV infection.

Self-Donated (Autologous) Transfusions HHS will be conducting a major educational effort, "the National Blood Resources Education Program," to promote a safe supply of blood and the more effective use of blood and blood products. This program will include a public education campaign (radio, television and print PSAs) to promote autologous donation prior to elective surgery as a means of increasing the blood supply and assuring safety. The FDA is preparing an article for the FDA Drug Bulletin to present information to health professionals on the appropriate use of autologous transfusions.

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

# DRAFT

\*\* Specific details will be added 9/27/88.

9/26

# 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.**

## Status

Drug and HIV/AIDS Legislation: Unfortunately, almost \$13 million has been cut from your FY 1989 budget request. Most of your more recent proposals for both HIV/AIDS and anti-drug efforts exist in pending legislation, but their status is uncertain at this point. On September 23, 1988, the House passed anti-drug legislation which contains: evaluation of "what works" in treatment; targeting block grants through HHS to States for specific population groups, i.e. pregnant women; and, programs aimed at high risk youth. The Senate has yet to take action but is expected to successfully negotiate an anti-drug and a HIV/AIDS bill before the October recess.

Several important HIV-related issues which remain unresolved:

- o **Increased Drug Treatment Capacity** There may or may not be additional funds for drug treatment and although money is important, it is not the only constraint to increased treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS, however administration of these grants is dependent upon increased funding for treatment.
- o **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of what works in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.
- o **High-Risk Populations** HHS is developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. The Office of Juvenile Justice Drug Prevention at Justice and the Office of Substance Abuse Prevention at HHS are providing technical assistance to major metropolitan areas working with high-risk youth.

# DRAFT

9/26



# DRAFT

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

### Status

Accelerate Approval Process As directed by the Vice President and the Presidential Task Force on Regulatory Relief, FDA is expected to release on \_\_\_\_\_ the details of a process to speed approval of therapies to treat life-threatening illnesses such as AIDS. The key elements of the plan include:

- o Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.
- o Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).
- o Appropriate drugs will be made available for patient use through Treatment Investigational New Drug status as a bridge between completion of the expedited testing process and marketing approval.
- o Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.
- o Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

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

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

DRAFT

9/26

# DRAFT

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

## Status

Space Needs OMB will soon recommend to you that a budget amendment be sent to Congress seeking authority for the NIH to initiate construction of a consolidated office building on the NIH campus in Bethesda. Your HIV Commission recommended construction of a consolidated office building to remove "one of the most serious research administrative obstacles ... encountered." In addition, Congress is expected to approve a lease-purchase acquisition for the Centers for Disease Control to provide additional laboratory and office space.

Resource Needs Because of the urgency of need, \_\_\_\_\_ additional FTEs have been approved for HHS for FY 1989. OMB will continue to work with the Secretary to assure that adequate resources are available for HIV efforts. HHS Secretary Bowen has the authority to transfer FTEs and HIV funds among HHS agencies. OMB will address dollar resources and FTEs for HIV infection as it prepares your FY 1990 budget.

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

# DRAFT

9/26



# DRAFT

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

## Status

Presidential Action Much of the FY 1989 HIV appropriations request has been enacted and signed. On August 5, you sent a letter to the Congress announcing his 10-point plan and asked Congress to expeditiously enact both the FY 1989 and FY 1990 appropriations request for HIV activities. The Labor, Health and Human Services and Education Bill was signed on September 20, and included \$1.29 billion -- a 1.2 percent decrease from your budget request.

Status of FY 1990 Request HHS submitted its FY 1990 budget request to OMB on September 1, which includes an AIDS emergency fund request to meet unanticipated problems or opportunities. The request will go to Congress with the President's budget in February 1989.

FEDERAL AIDS SPENDING  
By Year and Department  
(in millions of dollars)

	1982	1983	1984	1985	1986	1987	1988	1989
<b>Health &amp; Human Services</b>								
Public Health Service								
NIH	3.4	21.7	44.1	63.7	134.7	260.9	467.8	607.0
CDC	2.1	6.2	13.8	33.3	62.1	136.0	304.9	382.3
ADAMHA	0.0	0.5	2.8	2.6	12.2	47.5	112.3	175.5
HRSA	0.0	0.0	0.0	0.0	15.3	41.9	37.0	45.4
FDA	0.2	0.4	0.8	9.0	9.5	15.8	24.8	65.4
OASH	0.0	0.0	0.0	0.0	0.0	0.2	3.7	13.4
IHS	0.0	0.0	0.0	0.0	0.0	0.1	0.6	0.8
SUB-TOTAL PHS	5.6	28.7	61.5	108.6	233.8	502.5	951.0	1289.8
<b>Hlth Care Finc. Admin.</b>								
Medicaid (Fed Share)	0.0	10.0	30.0	70.0	130.0	200.0	330.0	490.0
Medicare	0.0	0.0	0.0	5.0	5.0	10.0	15.0	30.0
SUB-TOTAL HCFA	0.0	10.0	30.0	75.0	135.0	210.0	345.0	520.0
<b>Social Security Admin.</b>								
Disability Income	0.0	0.0	5.0	10.0	25.0	40.0	70.0	110.0
Supp. Security Income	0.0	0.0	1.0	3.0	8.0	11.0	18.0	28.0
SUB-TOTAL SSA	0.0	0.0	6.0	13.0	33.0	51.0	88.0	138.0
Human Development Serv.	0.0	0.0	0.0	0.0	0.0	0.0	5.7	5.2
SUB-TOTAL HHS	5.6	38.7	97.5	196.6	401.8	763.5	1389.7	1947.8
<b>Other Departments</b>								
Veterans Admin.	2.0	5.0	6.1	10.1	22.9	52.6	82.9	99.3
Dept. of Defense	0.0	0.0	0.0	0.0	79.0	74.0	52.0	52.0
Dept. of Justice	0.0	0.0	0.0	0.0	1.0	3.0	6.0	6.0
Dept. of Labor	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
Dept. of State	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
Dept. of Education	0.0	0.0	0.0	0.0	0.0	0.0	1.2	0.0
Dept. of Agriculture	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3
SUB-TOTAL NON HHS	2.0	5.0	6.1	10.1	102.9	131.6	144.3	159.6
* * * GRAND TOTAL	7.6	43.7	103.6	206.7	504.7	895.0	1534.0	2107.4

Detail may not add to total due to rounding.

DRAFT

# DRAFT

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

## Status

Evaluation of Health Care Financing In response to your directive, HHS, in consultation with outside experts, has begun an evaluation of access to health care with a focus on financing and insurance issues, especially for the underinsured and uninsured, experiences of low-income disabled individuals, and disability coverage through the Social Security Administration and/or Medicaid.

Alternatives to Acute Care HHS is encouraging states and other organizations to study the efficacy of care and to provide more cost effective care for persons who would otherwise be at risk for institutionalization through:

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

Risk Pools HHS has proposed to OMB that the Administration support enactment of S.1634 which would encourage states to establish risk pools, would establish very limited Federal requirements (needing modification), and would provide \$30 million in "seed money" spread over 3 years. HHS plans to promote risk pools through the consensus conference approach and through interaction with outside organizations such as the National Governors Association.

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

# DRAFT



# DRAFT

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

## Status

Draft Plan The outline for a 3-year plan has been drafted by the Department of State, with the U.S. Agency for International Development (A.I.D.). The development of the plan from the outline will be coordinated with other Federal agencies through the HHS's Federal Coordinating Committee on AIDS, but focusses on four broad areas:

- o multilateral and bilateral activities for the prevention and control of HIV infection;
- o development of new methods of treatment and a vaccine;
- o foreign policy implications of AIDS; and,
- o budgetary implications.

The plan should be available for review by mid-October and the final report completed by mid-December.

Financial Support A.I.D. will increase its financial support for international assistance for HIV prevention programs from \$30 million in FY 1988 to \$35-40 million in FY 1989.

# DRAFT

9/26

# DRAFT

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

### Status

The Public Health Service will submit a HIV Implementation Plan in December which will identify the major goals to be carried out during FY 1989. This plan will be developed from the report of your HIV Commission and the October 1988 report of the second PHS AIDS Prevention and Control Conference, held by the Assistant Secretary for Health in June 1988. A computerized tracking and monitoring system for HHS activities in combatting HIV infection, including implementation of the Commission's recommendations will be established.

Issues, goals and objectives will be divided into nine (9) broad categories:

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

# DRAFT

9/26



# DRAFT

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

## Status

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

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

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

OPM AIDS Clearinghouse Established OPM has established a clearinghouse to make AIDS information available to agencies seeking assistance. Items included in the clearinghouse are: the President's action plan; copies of all agency policy statements; education and training materials; results of periodic surveys regarding extent of AIDS policies and programs; and AIDS education programs.

Private Sector Responding On August 17, 1988 the Director of OPM sent a letter to each of the Fortune 1000 companies telling them of the President's ten point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines."

Discrimination Law We have yet to receive a response from the Attorney General on this most sensitive and important issue, discrimination. A response is expected by \_\_\_\_\_.

# DRAFT

9/26

DRAFT

9/27  
11:00am

(date)

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

I am pleased to report that progress during the past six weeks on your 10-point action plan to fight the human immunodeficiency virus (HIV) epidemic has been remarkable.

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

Discussion Details of the progress on each of the ten points are attached (Tab A); highlights include:

- o A U.S. Health Summit on HIV infection will be held on November 28-29. This will be the first in a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- o In response to your directive to promote fairness and compassion, the largest Federal agencies (96 percent of the workforce) will have OPM guidelines in place by December.
- o FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has released approved a process to speed approval of therapies to treat life-threatening illnesses such as AIDS.

2. [ o Over half of the Presidential HIV Commission's recommendations for the Federal Government have been or soon will be implemented (up from 42 percent in July). ]

o Unresolved Issue We have not yet received a response from the Attorney General on a most sensitive and important issue -- discrimination. A response is expected by \_\_\_\_\_.

In December I will provide you with another progress report on implementation of your 10-point plan.

DRAFT



**DRAFT**

THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HIV INFECTION

September Progress Report

**DRAFT**

9/27

# 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.**

## Status

Consensus Conferences In response to your letter to Secretary Bowen, HHS will convene a series of ten conferences over the next year to intensify public/private sector collaboration on a variety of HIV-related public health problems. A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989, with public and private state health officials. ISSUES: counseling, testing and partner notification, reporting of HIV infection, and health care worker safety.

- o Five regional mini-summits on the "Summit" issues will be held between January and May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

Four conferences will address specific issues you raised in your directive to HHS:

- o "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety and liability.
- o "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.
- o "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit the infection and other legal issues.
- o "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

Community Based Education Programs Funding for local HIV prevention programs will be increased by 44 percent -- from \$15 million to \$21.6 million in FY 1989.

Competitive awards for HIV prevention activities will be made in October to 15 to 20 areas with high prevalence of HIV infection.

DRAFT

9/27



# DRAFT

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

## Status

Notification of Transfusion Recipients Notification of transfusion recipients through "look-back" programs are underway. These programs will be strengthened through: (a) regulations making current voluntary programs mandatory (draft due mid-1989); (b) requiring the blood industry and hospitals to notify physicians that potentially contaminated blood units may have been released and "look-back" should be initiated; and, (c) education programs for transfusion recipients including notification, testing and counselling. By the end of 1988, special out-reach efforts will begin to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available).

Improving Laboratory Quality HHS is initiating an integrated strategy to improve laboratory testing accuracy, including: (a) regulation for proficiency testing and development of standards for laboratory quality (draft due January 1989); (b) doubled inspections and surveillance of blood bank facilities; (c) enhanced training of FDA investigators who inspect blood banks; and, (d) training programs for blood establishment staff. In addition, NIH is conducting research to develop and evaluate new tests to detect HIV infection.

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

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

# DRAFT

9/27

# 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.**

## Status

**Drug and HIV/AIDS Legislation:** Most of your recent proposals for both HIV/AIDS and anti-drug efforts exist in pending legislation, but their status is uncertain at this point. On September 23, 1988, the House passed anti-drug legislation which contains: evaluation of "what works" in treatment; targeting block grants through HHS to States for specific population groups, i.e. pregnant women; and, programs aimed at high risk youth. The Senate has yet to take action but is expected to successfully negotiate an anti-drug and a HIV/AIDS bill before the October recess.

Several important HIV-related issues which remain unresolved:

- o **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on Congressional action on your budget request. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS, however administration of these grants is dependent upon increased funding for treatment.
- o **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.
- o **High-Risk Populations** HHS is developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. The Office of Juvenile Justice Drug Prevention at Justice and the Office of Substance Abuse Prevention at HHS are providing technical assistance to major metropolitan areas working with high-risk youth.

# DRAFT

9/27



# DRAFT

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

### Status

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

- o Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.
- o Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).
- o Appropriate drugs will be made available for patient use through Treatment Investigational New Drug status as a bridge between completion of the expedited testing process and marketing approval.
- o Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.
- o Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

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

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

DRAFT

DRAFT

9/27

# DRAFT

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

## Status

Space Needs OMB will soon recommend to you that a budget amendment be sent to Congress seeking authority for the NIH to initiate construction of a consolidated office building on the NIH campus in Bethesda. Your HIV Commission recommended construction of a consolidated office building to remove "one of the most serious research administrative obstacles ... encountered." In addition, Congress is expected to approve a lease-purchase acquisition for the Centers for Disease Control to provide additional laboratory and office space.

Resource Needs Because of the urgent need, \_\_\_\_\_ additional FTEs have been approved for HHS for FY 1989. OMB will continue to work with the Secretary to assure that adequate resources are available for HIV efforts. HHS Secretary Bowen has the authority to transfer FTEs and HIV funds among HHS agencies. OMB will address dollar resources and FTEs for HIV infection in preparing your FY 1990 budget.

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

# DRAFT

9/27



# DRAFT

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

## Status

Presidential Action Much of the FY 1989 HIV appropriations request has been enacted and signed. On August 5, you sent a letter to the Congress announcing your 10-point plan and asked Congress to expeditiously enact both the FY 1989 and FY 1990 appropriations request for HIV activities. The Labor, Health and Human Services and Education Bill was signed on September 20, and included \$1.29 billion -- a 1.2 percent decrease from your budget request.

Status of FY 1990 Request HHS submitted its FY 1990 budget request to OMB on September 1, which includes an AIDS emergency fund to meet unanticipated problems or opportunities.

### FEDERAL AIDS SPENDING By Year and Department (in millions of dollars)

	1982	1983	1984	1985	1986	1987	1988	1989
<b>Health &amp; Human Services</b>								
Public Health Service								
NIH	3.4	21.7	44.1	63.7	134.7	260.9	467.8	607.0
CDC	2.1	6.2	13.8	33.3	62.1	136.0	304.9	382.3
ADAMHA	0.0	0.5	2.8	2.6	12.2	47.5	112.3	175.5
HRSA	0.0	0.0	0.0	0.0	15.3	41.9	37.0	45.4
FDA	0.2	0.4	0.8	9.0	9.5	15.8	24.8	65.4
OASH	0.0	0.0	0.0	0.0	0.0	0.2	3.7	13.4
IHS	0.0	0.0	0.0	0.0	0.0	0.1	0.6	0.8
<b>SUB-TOTAL PHS</b>	<b>5.6</b>	<b>28.7</b>	<b>61.5</b>	<b>108.6</b>	<b>233.8</b>	<b>502.5</b>	<b>951.0</b>	<b>1289.8</b>
<b>Hlth Care Finc. Admin.</b>								
Medicaid (Fed Share)	0.0	10.0	30.0	70.0	130.0	200.0	330.0	490.0
Medicare	0.0	0.0	0.0	5.0	5.0	10.0	15.0	30.0
<b>SUB-TOTAL HCFA</b>	<b>0.0</b>	<b>10.0</b>	<b>30.0</b>	<b>75.0</b>	<b>135.0</b>	<b>210.0</b>	<b>345.0</b>	<b>520.0</b>
<b>Social Security Admin.</b>								
Disability Income	0.0	0.0	5.0	10.0	25.0	40.0	70.0	110.0
Supp. Security Income	0.0	0.0	1.0	3.0	8.0	11.0	18.0	28.0
<b>SUB-TOTAL SSA</b>	<b>0.0</b>	<b>0.0</b>	<b>6.0</b>	<b>13.0</b>	<b>33.0</b>	<b>51.0</b>	<b>88.0</b>	<b>138.0</b>
<b>Human Development Serv.</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>5.7</b>	<b>5.2</b>
<b>SUB-TOTAL HHS</b>	<b>5.6</b>	<b>38.7</b>	<b>97.5</b>	<b>196.6</b>	<b>401.8</b>	<b>763.5</b>	<b>1389.7</b>	<b>1947.8</b>
<b>Veterans Admin.</b>								
Dept. of Defense	0.0	0.0	0.0	0.0	79.0	74.0	52.0	52.0
Dept. of Justice	0.0	0.0	0.0	0.0	1.0	3.0	6.0	6.0
Dept. of Labor	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
Dept. of State	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
Dept. of Education	0.0	0.0	0.0	0.0	0.0	0.0	1.2	0.0
Dept. of Agriculture	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3
<b>SUB-TOTAL NON HHS</b>	<b>2.0</b>	<b>5.0</b>	<b>6.1</b>	<b>10.1</b>	<b>102.9</b>	<b>131.6</b>	<b>144.3</b>	<b>159.6</b>
<b>* * * GRAND TOTAL</b>	<b>7.6</b>	<b>43.7</b>	<b>103.6</b>	<b>206.7</b>	<b>504.7</b>	<b>895.0</b>	<b>1534.0</b>	<b>2107.4</b>

Detail may not add to total due to rounding.

9/27

# DRAFT

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

## Status

Evaluation of Health Care Financing In response to your directive, HHS, in consultation with outside experts, has begun an evaluation of access to health care with a focus on financing and insurance, including the underinsured and uninsured, experiences of low-income disabled individuals, and disability coverage through the Social Security Administration and/or Medicaid.

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

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

Risk Pools HHS has proposed to OMB that the Administration support enactment of S.1634 which would encourage states to establish risk pools, would establish very limited Federal requirements (needing modification), and would provide \$30 million in "seed money" spread over 3 years. HHS plans to promote risk pools through the consensus conference approach and through interaction with outside organizations such as the National Governors Association.

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

# DRAFT

9/27



# DRAFT

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

## Status

Draft Plan The outline for a 3-year plan has been drafted by the Department of State, with the U.S. Agency for International Development (A.I.D.). The development of the plan will be coordinated with other Federal agencies through the HHS's Federal Coordinating Committee on AIDS, but focusses on four broad areas:

- o multilateral and bilateral activities for the prevention and control of HIV infection;
- o development of new methods of treatment and a vaccine;
- o foreign policy implications of AIDS; and,
- o budgetary implications.

The plan should be available for review by mid-October and the final report completed by mid-December.

Financial Support A.I.D. will increase its financial support for international assistance for HIV prevention programs from \$30 million in FY 1988 to \$35-40 million in FY 1989.

# DRAFT

9/27

# DRAFT

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

### Status

The Public Health Service will submit a HIV Implementation Plan in December which will identify the major goals to be carried out during FY 1989. This plan will be developed from the report of your HIV Commission and the October 1988 report of the second PHS AIDS Prevention and Control Conference, held by the Assistant Secretary for Health in June 1988. A computerized tracking and monitoring system for HHS activities in combatting HIV infection, including implementation of the Commission's recommendations will be established.

Issues, goals and objectives will be divided into nine (9) broad categories:

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

# DRAFT

9/27



# DRAFT

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

## Status

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

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

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

OPM AIDS Clearinghouse Established OPM has established a clearinghouse to make AIDS information available to agencies seeking assistance. Items included in the clearinghouse are: the President's action plan; copies of all agency policy statements; education and training materials; results of periodic surveys regarding extent of AIDS policies and programs; and AIDS education programs.

Private Sector Responding On August 17, 1988 the Director of OPM sent a letter to each of the Fortune 1000 companies telling them of the President's ten point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines."

Discrimination Laws We have not yet received a response from the Attorney General on this most sensitive and important issue, discrimination. A response is expected by \_\_\_\_\_.

DRAFT

9/27

9/27  
1:00pm

(date)

INFORMATION

**DRAFT**

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

I am pleased to report that progress during the past six weeks on your 10-point action plan to fight the human immunodeficiency virus (HIV) epidemic has been remarkable.

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

Discussion Details of the progress on each of the ten points are attached (Tab A); highlights include:

- o A U.S. Health Summit on HIV infection will be held on November 28-29. This will be the first in a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- o In response to your directive to promote fairness and compassion, the largest Federal agencies (96 percent of the workforce) will have OPM guidelines in place by December.
- o FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has released approved a process to speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o Unresolved Issue We have not yet received a response from the Attorney General on a most sensitive and important issue -- discrimination laws.

In December I will provide you with another progress report on implementation of your 10-point plan.

**DRAFT**



**DRAFT**

THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HIV INFECTION

September Progress Report

**DRAFT**

9/27

# 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.

## Status

Consensus Conferences In response to your letter to Secretary Bowen, HHS will convene a series of ten conferences over the next year to intensify public/private sector collaboration on a variety of HIV-related public health problems. A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989, with public and private state health officials. ISSUES: counseling, testing and partner notification, reporting of HIV infection, and health care worker safety.

- o Five regional mini-summits on the "Summit" issues will be held between January and May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

Four conferences will address specific issues you raised in your directive to HHS:

- o "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety and liability.
- o "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.
- o "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit the infection and other legal issues.
- o "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

Community Based Education Programs Funding for local HIV prevention programs will be increased by 44 percent -- from \$15 million to \$21.6 million in FY 1989.

Competitive awards for HIV prevention activities will be made in October to 15 to 20 areas with high prevalence of HIV infection.

DRAFT

9/27



# DRAFT

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

## Status

Notification of Transfusion Recipients Notification of transfusion recipients through "look-back" programs are underway. These programs will be strengthened through: (a) regulations making current voluntary programs mandatory (draft due mid-1989); (b) requiring the blood industry and hospitals to notify physicians that potentially contaminated blood units may have been released and "look-back" should be initiated; and, (c) education programs for transfusion recipients including notification, testing and counselling. By the end of 1988, special out-reach efforts will begin to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available).

Improving Laboratory Quality HHS is initiating an integrated strategy to improve laboratory testing accuracy, including: (a) regulation for proficiency testing and development of standards for laboratory quality (draft due January 1989); (b) doubled inspections and surveillance of blood bank facilities; (c) enhanced training of FDA investigators who inspect blood banks; and, (d) training programs for blood establishment staff. In addition, NIH is conducting research to develop and evaluate new tests to detect HIV infection.

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

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

# DRAFT

9/27

# 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.

## Status

Drug and HIV/AIDS Legislation: Most of your recent proposals for both HIV/AIDS and anti-drug efforts exist in pending legislation, but their status is uncertain at this point. On September 23, 1988, the House passed anti-drug legislation which contains: evaluation of "what works" in treatment; targeting block grants through HHS to States for specific population groups, i.e. pregnant women; and, programs aimed at high risk youth. The Senate has yet to take action but is expected to successfully negotiate an anti-drug and a HIV/AIDS bill before the October recess.

Several important HIV-related issues which remain unresolved:

- o **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on Congressional action on your budget request. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS, however administration of these grants is dependent upon increased funding for treatment.
- o **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.
- o **High-Risk Populations** HHS is developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. The Office of Juvenile Justice Drug Prevention at Justice and the Office of Substance Abuse Prevention at HHS are providing technical assistance to major metropolitan areas working with high-risk youth.

# DRAFT

9/27



# DRAFT

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

### Status

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

- o Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.
- o Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).
- o Appropriate drugs will be made available for patient use through Treatment Investigational New Drug status as a bridge between completion of the expedited testing process and marketing approval.
- o Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.
- o Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

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

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

DRAFT

DRAFT

9/27

# DRAFT

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

## Status

Space Needs OMB will soon recommend to you that a budget amendment be sent to Congress seeking authority for the NIH to initiate construction of a consolidated office building on the NIH campus in Bethesda. Your HIV Commission recommended construction of a consolidated office building to remove "one of the most serious research administrative obstacles ... encountered." In addition, Congress is expected to approve a lease-purchase acquisition for the Centers for Disease Control to provide additional laboratory and office space.

Resource Needs Because of the urgent need, \_\_\_\_\_ additional FTEs have been approved for HHS for FY 1989. OMB will continue to work with the Secretary to assure that adequate resources are available for HIV efforts. HHS Secretary Bowen has the authority to transfer FTEs and HIV funds among HHS agencies. OMB will address dollar resources and FTEs for HIV infection in preparing your FY 1990 budget.

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

# DRAFT

9/27



# DRAFT

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

## Status

Presidential Action Much of the FY 1989 HIV appropriations request has been enacted and signed. On August 5, you sent a letter to the Congress announcing your 10-point plan and asked Congress to expeditiously enact both the FY 1989 and FY 1990 appropriations request for HIV activities. The Labor, Health and Human Services and Education Bill was signed on September 20, and included \$1.29 billion -- a 1.2 percent decrease from your budget request.

Status of FY 1990 Request HHS submitted its FY 1990 budget request to OMB on September 1, which includes an AIDS emergency fund to meet unanticipated problems or opportunities.

FEDERAL AIDS SPENDING By Year and Department (in millions of dollars)		1982	1983	1984	1985	1986	1987	1988	1989
<b>Health &amp; Human Services</b>									
Public Health Service									
NIH		3.4	21.7	44.1	63.7	134.7	260.9	467.8	607.0
CDC		2.1	6.2	13.8	33.3	62.1	136.0	304.9	382.3
ADAMHA		0.0	0.5	2.8	2.6	12.2	47.5	112.3	175.5
HRSA		0.0	0.0	0.0	0.0	15.3	41.9	37.0	45.4
FDA		0.2	0.4	0.8	9.0	9.5	15.8	24.8	65.4
OASH		0.0	0.0	0.0	0.0	0.0	0.2	3.7	13.4
IHS		0.0	0.0	0.0	0.0	0.0	0.1	0.6	0.8
SUB-TOTAL PHS		5.6	28.7	61.5	108.6	233.8	502.5	951.0	1289.8
Hlth Care Finc. Admin.									
Medicaid (Fed Share)		0.0	10.0	30.0	70.0	130.0	200.0	330.0	490.0
Medicare		0.0	0.0	0.0	5.0	5.0	10.0	15.0	30.0
SUB-TOTAL HCFA		0.0	10.0	30.0	75.0	135.0	210.0	345.0	520.0
Social Security Admin.									
Disability Income		0.0	0.0	5.0	10.0	25.0	40.0	70.0	110.0
Supp. Security Income		0.0	0.0	1.0	3.0	8.0	11.0	18.0	28.0
SUB-TOTAL SSA		0.0	0.0	6.0	13.0	33.0	51.0	88.0	138.0
Human Development Serv.									
SUB-TOTAL HHS		5.6	38.7	97.5	196.6	401.8	763.5	1389.7	1947.8
Veterans Admin.									
Dept. of Defense		2.0	5.0	6.1	10.1	22.9	52.6	82.9	99.3
Dept. of Justice		0.0	0.0	0.0	0.0	79.0	74.0	52.0	52.0
Dept. of Labor		0.0	0.0	0.0	0.0	1.0	3.0	6.0	6.0
Dept. of State		0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
Dept. of Education		0.0	0.0	0.0	0.0	0.0	0.0	1.2	0.0
Dept. of Agriculture		0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3
SUB-TOTAL NON HHS		2.0	5.0	6.1	10.1	102.9	131.6	144.3	159.6
* * * GRAND TOTAL		7.6	43.7	103.6	206.7	504.7	895.0	1534.0	2107.4

Detail may not add to total due to rounding.

9/27

# DRAFT

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

## Status

Evaluation of Health Care Financing In response to your directive, HHS, in consultation with outside experts, has begun an evaluation of access to health care with a focus on financing and insurance, including the underinsured and uninsured, experiences of low-income disabled individuals, and disability coverage through the Social Security Administration and/or Medicaid.

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

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

Risk Pools HHS has proposed to OMB that the Administration support enactment of S.1634 which would encourage states to establish risk pools, would establish very limited Federal requirements (needing modification), and would provide \$30 million in "seed money" spread over 3 years. HHS plans to promote risk pools through the consensus conference approach and through interaction with outside organizations such as the National Governors Association.

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

# DRAFT

9/27



# DRAFT

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

## Status

Draft Plan The outline for a 3-year plan has been drafted by the Department of State, with the U.S. Agency for International Development (A.I.D.). The development of the plan will be coordinated with other Federal agencies through the HHS's Federal Coordinating Committee on AIDS, but focusses on four broad areas:

- o multilateral and bilateral activities for the prevention and control of HIV infection;
- o development of new methods of treatment and a vaccine;
- o foreign policy implications of AIDS; and,
- o budgetary implications.

The plan should be available for review by mid-October and the final report completed by mid-December.

Financial Support A.I.D. will increase its financial support for international assistance for HIV prevention programs from \$30 million in FY 1988 to \$35-40 million in FY 1989.

# DRAFT

9/27

# DRAFT

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

## Status

The Public Health Service will submit a HIV Implementation Plan in December which will identify the major goals to be carried out during FY 1989. This plan will be developed from the report of your HIV Commission and the October 1988 report of the second PHS AIDS Prevention and Control Conference, held by the Assistant Secretary for Health in June 1988. A computerized tracking and monitoring system for HHS activities in combatting HIV infection, including implementation of the Commission's recommendations will be established.

Issues, goals and objectives will be divided into nine (9) broad categories:

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

# DRAFT

9/27



# DRAFT

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

## Status

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

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

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

OPM AIDS Clearinghouse Established OPM has established a clearinghouse to make AIDS information available to agencies seeking assistance. Items included in the clearinghouse are: the President's action plan; copies of all agency policy statements; education and training materials; results of periodic surveys regarding extent of AIDS policies and programs; and AIDS education programs.

Private Sector Responding On August 17, 1988 the Director of OPM sent a letter to each of the Fortune 1000 companies telling them of the President's ten point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines."

Discrimination Laws We have not yet received a response from the Attorney General on this most sensitive and important issue, discrimination. A response is expected by \_\_\_\_\_.

# DRAFT

9/27

DRAFT

9/27  
11:00am

(date)

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

I am pleased to report that progress during the past six weeks on your 10-point action plan to fight the human immunodeficiency virus (HIV) epidemic has been remarkable.

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

Discussion Details of the progress on each of the ten points are attached (Tab A); highlights include:

- o A U.S. Health Summit on HIV infection will be held on November 28-29. This will be the first in a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- o In response to your directive to promote fairness and compassion, the largest Federal agencies (96 percent of the workforce) will have OPM guidelines in place by December.
- o FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has released approved a process to speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o Over half of the Presidential HIV Commission's recommendations for the Federal Government have been or soon will be implemented (up from 42 percent in July).
- o Unresolved Issue We have not yet received a response from the Attorney General on a most sensitive and important issue -- discrimination. A response is expected by \_\_\_\_\_.

In December I will provide you with another progress report on implementation of your 10-point plan.

DRAFT



9/27  
1:00pm  
Printer f

(date)

INFORMATION

DRAFT

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

I am pleased to report that progress during the past six weeks on your 10-point action plan to fight the human immunodeficiency virus (HIV) epidemic has been remarkable.

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

Discussion Details of the progress on each of the ten points are attached (Tab A); highlights include:

- o A U.S. Health Summit on HIV infection will be held on November 28-29. This will be the first in a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- o In response to your <sup>22</sup> directive to promote fairness and compassion, the largest Federal agencies (~~96 percent of the workforce~~) will have OPM guidelines in place by December.
- o ~~the~~ FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has ~~released~~ <sup>announced</sup> a process <sup>which</sup> will to speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o Unresolved Issue We have not yet received a response from the Attorney General on a most sensitive and important issue -- ~~anti-~~ discrimination laws.

In December I will provide you with another progress report on implementation of your 10-point plan.

DRAFT

**DRAFT**

**THE PRESIDENT'S 10-POINT ACTION PLAN**

**AGAINST HIV INFECTION**

**September Progress Report**

**DRAFT**

9/27



# 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.

## Status

Consensus Conferences In response to your letter to Secretary Bowen, HHS will convene a series of ten conferences over the next year to intensify public/private sector collaboration on a variety of HIV-related public health problems. A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989, with public and private state health officials. ISSUES: counseling, testing, and partner notification, reporting of HIV infection, and health care worker safety.

- o Five regional "mini-summits" on the "Summit" issues will be held between January and May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

o Four conferences will address specific issues you raised in your directive to HHS:

- o "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety and liability.
- o "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.
- o "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit the infection and other legal issues.
- o "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

Community Based Education Programs Funding for local HIV prevention programs will be increased by 44 percent -- from \$15 million to \$21.6 million in FY 1989.

In October <sup>these</sup> Competitive awards for HIV prevention activities will be made in October to 15 to 20 areas with high prevalence of HIV infection.

and will  
go  
9/27

DRAFT



# DRAFT

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

## Status

Notification of Transfusion Recipients Notification of transfusion recipients through "look-back" programs are underway. These programs will be strengthened through: (a) regulations making current voluntary programs mandatory (draft due mid-1989); (b) <sup>requirements</sup> ~~requiring~~ the blood industry and hospitals to notify physicians ~~that~~ <sup>which involve</sup> potentially contaminated blood units may have been released and "look-back" should be initiated; and, (c) education programs for transfusion recipients including notification, testing and counselling. By the end of 1988, special out-reach efforts will begin to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available).

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

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

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

# DRAFT

and the American  
Hospital Association

9/27



# 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.

## Status

Drug and HIV/AIDS Legislation: Most of your recent proposals for both HIV/AIDS and anti-drug efforts exist in pending legislation, but their status is uncertain at this point. On September 23, 1988, the House passed anti-drug legislation which contains many ~~evaluation of "what works" in treatment; targeting block grants through HHS to States for specific population groups, if pregnant women; and, programs aimed at high risk youth.~~ The Senate has yet to take action but is expected to successfully negotiate an anti-drug and a HIV/AIDS bill before the October recess.

*desirable features*  
*treatment features*

Several important HIV-related issues which remain unresolved:

- o **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on Congressional action on your budget request. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS, however administration of these grants is dependent upon increased funding for treatment.
- o **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.
- o **High-Risk Populations** HHS <sup>and Dept of J are</sup> is developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. The ~~Office of Juvenile Justice Drug Prevention at Justice and the Office of Substance Abuse Prevention at HHS~~ are providing technical assistance to major metropolitan areas working with high-risk youth.

# DRAFT

~~o Targeting Treatment - Block grants to the~~

9/27



# DRAFT

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

*Announced*  
Accelerate Approval Process ~~to~~ <sup>Status</sup> FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has ~~released~~ <sup>which will</sup> approved a process to speed approval of therapies to treat life-threatening illnesses such as AIDS. Key elements of the plan include:

- o Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.
- o Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).
- o Appropriate drugs will be made available for patient <sup>treatment</sup> ~~use~~ through ~~Treatment~~ Investigational New Drug <sup>status</sup> as a bridge between completion of the expedited testing process and marketing approval.
- o Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.
- o Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

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

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

DRAFT

DRAFT



# DRAFT

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

## Status

Space Needs OMB will soon recommend to you that a budget amendment be sent to Congress seeking authority for the NIH to initiate construction of a consolidated office building on the NIH campus in Bethesda. Your HIV Commission recommended construction of a consolidated office building to remove "one of the most serious research administrative obstacles ... encountered." In addition, Congress is expected to approve a lease-purchase acquisition for the Centers for Disease Control to provide additional laboratory and office space.

Resource Needs Because of the urgent need, <sup>1</sup> additional FTEs have been approved for HHS for FY 1989. OMB will continue to work with the Secretary to assure that adequate resources are available for HIV efforts. ~~HHS Secretary Bowen has the authority to transfer FTEs and HIV funds among HHS agencies. OMB will address dollar and resources and FTEs for HIV infection in preparing your FY 1990 budget.~~ *will receive priority consideration in the*

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

# DRAFT

9/27

# DRAFT

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.

*Included was a*  
*In this bill the Congress*

## Status

~~Presidential Action~~ <sup>Your</sup> Much of the FY 1989 HIV appropriations request has been enacted and signed. (On August 5, you sent a letter to the Congress announcing your 10-point plan and asked Congress to expeditiously enact both the FY 1989 and FY 1990 appropriations request for HIV activities) The Labor, Health and Human Services and Education Bill was signed on September 20, and included \$1.29 billion -- a 1.2 percent decrease from your budget request.

~~Status of FY 1990 Request~~ HHS submitted its FY 1990 budget request to OMB on September 1, which includes an AIDS emergency fund to meet unanticipated problems or opportunities.

*was appropriation*

*which you*

*was contained in the*

*address many HIV commission recommendations.*

*get the HIV commission*

FEDERAL AIDS SPENDING  
By Year and Department  
(in millions of dollars)

	1982	1983	1984	1985	1986	1987	1988	1989
<b>Health &amp; Human Services</b>								
<b>Public Health Service</b>								
NIH	3.4	21.7	44.1	63.7	134.7	260.9	467.8	607.0
CDC	2.1	6.2	13.8	33.3	62.1	136.0	304.9	382.3
ADAMHA	0.0	0.5	2.8	2.6	12.2	47.5	112.3	175.5
HRSA	0.0	0.0	0.0	0.0	15.3	41.9	37.0	45.4
FDA	0.2	0.4	0.8	9.0	9.5	15.8	24.8	65.4
OASH	0.0	0.0	0.0	0.0	0.0	0.2	3.7	13.4
IHS	0.0	0.0	0.0	0.0	0.0	0.1	0.6	0.8
<b>SUB-TOTAL PHS</b>	<b>5.6</b>	<b>28.7</b>	<b>61.5</b>	<b>108.6</b>	<b>233.8</b>	<b>502.5</b>	<b>951.0</b>	<b>1289.8</b>
<b>Hlth Care Finc. Admin.</b>								
Medicaid (Fed Share)	0.0	10.0	30.0	70.0	130.0	200.0	330.0	490.0
Medicare	0.0	0.0	0.0	5.0	5.0	10.0	15.0	30.0
<b>SUB-TOTAL HCFA</b>	<b>0.0</b>	<b>10.0</b>	<b>30.0</b>	<b>75.0</b>	<b>135.0</b>	<b>210.0</b>	<b>345.0</b>	<b>520.0</b>
<b>Social Security Admin.</b>								
Disability Income	0.0	0.0	5.0	10.0	25.0	40.0	70.0	110.0
Supp. Security Income	0.0	0.0	1.0	3.0	8.0	11.0	18.0	28.0
<b>SUB-TOTAL SSA</b>	<b>0.0</b>	<b>0.0</b>	<b>6.0</b>	<b>13.0</b>	<b>33.0</b>	<b>51.0</b>	<b>88.0</b>	<b>138.0</b>
<b>Human Development Serv.</b>								
	0.0	0.0	0.0	0.0	0.0	0.0	5.7	5.2
<b>SUB-TOTAL HHS</b>	<b>5.6</b>	<b>38.7</b>	<b>97.5</b>	<b>196.6</b>	<b>401.8</b>	<b>763.5</b>	<b>1389.7</b>	<b>1947.8</b>
<b>Veterans Admin.</b>								
	2.0	5.0	6.1	10.1	22.9	52.6	82.9	99.3
<b>Dept. of Defense</b>								
	0.0	0.0	0.0	0.0	79.0	74.0	52.0	52.0
<b>Dept. of Justice</b>								
	0.0	0.0	0.0	0.0	1.0	3.0	6.0	6.0
<b>Dept. of Labor</b>								
	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
<b>Dept. of State</b>								
	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
<b>Dept. of Education</b>								
	0.0	0.0	0.0	0.0	0.0	0.0	1.2	0.0
<b>Dept. of Agriculture</b>								
	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3
<b>SUB-TOTAL NON HHS</b>	<b>2.0</b>	<b>5.0</b>	<b>6.1</b>	<b>10.1</b>	<b>102.9</b>	<b>131.6</b>	<b>144.3</b>	<b>159.6</b>
<b>* * * GRAND TOTAL</b>	<b>7.6</b>	<b>43.7</b>	<b>103.6</b>	<b>206.7</b>	<b>504.7</b>	<b>895.0</b>	<b>1534.0</b>	<b>2107.4</b>

Detail may not add to total due to rounding.

9/27



# DRAFT

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

## Status

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

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

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

Risk Pools (HHS has proposed to OMB that the Administration support enactment of S.1634 which would encourage states to establish risk pools, would establish very limited Federal requirements (needing modifications), and would provide \$30 million in "seed money" spread over 3 years.) HHS plans to promote risk pools through the consensus conference approach, and through interaction with outside organizations such as the National Governors Association, *and*

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

# DRAFT

*the possibly through "seed money" to encourage states to establish such pools*

9/27

# DRAFT

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

## Status

Draft Plan ~~The outline for~~ <sup>by</sup> a 3-year plan <sup>has</sup> been drafted by the Department of State, with the U.S. Agency for International Development (A.I.D.). ~~The~~ <sup>Final</sup> development of the plan will be coordinated with other Federal agencies through the HHS's Federal Coordinating Committee on AIDS, ~~but focuses~~ <sup>and will</sup> on four broad areas:

- o multilateral and bilateral activities for the prevention and control of HIV infection;
- o development of ~~new methods of treatment and a vaccine,~~ <sup>therapeutic agents and vaccines</sup>
- o foreign policy implications of AIDS; and,
- o budgetary implications.

The plan should be available for review by mid-October and the final report completed by mid-December.

Financial Support A.I.D. will increase its financial support for international assistance for HIV prevention programs from \$30 million in FY 1988 to \$35-40 million in FY 1989.

DRAFT

of

9/27



# DRAFT

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

Status

held in June 1988

The Public Health Service will submit a HIV Implementation Plan in December which will identify ~~the~~ major goals to be carried out during FY 1989. This plan will be developed from the report of your HIV Commission and the October 1988 report of the second PHS AIDS Prevention and Control Conference, ~~held by the Assistant Secretary for Health in June 1988.~~ A computerized tracking and monitoring system for HHS activities in combatting HIV infection, including implementation of the Commission's recommendations will be established.

Issues, goals and objectives will be divided into nine (9) broad categories:

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

# DRAFT

9/27

# DRAFT

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

## Status

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

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

- o ~~Twenty-one agencies~~ have initiated formal training/education programs on AIDS-related issues for employees, supervisors, and managers. ~~The one remaining agency is currently developing a program.~~ *Which one?*

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

OPM AIDS Clearinghouse Established OPM has established a clearinghouse to make AIDS information available to agencies seeking assistance. ~~Items included in the clearinghouse are:~~ the President's action plan; copies of all agency policy statements; education and training materials; results of periodic surveys regarding extent of AIDS policies and programs; and AIDS education programs.

Private Sector Responding On August 17, 1988 the Director of OPM sent a letter to each of the Fortune 1000 companies telling them of the President's ten point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines." *Positive response has been*

Discrimination Laws We have not yet received a response from the Attorney General on this most sensitive and important issue, discrimination. A response is expected by \_\_\_\_\_.

*received from a number of companies thanking OPM for the mailing and announcing plans to implement the guidelines.*

*See check this out*

9/27



SD - —

ask me

@ p I

Ra

DRAFT

7:15 9/28

(date)

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

I am pleased to report that progress during the past six weeks on your 10-point action plan to fight the human immunodeficiency virus (HIV) epidemic has been remarkable.

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

Discussion Details of the progress on each of the ten points are attached (Tab A); highlights include:

- o A U.S. Health Summit on HIV infection will be held on November 28-29. This will be the first in a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- o In response to your directive to promote fairness and compassion, the 22 largest Federal agencies will have OPM guidelines in place by December.
- o FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has announced a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o Unresolved Issue We have not yet received a response from the Attorney General on a most sensitive and important issue -- anti-discrimination law.

In December I will provide you with another progress report on implementation of your 10-point plan.



THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

September Progress Report

29 September 1988

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

#### Status

Consensus Conferences In response to your letter to Secretary Bowen, HHS will convene a series of ten conferences over the next year to intensify public/private sector collaboration on a variety of HIV-related public health problems. A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989. ISSUES: counseling, testing and partner notification, reporting of HIV infection, and health care worker safety.

- o Five regional "mini-summits" will be held between January and May in New York City, Chicago, San Francisco, Dallas, and Atlanta.
- o Four conferences will address specific issues you raised in your directive to HHS:
  - "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety and liability.
  - "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.
  - "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in behaviors that transmit the infection and other legal issues.
  - "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

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



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

#### Status

Notification of Transfusion Recipients Notification of transfusion recipients through "look-back" programs are underway. These programs will be strengthened through: (a) regulations making current voluntary programs mandatory (draft due mid-1989); (b) requirements that the blood industry and hospitals notify physicians when potentially contaminated blood units may have been released and "look-back" should be initiated; and, (c) education programs for transfusion recipients including notification, testing and counselling. By the end of 1988, special out-reach efforts will begin to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available).

Improving Laboratory Quality HHS is initiating an integrated strategy to improve laboratory testing accuracy, including: (a) regulation for proficiency testing and development of standards for laboratory quality (draft due January 1989); (b) doubled inspections and surveillance of blood bank facilities; (c) enhanced training of FDA investigators who inspect blood banks; and, (d) training programs for blood establishment staff. In addition, NIH is conducting research to develop and evaluate new tests to detect HIV infection.

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

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

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

Status

Drug and HIV/AIDS Legislation: Most of your recent proposals for both HIV/AIDS and anti-drug efforts exist in pending legislation, but their status is uncertain at this point. On September 23, 1988, the House passed an anti-drug bill which contains many desirable features. The Senate has yet to take action but is expected to successfully negotiate an anti-drug and a HIV/AIDS bill before the October recess.

Several important HIV-related issues:

- o **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.
- o **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on Congressional action on your budget request. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS, however administration of these grants is dependent upon increased funding for treatment.
- o **High-Risk Populations** HHS and DoJ are developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. HHS and DoJ are providing technical assistance to major metropolitan areas working with high-risk youth.



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

Status

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

- o Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.
- o Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).
- o Appropriate drugs will be made available for patient treatment as Investigational New Drug's serve as a bridge between completion of the expedited testing process and marketing approval.
- o Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.
- o Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

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

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

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

#### Status

Space Needs OMB will soon recommend to you that a budget amendment be sent to Congress seeking authority for the NIH to initiate construction of a consolidated office building on the NIH campus in Bethesda. Your HIV Commission recommended construction of a consolidated office building to remove "one of the most serious research administrative obstacles ... encountered." In addition, Congress is expected to approve a lease-purchase acquisition for the Centers for Disease Control to provide additional laboratory and office space.

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

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



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

#### Status

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

Status of FY 1990 Request HHS submitted its FY 1990 budget request to OMB on September 1, which addresses many of your HIV commission recommendations.

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

#### Status

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

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

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

Risk Pools HHS plans to promote risk pools through the consensus conference approach, through interaction with outside organizations such as the National Governors Association, and possibly through "seed money" to encourage states to establish such pools.

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



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

Status

Draft Plan A 3-year plan outline has been drafted by the Department of State, with the U.S. Agency for International Development (A.I.D.). Final development of the plan will be coordinated with other Federal agencies through the HHS's Federal Coordinating Committee on AIDS, and will focus on four broad areas:

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

The plan should be available for review by mid-October and the final report completed by mid-December.

Financial Support A.I.D. will increase its financial support for international assistance of HIV prevention programs from \$30 million in FY 1988 to \$35-40 million in FY 1989.

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

Status

The Public Health Service will submit a HIV Implementation Plan in December which will identify major goals to be carried out during FY 1989. This plan will be developed from the report of your HIV Commission and the October 1988 report of the second PHS AIDS Prevention and Control Conference, held in June 1988. Issues, goals and objectives will be divided into nine (9) broad categories:

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

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



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

#### Status

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

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

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

OPM AIDS Clearinghouse Established A clearinghouse to make AIDS information available to agencies seeking assistance contains the President's action plan, copies of all agency policy statements, education and training materials, results of periodic surveys regarding extent of AIDS policies and programs and AIDS education programs.

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

9/28/88  
8:15 pm

DRAFT

(date)

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

I am pleased to report that progress during the past six weeks on your 10-point action plan to fight the human immunodeficiency virus (HIV) epidemic has been remarkable.

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

Discussion Details of the progress on each of the ten points are attached (Tab A); highlights include:

- o A U.S. Health Summit on HIV infection will be held on November 28-29. This will be the first in a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- o In response to your directive to promote fairness and compassion, the 22 largest Federal agencies will have OPM guidelines in place by December.
- o FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has announced a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o The Attorney General is working on issues related to anti-discrimination law -- a most sensitive and important issue.

In December I will provide you with another progress report on implementation of your 10-point plan.



THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

September Progress Report

29 September 1988

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

#### Status

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

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

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

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



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

#### Status

Notification of Transfusion Recipients Notification of transfusion recipients through "look-back" programs are underway. These programs will be strengthened through: (a) regulations making current voluntary programs mandatory (draft due mid-1989); (b) requirements that the blood industry and hospitals notify physicians when potentially contaminated blood units may have been released and "look-back" should be initiated; and, (c) education programs for transfusion recipients including notification, testing and counselling. By the end of 1988, special out-reach efforts will begin to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available).

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

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

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

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

Status

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

Several important HIV-related issues:

- o **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.
- o **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on Congressional action on your budget request. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS, however administration of these grants is dependent upon increased funding for treatment.
- o **High-Risk Populations** HHS and DoJ are developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. HHS and DoJ are providing technical assistance to major metropolitan areas working with high-risk youth.



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

Status

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

- o Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.
- o Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).
- o Appropriate drugs will be made available for treatment as Investigational New Drug's between completion of the expedited testing process and marketing approval.
- o Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.
- o Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

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

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

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

#### Status

Space Needs OMB will soon recommend to you that a budget amendment be sent to Congress seeking authority for the NIH to initiate construction of a consolidated office building on the NIH campus in Bethesda. Your HIV Commission recommended construction of a consolidated office building to remove "one of the most serious research administrative obstacles ... encountered." In addition, Congress is expected to approve a lease-purchase acquisition for the Centers for Disease Control to provide additional laboratory and office space.

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

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



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

#### Status

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

Status of FY 1990 Request HHS submitted its FY 1990 budget request to OMB on September 1, which addresses many of your HIV commission recommendations.

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

#### Status

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

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

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

Risk Pools HHS plans to promote risk pools through the consensus conference approach, through interaction with outside organizations such as the National Governors Association, and possibly through "seed money" to encourage states to establish such pools.

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