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Action Plan to Fight the Human Immunodeficiency Virus
(HIV) Epidemic] (2)

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7/14
2:30pm

(date)

DRAFT

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 To further ensure the safety of our blood supply, a number of steps have been undertaken, for example: (a) a new education program to encourage persons about to undergo elective surgery to pre donate their own blood; (b) increased inspections and proficiency testing of laboratories to ensure adequate testing of blood; and, (c) expansion of current efforts to notify transfusion recipients at risk for HIV infection.
- o Of the Presidential AIDS Commission recommendations in which the Federal Government has the primary responsibility, over half have been or soon will be implemented (up from 42 percent in July).
- o In response to your directive to promote fairness and compassion, all of the 22 largest Federal agencies are putting the OPM guidelines in place.

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

THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

HHS

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 A "U.S. Health Summit" on HIV infection will be held on November 28-29. This will be the first of a series of consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of HIV infection. [The complete conference schedule is being finalized and should be available 9/23]

10 Conf

In addition, HHS has reprogrammed a series of previously scheduled conferences to respond to the HIV epidemic, including:

- o HIV infection in racial/ethnic minority populations, FY 1989;
- o OSHA workplace standards for bloodborne diseases, January 1989;
- o Planning and management of health care services for HIV-infected patients, FY 1989;
- o Drug Abuse and AIDS, October 1988;
- o Developing appropriate services for adolescents and youth at risk of HIV infection, FY 1989;
- o Safety of health care workers, FY 1989;
- o Federal-State strategies to overcome neighborhood resistance to drug abuse treatment facilities, FY 1989.

Community Based Education Programs In FY 1989, funding for local HIV prevention programs will be doubled and will include direct funding to 15 to 20 areas with the highest prevalence of HIV infection and AIDS.

Which over PRATT

from what level over what period FY88-89

\$5.4m NY Texas
 → Not decided (done in Oct.)

CDC	→ 11.5m	16.9m
Minority Prev		412
US Conf of mayors	384	5.4m
Direct \$	-	
	<hr/>	<hr/>
	120m	23m

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THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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.

Just a plan
is HCFA

doe
NXT
early
NXT
wk

Status

Notification of Transfusion Recipients Current efforts to notify transfusion recipients through "look-back" programs are being intensified. 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. Special out-reach efforts will be taken to notify, educate, test and counsel those who were transfusion recipients between 1977 and 1985 (before the HIV screening test was available). CDC when

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Sensitive
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Mostly
tightening
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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) increased 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.

key how
much

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 media campaign 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 that will present information to health professionals on the appropriate use of autologous (and intraoperative) transfusions.

DRAFT

Mac; talk to
Frank Young
after Young
received
to discuss
presentation

FDA
Drug Bulletin
Conf. in Oct
to determine
pub. ed. campaign

DRAFT

THE PRESIDENT'S 10-POINT ACTION PLAN September Update

- 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

support?

Drug and HIV/AIDS Legislation: Your repeated calls for Congress to adopt your recommendations regarding HIV infection and drug use have resulted in positive legislation working its way through Capital Hill. [It is possible that the Omnibus Drug Bill of 1988 and separate HIV/AIDS legislation may pass before recess in October. Both these bills respond to your Ten-Point plan and support the Watkins' Commission recommendations.]

Increasing Drug Treatment Capacity: FY 89 funding for drug treatment is increased by _____. The House drug bill contains \$100 million dollars outside the block grant for IV drug users at high risk for contracting HIV/AIDS. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS.

Evaluation of Effective Treatment: Your legislative package emphasizes increased evaluation of what works in drug treatment. Both the House and Senate contain provisions for increased evaluation at the state level. [Surveys were initiated in New York City last month under contract through the CDC which will provide increased information on IV drug users and HIV/AIDS.]

Targeting High-Risk Populations: Demonstration projects are in development under HHS targeting populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. Both the House and Senate bills provide additional resources for demonstration projects targeting these groups, with concern to IV use of crack/cocaine as well as heroin. The Office of Juvenile Justice Drug Prevention (OJJDP) at the DoJ and the Office of Substance Abuse Prevention (OSAP) at HHS are providing technical assistance to major metropolitan areas working with high-risk youth. OJJDP will be holding a meeting on high-risk youth and HIV/AIDS on [September 28]. *U*

Drug Prevention Efforts: As treatment demands are met, it is critical to further the successes of our prevention and education efforts. The continued public commitment of yourself and The First Lady is invaluable in this effort. HHS has distributed a video which is being used in high schools across the country on AIDS.

Unresolved Issues: The funding of drug treatment is uncertain at this point. The negotiators you appointed on May 18 to work with Congress regarding drug legislation are addressing this matter.

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THE PRESIDENT'S 10-POINT ACTION PLAN September Update

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

avg. time ^{1/4 time} save ^{status} to a 1/5
(5 yrs)

young Jay Hoopes today

Accelerate Approval Process Working with the Vice President and the Presidential Task Force on Regulatory Relief, on September 6, the FDA forwarded to OMB a proposal that will expedite approvals for therapies to treat life-threatening illnesses such as AIDS. The proposal compresses the total premarket drug development time by having FDA work with the drug sponsor early in the course of the approval process to design and conduct controlled clinical trials to provide definitive data regarding safety and effectiveness. Other components of the proposal include the use of: treatment (IND as a bridge to) provide patients with experimental drugs between the completion of promising clinical trials and the point of marketing approval; risk-benefit considerations appropriate for drugs to treat life-threatening illnesses; and, post-marketing studies to gather additional information about the drug's risks and benefits.

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side effects

Incentives for Drug Development The Public Health Service Technology Management Advisory Board appointed a Working Group to assess private incentives for development and marketing of HIV products, including issues such as granting marketing rights and waivers of royalty or patent licensing rights. The Working Group will also examine the Federal role in encouraging reasonable pricing for HIV-related products, such as AZT, developed in part with Federal funds. The group will have a more complete submission for the December report.

under sec
does not
agree
w/indus
controversial

Liability Issue HHS is investigating the liability issue as to whether it might pose impediments for the development of HIV-related products, in particular vaccines. HHS will consult with private groups -- the Keystone Group and the Institute of Medicine -- who are also studying the issue, and will collaborate with representatives from the Department of Justice and the Department of Defense. A more complete submission will be available for the December report.

weak

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for legis prof
(not drastic)

DRAFT

→ Childrens drug liability law
→ IOM mtg
Rpt
send
devel legis

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THE PRESIDENT'S 10-POINT ACTION PLAN September Update

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 direct construction of a consolidated office building on its Bethesda campus. The amendment does not affect budget authority or outlays and is consistent with the Bipartisan Budget Agreement. Congress is expected to approve a lease-purchase acquisition for the Centers for Disease Control which they have under review to provide additional laboratory and office space.

Resource Needs Mr. Miller has written to Secretary Bowen stating that OMB intends to work with HHS to remove all other impediments to the use of resources and will continue to encourage HHS to reallocate resources within its purview to address pressing AIDS resource needs. OMB expects to address dollar resources for AIDS and HIV infection in the context of the FY 1990 budget.

Unresolved Issues No decision has been made by [OMB] regarding the HHS proposed Senior Biomedical Research Service at NIH to recruit scientists to the Federal laboratory to perform HIV-related research. HHS is also concerned that funding for HIV activities is done by offsets within their budget.

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THE PRESIDENT'S 10-POINT ACTION PLAN September Update

6. **Asks Congress to accelerate enactment of his FY 1989 HIV appropriations request & 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, the President 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.

Congressional Action on FY 1989 Appropriation Congress has not yet approved the appropriations for HIV-related activities so the total Federal funding picture for AIDS is uncertain. The House passed the Labor, Health and Human Services and Education Bill on September 9, 1988 providing \$1.29 billion -- a 1.2 percent decrease from the President's budget request. The Senate has not set a date for action.

signed

Status of FY 1990 Request HHS submitted its FY 1990 budget request to OMB on September 1. The component of the budget related to HIV activities has been developed taking into account the Presidential Commission recommendations. It also contains funding for a special HIV emergency fund.

how much?

DRAFT

*Rich Jacob
at OMB*

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THE PRESIDENT'S 10-POINT ACTION PLAN September Update

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.

(Planning) Status
1 year

Evaluation of Health Care Financing By December 1, a Health Care Financing Administration (HCFA) team, with outside contract experts, will begin an evaluation of the availability of health care as well as financing and insurance issues. Particular attention will be paid to experiences of low-income disabled individuals and disability coverage through the Social Security Administration and/or Medicaid.

Uninsured &
Underinsured

Alternatives to Acute Care HCFA has included studies of the effectiveness of out-of-hospital and case managed care in their 1989 research and demonstration project solicitation. The solicitation encourages studies on the use of Medicaid waivers, hospice care, home health and other ambulatory services to provide cost-effective alternatives to inpatient care for HIV patients. HCFA will coordinate its activities with PHS service demonstration and research grants activities.

due
when

Risk Pools HHS has begun development of several model risk pool statutes and tentatively plans to promote risk pools through the consensus conferences and through interaction with outside organizations. HHS has proposed to OMB that the Administration support S. 1634 which would encourage state risk pools.

Moving
forward

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

Promoting
model statutes
Durenberger Bill
HHS vs. OMB

Nat Gov Assn
Nat Cong of Leg's
Nat Assn of
Ins Commissioners

DRAFT

THE PRESIDENT'S 10-POINT ACTION PLAN September Update

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 Department of State, with the U.S. Agency for International Development (A.I.D.), has drafted an outline for the 3-year plan. 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.

all allowed budget wise

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THE PRESIDENT'S 10-POINT ACTION PLAN September Update

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

Status

The Assistant Secretary for Health convened a second PHS AIDS Prevention and Control Conference in early June 1988 in Charlottesville, Virginia, to develop an updated plan for combatting HIV infection. The report of that meeting is scheduled to be published in October and is intended as a guide for the Public Health Service to manage its billion dollar a year HIV program. The issues, goals and objectives are 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.

The PHS report will be used to develop an HIV Implementation Plan which will identify the major goals to be carried out in FY 1989. HHS plans to use the Report and the report of the Presidential Commission Report to establish a tracking and monitoring system for HHS activities in combatting HIV infection.

computer

A more complete submission will be available for the December report.

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THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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 are Complying The Office of Personnel Management's Agency of Compliance and Evaluation staff conducted a telephone survey of the largest 22 Federal agencies in July and a follow in August and report the following:

- 96% of workforce*
- o All 22 agencies are putting AIDS policy guidelines in place. Seven agencies have issued AIDS policies. Fourteen others are presently drafting policies/guideline 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 now offer counseling and referral services for AIDS-related issues through their Employee Assistance Programs or medical services facilities.

Identify the 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 200 companies telling them of the President's ten point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines." [examples of industry response to be added]

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THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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 The date has been set for the first conference. HHS will host a "U.S. Health Summit" on HIV infection November 28-29. This will be the first of a series of ten consensus conferences to address ways in which to intensify public/private sector collaboration on public health measures to reduce the spread of HIV infection. Thus far, the following conferences have been scheduled:

????????????????????

In addition, HHS has reprogrammed a series of previously scheduled conferences to respond to the HIV epidemic, including:

- o HIV infection in racial/ethnic minority populations, FY 1989;
- o OSHA workplace standards for bloodborne diseases, January 1989;
- o Planning and management of health care services for HIV-infected patients, FY 1989;
- o Drug Abuse and AIDS, October 1988;
- o Developing appropriate services for adolescents and youth at risk of HIV infection, FY 1989;
- o Safety of health care workers, FY 1989;
- o Federal-State strategies to overcome neighborhood resistance to drug abuse treatment facilities, FY 1989.

Community Based Education Programs In FY 1989, funding for local HIV prevention programs will increase by 44 percent -- from \$15 million to \$21.6 million. In October, grants will be awarded to 15 to 20 areas with high prevalence of HIV infection and AIDS.

DRAFT

THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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 virus in blood.

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

Status

Drug and HIV/AIDS Legislation: Resolution of your anti-drug proposals is uncertain at this point. We are working with Congress regarding the pending drug legislation. Your proposals for both HIV/AIDS and anti-drug efforts exist in pending legislation. However, almost \$13 million has been cut from your budget request during the FY 1989 appropriations process and Congress is not expected to successfully negotiate either an anti-drug or HIV/AIDS bill before the October recess. The important issues may remain unresolved, including:

- **Increasing Drug Treatment Capacity** 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.
- **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of what works in drug treatment. Both the House and Senate contain provisions for increased evaluation at the state level.
- **Targeting High-Risk Populations** HHS is developing demonstration projects targeting 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 (OJJDP) at DOJ and the Office of Substance Abuse Prevention (OSAP) at HHS are providing technical assistance to major metropolitan areas working with high-risk youth. OJJDP will be holding a meeting on high-risk youth and HIV/AIDS on [September 28].

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THE PRESIDENT'S 10-POINT ACTION PLAN September Update

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

Status

Accelerate Approval Process On September 6, the FDA forwarded to OMB a proposal that will expedite approvals for therapies to treat life-threatening illnesses such as AIDS. Developed, in coordination with the Vice President and the Presidential Task Force on Regulatory Relief, the proposal compresses the total premarket drug development time by having FDA work with the drug sponsor early in the course of the approval process to design and conduct controlled clinical trials to provide definitive data regarding safety and effectiveness -- this could save from _____ to _____. Other components of the proposal include: providing patients with clinically tested yet experimental drugs prior to marketing approval; exceptions for the use of possible, yet unproven, drugs to treat life-threatening illnesses; and, post-marketing studies regarding to gather additional information about the drug's risks and benefits.

Incentives for Drug Development The Public Health Service Technology Management Advisory Board appointed a Working Group to assess private incentives for development and marketing of HIV products, including issues such as granting marketing rights and waivers of royalty or patent licensing rights. The Working Group will also examine the Federal role in encouraging reasonable pricing for HIV-related products, such as AZT, developed in part with Federal funds. The group will have a more complete submission for the December report.

Liability Issue HHS is investigating the liability issue as to whether it might pose impediments for the development of HIV-related products, in particular vaccines. HHS, per one Commission recommendation, is doing so in consultation with private groups, particularly the Keystone Group and the Institute of Medicine, and will collaborate with representatives from the Department of Justice and the Department of Defense.

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THE PRESIDENT'S 10-POINT ACTION PLAN September Update

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 which they have under review to provide additional laboratory and office space.

Resource Needs 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 Recruitment and retention of science personnel are being address by OPM and a more complete answer will be available for the December report.

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THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

6. Asks Congress to accelerate enactment of his FY 1989 HIV appropriations request & 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 and 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
Health & Human Services								
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	
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	1224.4
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.	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	1963.2
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	2122.8

THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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 By December 1, a Health Care Financing Administration (HCFA) team, with outside contract experts, will begin an evaluation of the availability of health care as well as financing and insurance issues, especially for the underinsured and uninsured. Particular attention will be paid to experiences of low-income disabled individuals and disability coverage through the Social Security Administration and/or Medicaid.

Alternatives to Acute Care HCFA has included studies of the effectiveness of out-of-hospital and case managed care in their 1989 research and demonstration project solicitation. The solicitation will begin early in FY 1989 and encourages studies on the use of Medicaid waivers, hospice care, home health and other ambulatory services to provide cost-effective alternatives to inpatient care for HIV patients. HCFA will coordinate its activities with PHS service demonstration and research grants activities.

Risk Pools HHS has evaluated existing risk pools in States and has begun development of several model risk pool statutes. 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

THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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

THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

DRAFT

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

Status

The report of the second PHS AIDS Prevention and Control Conference, held by the Assistant Secretary for Health in June 1988, is scheduled to be published in October. The report will be a guide for the Public Health Service to manage its billion dollar a year HIV program. The issues, goals and objectives are 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.

The PHS report will be used to develop an HIV Implementation Plan which will identify the major goals to be carried out in FY 1989. HHS plans to use the Report and the report of the Presidential Commission Report to establish a computerized tracking and monitoring system for HHS activities in combatting HIV infection, including implementation of the Commission's recommendations.

A more complete submission will be available for the December report.

DRAFT

THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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 are Complying A telephone survey of the largest 22 Federal agencies (96 percent of the Federal workforce) begun in July, followed in August with a supplemental survey. The Office of Personnel Management reports the following:

- o All 22 agencies are putting AIDS policy guidelines in place. Seven agencies have issued AIDS policies. Fourteen others are presently drafting policies/guideline 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 now offer counseling and referral services for AIDS-related issues through their Employee Assistance Programs or medical services facilities.

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."

DRAFT



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

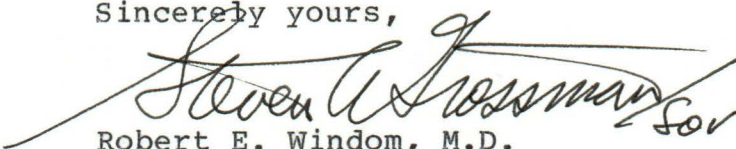
SEP 19 1988

Donald I. Macdonald, M.D.
Deputy Assistant to the President
Director, Drug Abuse Policy Board
The White House
Washington, D.C. 20500

Dear Dr. Macdonald:

The Secretary asked me to respond to your request of September 14. Please find enclosed the responses to individual recommendations of the Presidential Commission on the HIV Epidemic detailing the additional specific information you requested. My staff worked with Sue Daoulas in preparing this package. We appreciate having the opportunity to clarify these responses.

Sincerely yours,


Robert E. Windom, M.D.
Acting Assistant Secretary for Health

Enclosures

COMMENTS ON HIV REPORT RECOMMENDATIONS

1-6 In all federal agencies all relevant job and program titles should clearly reflect HIV infection as the target of concern.

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- A = Completed/Ongoing
- B = Planned
- C = Under Consideration
- D = Disagree
- E = Other

- F = Agree
- G = Disagree
- H = Neutral
- I = Other

Organizations Providing Comments

Federal : HHS (CDC)
Non-Federal:

Comments

Where appropriate, this has been done. However, widespread use of the term could become a source of confusion for the general public. For the sake of clarity in educational materials and programs, infection with HIV has been referred to as infection with the AIDS virus. This recommendation needs further consideration.

Staff position Within 60 days, HHS should submit a report on whether job or program titles need any modification to reflect concern for HIV infection.

AsPE - Suggests the President ask OPM to consider this recommendation and act if appropriate. Meanwhile, within HHS, assign to ASPE



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

Recommendation # 1-6 Department/Agency HHS/CDC

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

- | | |
|---|---|
| <input type="checkbox"/> Planned for FY 1990 | <input type="checkbox"/> Further study needed |
| <input type="checkbox"/> Alternative approach | <input checked="" type="checkbox"/> Other |

Please elaborate on the status below:

CDC has been including reference to HIV in job descriptions, as appropriate, as new descriptions are written. ~~During the~~ Changes in the names of programs and organizational units within CDC also are being considered and recommendations submitted for approval ~~is~~ as part of reorganization.

OK-ASPE

COMMENTS ON HIV REPORT RECOMMENDATIONS

3-1 DHHS should administer a competitive grant or contract program, or organized consensus conferences, to construct HIV treatment guidelines for practitioners in differing practice environments encompassing a range of medical specialties and including other disciplines. The guidelines developed should then be made available to all practitioners who request them.

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- X A = Completed/Ongoing
- B = Planned
- C = Under Consideration
- D = Disagree
- E = Other

- F = Agree
- G = Disagree
- H = Neutral
- I = Other

Let's let the health professions make the recommendations

Organizations Providing Comments

Federal : HHS (HRSA, NIH), DoD
Non-Federal:

Comments

The HRSA acts as a catalyst in this effort, sponsoring and convening conferences and meetings to help the health professions reach consensus on the need for such treatment guidelines, following on the guidelines issued by the CDC and the recommendations of the Intragovernmental Task Force on AIDS Health Care Delivery. The responsibility for actually developing such guidelines belongs to the health professions.

NIH also has a major role to play in developing consensus regarding the state-of-the-art care for individuals infected with HIV.

DoD developed the Walter Reed staging system to aid practitioners in defining the disease process and providing a means of comparing treatment guidelines for various stages of the disease process. DoD part icipates in national and international exchanges of information focusing on recent developments in treatments.

Staff position: Within 60 days, HHS, in consultation with relevant agencies, should make a recommendation whether the development of such guidelines are possible or practical at present and, if so, how they should be developed.

2

COMMENTS ON HIV REPORT RECOMMENDATIONS

3-27 The NHSC should provide scholarship funds at the undergraduate level to minority students to allow more minorities to continue their education through the professional degree level, with repayment of these scholarship through service in underserved, HIV-endemic areas.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<input type="checkbox"/> A = Completed/Ongoing	<input type="checkbox"/> F = Agree
<input type="checkbox"/> B = Planned	<input type="checkbox"/> G = Disagree
<input type="checkbox"/> C = Under Consideration	<input type="checkbox"/> H = Neutral
<input checked="" type="checkbox"/> D = Disagree	<input type="checkbox"/> I = Other
<input type="checkbox"/> E = Other	

Organizations Providing Comments

Federal : HHS (HRSA)
Non-Federal:

Comments

Staff position: The NHSC was created in 1970 to remedy a physician shortage. Focusing efforts to serve HIV-infected individuals through expansion of the NHSC is the wrong direction because it: really does not resolve any larger issues of recruitment of health care providers to care of HIV patients; and suggests that government and the professional organizations like the American Medical Association are not serious about the general obligation of all physicians and other health care providers to serve HIV-infected patients in their practice. However, this is not inconsistent with the assignment of some NHSC physicians and other health care providers, in appropriate circumstances, to facilities with significant HIV infected populations.

There are no \$'s to give for any scholarship programs & there is no authority to give \$ to undergraduates. Would require new legislation

COMMENTS ON HIV REPORT RECOMMENDATIONS

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

Proposed Federal Position

Federal Responsibility		Non-Federal Responsibility	
_____	A = Completed/Ongoing	_____	F = Agree
_____	B = Planned	_____	G = Disagree
<u>X</u>	C = Under Consideration	_____	H = Neutral
_____	D = Disagree	_____	I = Other
_____	E = Other		

Organizations Providing Comments

Federal : HHS (NIH)
Non-Federal: PMA

Comments

by *in the* The recommendation has budget considerations and ~~will be considered~~ *has been addressed* within HHS ~~during~~ the 1990 budget process. In general, the problem of crowding at the NIH Bethesda facility is recognized.

PMA in general agrees with recommendation but defers to federal sector for evaluation.

Staff position: Recommendation ^{is} ~~should be included in the list of items that the proposed OMB committee consider.~~

By FY 1990 budget submission preliminary

COMMENTS ON HIV REPORT RECOMMENDATIONS

4-8 Construction of the NIH Consolidated Office Building should be made a high priority and GSA's approval be expedited.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
_____ A = Completed/Ongoing	_____ F = Agree
_____ B = Planned	_____ G = Disagree
<u>X</u> _____ C = Under Consideration	_____ H = Neutral
_____ D = Disagree	_____ I = Other
_____ E = Other	

Organizations Providing Comments

Federal : HHS (NIH)
 Non-Federal: PMA

Comments

The building raises problems of funding and policy (lease-purchase) that are currently under consideration at OMB. NIH supports the recommendation as does PMA. PMA defers to the federal sector for evaluation.

~~Staff position: Recommendation should be included in the list of items that the proposed OMB committee considers.~~

Additional included in '89 Conference acting on proposed budget amendment, and limited to in conference '89 budget for build the preliminary FY 1990 budget submission.

15 M in '89 for initial work (planning) conference OMB has not made a formal decision on this.

In its FY 1989 Conference Action on HHS appropriations Congress provided \$15 M for planning and design of the building. Also, OMB is reviewing a budget amendment for NIH which will allow NIH to use funds appropriated in FY 88, FY 89, and FY 90 along with unobligated/recovered grant funds from FY 88 and FY 89 to complete the building (not to exceed \$96 million in total cost). Additional resources for this building are included in the HHS FY 1990 preliminary budget to OMB.

COMMENTS ON HIV REPORT RECOMMENDATIONS

4-9 NIH construction authority should be reinstated during the Congressional reauthorization of NIH in 1988 to provide for the expeditious granting of funds to universities or medical centers for construction or renovation of research facilities. Construction funds should be available in FY89.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
_____ A = Completed/Ongoing	_____ F = Agree
_____ B = Planned	_____ G = Disagree
<u>X</u> _____ C = Under Consideration	_____ H = Neutral
_____ D = Disagree	_____ I = Other
_____ E = Other	

Organizations Providing Comments

Federal : HHS (NIH)
Non-Federal: PMA

Comments

Implementation of the recommendation poses major budgetary, policy, and legislative (no authority) concerns for NIH, *AND does not represent*

~~Staff position: Since this recommendation is more generic than HIV related, it should be considered by HHS as part of the FY 1990 budget request.~~

AND must be balanced against other competing high priority needs.

→ the highest priority of NIH which still remains research project grants, intramural research, research training and career development. Extramural AIDS construction funds were provided in FY88 (\$24M) and FY89 Conference Action (\$5M).

COMMENTS ON HIV REPORT RECOMMENDATIONS

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

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<input type="checkbox"/> A = Completed/Ongoing	<input type="checkbox"/> F = Agree
<input type="checkbox"/> B = Planned	<input type="checkbox"/> G = Disagree
<input checked="" type="checkbox"/> C = Under Consideration	<input type="checkbox"/> H = Neutral
<input type="checkbox"/> D = Disagree	<input type="checkbox"/> I = Other
<input type="checkbox"/> E = Other	

Organizations Providing Comments

Federal : HHS(NIH)
Non-Federal: PMA

Comments

Comment at 4-9 apply here.

PMA supports in concept but defers to federal sector for evaluation.

Staff position: ~~since~~ This recommendation is more generic than HIV related. ~~It should be considered by HHS as part of the FY 1990 budget request.~~

And must be weighed against other high priority needs. Funds for this purpose were provided in FY 88 (\$24m) and FY 89 (\$5m).

COMMENTS ON HIV REPORT RECOMMENDATIONS

4-11 Funds should be made available to the NIH Division of Research Services to upgrade or renovate 20 existing laboratories to P-3 level.

Proposed Federal Position

Federal Responsibility		Non-Federal Responsibility	
<u> </u>	A = Completed/Ongoing	<u> </u>	F = Agree
<u> X </u>	B = Planned	<u> </u>	G = Disagree
<u> </u>	C = Under Consideration	<u> </u>	H = Neutral
<u> </u>	D = Disagree	<u> </u>	I = Other
<u> </u>	E = Other		

Organizations Providing Comments

Federal : HHS (NIH), DoD
Non-Federal: PMA

Comments

Upgrading of several facilities to P3 are likely to be funded in 1988. Further implementation would require additional funds.

DoD has committed funds to upgrade one laboratory to P-3, and is planning to issue a contract to upgrade a separate facility for retroviral research.

PMA supports but defers to federal sector.

~~Staff position: Recommendation should be considered by HHS as part of the FY 1990 budget request.~~

COMMENTS ON HIV REPORT RECOMMENDATIONS

4-16 The OPM and the GSA should respond within 21 days to HIV-related priority requests from the Directors of the National Institute for Allergy and Infectious Diseases, National Cancer Institute, and the CDC, or any additional director designated by the Secretary of HHS. Since the Commission's interim report, no identifiable change has occurred.

Proposed Federal Position

Federal Responsibility		Non-Federal Responsibility	
<u>X</u>	A = Completed/Ongoing	<u> </u>	F = Agree
<u> </u>	B = Planned	<u> </u>	G = Disagree
<u> </u>	C = Under Consideration	<u> </u>	H = Neutral
<u> </u>	D = Disagree	<u> </u>	I = Other
<u> </u>	E = Other		

Organizations Providing Comments

Federal : OPM
Non-Federal: PMA

Comments

OPM already gives priority to requests to fill AIDS research or other AIDS-related positions. They say their turnaround time is faster than the 21 days the Commission recommends.

GSA did not respond.

Staff position: If HHS perceives there is a problem, they should raise the issue for discussion by the proposed OMB committee.

9/16/88

~~CDC has all PHS~~
NHS has responded
affirmatively to all
PHS request for AIDS
FTE.

ASMB
ASMB
edits →

Recommendation 4-16: CDC has not had problems with OPM concerning positions.

Any hiring delays have been due to ~~lack of PHS~~, normal ~~bureaucratic~~ recruitment and hiring procedures, and noncompetitive salaries. In acquiring additional rental space, GSA has been very cooperative. However, OMB has in the past, taken steps that prohibited GSA from exercising authority with respect to new construction. New language in 89 appropriations bills instructing GSA to construct three new buildings for CDC is expected to be approved by OMB, but no official notification from GSA that they will proceed has yet been received.

Recommendation 5-5: Completed.

ASMB
edits →

Recommendation 7-7: No funds have been budgeted in fiscal year 1989 for conducting a study of the use of paid advertising. ~~Funds had been requested in fiscal year 1990 for such a study; however, they have been eliminated from the budget request pending before OMB.~~

ASMB

Recommendation 11-23: CDC agrees with the staff position.

COMMENTS ON HIV REPORT RECOMMENDATIONS

4-95 Wherever legal restrictions bar the entry of "boarder babies" and other foster children into clinical trials, these restrictions must be examined and challenged as appropriate, to make certain that these children are not being denied access to palliative or possibly curative therapies.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<input type="checkbox"/> A = Completed/Ongoing	<input type="checkbox"/> F = Agree
<input type="checkbox"/> B = Planned	<input type="checkbox"/> G = Disagree
<input checked="" type="checkbox"/> C = Under Consideration	<input type="checkbox"/> H = Neutral
<input type="checkbox"/> D = Disagree	<input type="checkbox"/> I = Other
<input type="checkbox"/> E = Other	

Organizations Providing Comments

Federal : HHS (NIH)
Non-Federal:

Comments

Inclusion of boarder babies in pediatric clinical trials is under active consideration. See discussion under recommendation 4-91.

~~Staff position: Need to determine whether this is a federal or non-federal responsibility.~~

The babies are ~~not~~ wards of the ~~federal~~ ^{states} government.
The Department's pediatric AIDS ~~but once NIH determines whether or not~~ ^{subgroup is examining this issue in order} ~~clinical trials~~ ^{to identify technical assistance to help facilitate States' decision-making processes for permitting the infants} ~~these children can participate (protocols for clinical trials), then states will have~~ ^{to review their policies for allowing participation} ~~of such participation is an option.~~

COMMENTS ON HIV REPORT RECOMMENDATIONS

5-10 Congress, in conjunction with OPM, should analyze the recruitment of personnel to the CDC. Federal salaries and benefits should be assessed. Following such an analysis, Congress should make every effort to enact legislation that will attract first-rate personnel to CDC.

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- _____ A = Completed/Ongoing
- _____ B = Planned
- X _____ C = Under Consideration
- _____ D = Disagree
- _____ E = Other

- _____ F = Agree
- _____ G = Disagree
- _____ H = Neutral
- _____ I = Other

Organizations Providing Comments

Federal : HHS (CDC)
Non-Federal:

Comments

The PHS has developed a proposal that would provide extra compensation for certain scientific positions and is currently under consideration.

Staff position: Recommendation should be included in the list of items that the proposed OMB committee should consider in their 60 day plan.

THE ~~ADMINISTRATIVE~~ PROPOSAL ^{to establish} FOR A SENIOR BIOMEDICAL RESEARCH SERVICE IS UNDER CONSIDERATION AT OMB.

A SIMILAR PROPOSAL IS PART OF S. 2222 - ~~WHICH IS~~

C ①
ADAMHA

COMMENTS ON HIV REPORT RECOMMENDATIONS

8-1 In the near term, NIDA, with state agencies, local drug abuse officials, and drug treatment providers, should develop a plan for increasing the capacity of the drug treatment system so the goal of treatment-on-demand can be met. The plan should designate an implementing office with the staff and technical capacity to guide implementation of the plan. The plan should provide for matching funding on a 50 percent federal and 50 percent state-and-local basis. It should have elements for a phased, targeted increase in programs insuring the quality of care, and mechanisms to evaluate progress and make appropriate adjustments.

* NIDA has developed a draft 5-year plan that is currently under review within the Department.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
_____ A = Completed/Ongoing	_____ F = Agree
_____ B = Planned	_____ G = Disagree
_____ C = Under Consideration	_____ H = Neutral
_____ D = Disagree	_____ I = Other
<u>X</u> E = Other	

Organizations Providing Comments

Federal : DOD, HHS (ADAMHA)
Non-Federal:

Comments

DOD comments that it has a program for alcohol and/or drug abuse in place.

Staff position: Agree that expansion of drug capacity is ^{needed} needed. How best to achieve this goal and what level of expansion is appropriate is under consideration. In regard to the issue of "treatment on demand", the Administration supports the concept of providing high quality treatment to as many individuals as possible.

ADAMHA (NIDA) comments that "getting IVDA's into treatment to enable them to stop injecting drugs is a high priority in AIDS prevention". ^{Increased funding for drug abuse treatment is included in the FY 1990 preliminary budget submission to OMB.} ~~and states that it "agrees with reservations about targeting money and accountability"~~ ~~approximately \$1.5B annually beyond current expenditures is required.~~

2

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

Recommendation # 8-1

Department/Agency HHS (ADAMHA)

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

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

Please elaborate on the status below:

ADAMHA agrees with IVDA treatment expansion
~~but questions the use of~~
~~noting that: 1) it requires additional funds; and~~
~~2) such expansion is under consideration.~~

ADAMHA
~~ADAMHA~~
3

COMMENTS ON HIV REPORT RECOMMENDATIONS

8-6 As an interim step until new treatment facilities can be developed, state drug abuse agencies should consider contracting with allied health professionals and social workers or organizations to serve as case managers for drug abuse clients. Case managers, who need not be affiliated with traditional drug abuse facilities, could procure medical, educational, job training and social services, and other necessary services, from existing community resources. They could assess client needs develop individualized treatment plans, procure services, and monitor service delivery. The federal government should provide demonstration funds for projects that use the case management approach to bring external community resources into treatment plans.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<input type="checkbox"/> A = Completed/Ongoing	<input type="checkbox"/> F = Agree
<input type="checkbox"/> B = Planned	<input type="checkbox"/> G = Disagree
<input checked="" type="checkbox"/> C = Under Consideration	<input type="checkbox"/> H = Neutral
<input type="checkbox"/> D = Disagree	<input type="checkbox"/> I = Other
<input type="checkbox"/> E = Other	

Organizations Providing Comments

Federal : HHS (ADAMHA)
Non-Federal: IHPP

Comments

Agree with modification. State drug treatment programs vary in ability to provide inclusive services. Some case management services are ongoing through two NIDA programs -- the AIDS Community Outreach and Counseling Demonstration Project. Whether additional Federal efforts are needed is a matter of discussion within HHS.

ADAMHA (4)

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

Recommendation # 8-6 Department/Agency HHS (ADAMHA)

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

Planned for FY 1990 Further study needed
 Alternative approach Other

Please elaborate on the status below:

As noted, ADAMHA feels approach merits further study. Although coordinated, on-site care is desirable, ADAMHA notes "significant disadvantages" with this approach because of lack of experience by such professionals in working with addicts.

ADAMHA is looking at other alternatives ^{so as to} ~~not~~ provide primary ^{health} care services and drug abuse treatment services to those individuals on waiting lists. They think ^{that} there ~~are other~~ are other solutions beyond ^{using} case managers. They are negotiating with DoD and HHS to use unused DoD hospitals to care for IVDA's, and also ^{they are} working with HHS to use their community health program facilities. (3)

COMMENTS ON HIV REPORT RECOMMENDATIONS

8-10 Effective drug treatment, especially in this HIV epidemic, includes dealing not only with the health care needs of patients but also of their families. Treatment should include on-site primary services or referrals to community health centers, mental health centers, and other accessible community-based resources.

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- A = Completed/Ongoing
- B = Planned
- C = Under Consideration
- D = Disagree
- E = Other

- F = Agree
- G = Disagree
- H = Neutral
- I = Other

Organizations Providing Comments

Federal : HHS (ADAMHA)

Non-Federal:

Comments

~~States could use the ADMS Block Grant to implement this recommendation, ADAMHA reports.~~

~~Staff position: Ask HHS to evaluate the merits of this recommendation and consider whether implementation/demonstration through HRSA programs such as the Migrant Health Centers and Community Health Centers is feasible.~~

~~The~~ ADAMHA/HRSA are working on improving the integration of grant supported services in the fields of alcohol/drug Rx & treatment ~~at~~ ~~the~~ community & migrant health care centers.

COMMENTS ON HIV REPORT RECOMMENDATIONS

8-15 A significant increase in trained personnel will be needed to implement new programs. Approximately 59,000 persons will be needed to join the ranks of drug abuse workers. New staff training programs should be developed at universities, community colleges, vocational and technical schools, and through internships in existing drug programs and the training of ex-addicts. Curricula dealing with education, prevention, and treatment of substance abuse and HIV should be developed throughout the educational systems for physicians, nurses, and social service workers. Federal leadership is needed to foster and identify model curricula for training programs as well as establishing the fields of drug abuse prevention, treatment, and research as viable and rewarding professions.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<u> </u> A = Completed/Ongoing	<u> </u> F = Agree
<u> </u> B = Planned	<u> </u> G = Disagree
<u> </u> C = Under Consideration	<u> </u> H = Neutral
<u> </u> D = Disagree	<u> </u> I = Other
<u> X </u> E = Other	

Organizations Providing Comments

Federal : HHS (ADAMHA)
 Non-Federal:

Comments

NIDA's training program is limited to research and AIDS-related efforts. Basic training in drug treatment/outreach would require a major expansion of the Federal role. *plan prepared by PHS.*

Staff position: HHS should consider implementation of this recommendation within the context of the FY 1990 budget.

The need to improve substance abuse training in the curricula of health professionals is one of the activities included in the drug abuse demand reduction plan prepared by PHS.

~~This needs revision to reflect professional ~~activities~~ educational activities included in the new PHS Demand Reduction Plan - see Draddy Downs.~~

ADAMHA
5

COMMENTS ON HIV REPORT RECOMMENDATIONS

8-25 The ADAMHA's Office of Substance Abuse Prevention should sponsor more research into the root cause of drug abuse, determination of those at greatest risk, and the most effective means of preventing drug abuse.

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- _____ A = Completed/Ongoing
- _____ B = Planned
- ~~_____ C = Under Consideration~~
- ~~_____ D = Disagree~~
- _____ E = Other

- _____ F = Agree
- _____ G = Disagree
- _____ H = Neutral
- _____ I = Other

Organizations Providing Comments

Federal : HHS (ADAMHA)
Non-Federal:

Comments

Federal funding of such research is under consideration as part of the FY 1990 budget process.

Right idea. Wrong administrative entity:
 ADAMHA (NIDA) is responsible for studying the etiology of drug abuse, the assessment of risks, and the most effective ways to prevent drug abuse. ADAMHA (NIDA) agrees with intent of recommendation, noting that it requires additional funds.

→ NIDA's current research portfolio addresses these areas.

→ to sponsor more research.

COMMENTS ON HIV REPORT RECOMMENDATIONS

8-83 The HHS should study reimbursement regulations and practices with regard to those voluntary organizations which serve indigent populations to ensure that regulations are not unnecessarily restrictive.

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- A = Completed/Ongoing
- B = Planned
- C = Under Consideration
- D = Disagree
- E = Other

- F = Agree
- G = Disagree
- H = Neutral
- I = Other



Organizations Providing Comments

Federal :
Non-Federal:

Comments

~~HHS should be requested to report back with a response to this recommendation within 30 days.~~

ASPE

As part of the Department's ongoing attention to the public financing of health care for persons infected with HIV, the Department will continue to maintain a federal commitment to... and... and...

COMMENTS ON HIV REPORT RECOMMENDATIONS

9-6 The Office of Civil Rights within each agency should develop policy guidelines that state that all HIV-infected persons, including those who are asymptomatic, are subject to the jurisdiction of the Office. The agencies should publicize the availability of the services of their Offices of Civil Rights to those who have experienced HIV-related discrimination and should publish their intent to investigate actively all complaints. The agencies should distribute these policy guidelines to all contractors and grantees.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<input type="checkbox"/> A = Completed/Ongoing	<input type="checkbox"/> F = Agree
<input type="checkbox"/> B = Planned	<input type="checkbox"/> G = Disagree
<input checked="" type="checkbox"/> C = Under Consideration	<input type="checkbox"/> H = Neutral
<input type="checkbox"/> D = Disagree	<input type="checkbox"/> I = Other
<input type="checkbox"/> E = Other	

Organizations Providing Comments

Federal : DOJ, HHS, Treasury
Non-Federal:

Comments

DOJ would favor handling HIV-infection cases in the same manner as federal civil rights offices handle their other responsibilities on nondiscrimination activities.

HHS would like to take a more active role. It plans to issue a letter to all grantees alerting them to their AIDS-related anti-discrimination obligations.

Treasury will post policy in all bureau facilities. In addition, there will be disclosure of the procedures to process HIV-related complaints.

Staff position: Allow agencies to set their own policy above the minimum stated by DOJ.

HHS has issued this letter.

COMMENTS ON HIV REPORT RECOMMENDATIONS

9-7 All agency Offices of Civil Rights should establish a system of aggressive investigation of violations of Sec. 504 in HIV infection-related cases, including expedited procedures for review of complaints and regular monitoring of procedures.

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- A = Completed/Ongoing
- B = Planned
- C = Under Consideration
- D = Disagree
- E = Other

- F = Agree
- G = Disagree
- H = Neutral
- I = Other

Organizations Providing Comments

Federal : HHS, Treasury
Non-Federal:

Comments

* HHS reports that it has already implemented such procedures.

Treasury files cases under 504 directly with the Departmental decision-maker who can direct an expedited process.

The status of other agency efforts is unknown.

Staff position: More agency input is needed.

OCR Agrees with the recommendation as indicated by HHS having implemented these procedures.

COMMENTS ON HIV REPORT RECOMMENDATIONS .

10-11 The HCFA and the HRSA should institute a program of special project grants to private and public agencies for the development or expansion of outpatient services and home care. (SEE: 2-11)

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

→ X

X

- A = Completed/Ongoing
- B = Planned
- C = Under Consideration
- D = Disagree
- E = Other

- _____ F = Agree
- _____ G = Disagree
- _____ H = Neutral
- _____ I = Other

Organizations Providing Comments

Federal : HHS (HRSA, HCFA)
Non-Federal:

Comments

HRSA has the development of such a program under consideration.

HCFA does not have, or seek, statutory authority to make project grants of the type mentioned in the recommendation. However, in its research and demonstration proposal solicitation for FY88 and the one that will go out for FY89, the agency has solicited proposals related to development or expansion of outpatient services and home care for persons with AIDS.

the
 Health care services in home-health demonstration grants program will expand skilled home health care, in coordination with other supportive services, to persons who have serious medical problems such as AIDS.
 This program of grants to States is now under way. Grantees have been selected. Funds will be awarded in FY 1988 to initiate activities early in FY 1989.

ASPE - Suggests using attached

COMMENTS ON HIV REPORT RECOMMENDATIONS

10-17

The federal government should encourage all states to enact a qualified state pool for medically uninsurable individuals with the following provisions:

The federal government should experiment with providing technical assistance to states to ensure adequate coverage, financing from a combination of private and public sector funds, adequate provision of benefits, and mandated case management;

The federal government should consider amending the Employee Retirement Income Security Act (ERISA) to include self-insured plans in pool funding; and

The federal government should consider establishing a risk pool fund, administered by a non-profit or limited-profit corporation acting as a reinsurance organization and should be the source of stop-loss subsidies for state risk pools. HCFA should evaluate the various sources of public and private financing that would be available for this fund to cover administrative losses and to subsidize costs to patients.

This will be covered in response to #7 of the President's 10-point plan

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- _____ A = Completed/Ongoing
- _____ B = Planned
- X C = Under Consideration
- _____ D = Disagree
- _____ E = Other

- _____ F = Agree
- _____ G = Disagree
- _____ H = Neutral
- _____ I = Other

Organizations Providing Comments

Federal : HHS
Non-Federal: Blue Cross/Blue Shield

Comments

Approximately 15 States already have risk pools. HHS is willing to assist others and promote this concept. HCFA/IOM held a meeting in February 1988 of private insurers and State representatives to discuss issues/options concerning financing of AIDS care. The conclusion was that the existing public and private system, with some minor modifications can handle the AIDS issue.

Blue Cross/Blue Shield favors the risk pool approach, and particularly supports an amendment to ERISA to include self-funded programs in pool funding. They do not agree with the implication in the recommendation that private insurers are not involved and supportive of case management.

by identifying for those states alternative approaches to financing any deficits. The pools might experience.

H(2). SPECIFIC STUDIES ON HEALTH CARE -- STATE RISK POOLS (P)

Requirement: Conduct specific studies on ways to encourage states to establish insurance risk pools for medically uninsurable persons.

Background

About one percent of the United States population is estimated to be medically uninsurable due to pre-existing medical conditions, including AIDS. When private insurance is available, the price is often prohibitive or the pre-existing conditions are excluded from coverage for the first year or longer. Without insurance, many of these people are unable to pay the high medical bills they often incur. This results in financial strain on health providers. It also means financial hardship for the individuals and their families and the depletion of resources until the individual qualifies for government-subsidized care. Risk pools are legislatively established health insurance programs intended to make insurance available to people considered otherwise uninsurable. The resulting coverage can reduce the impact on personal finances and the dependency on Medicaid.

Fifteen states have enacted legislation establishing subsidized risk pools; of these, 13 are active. Some 20 states considered (but none enacted) risk pool legislation in 1987-88. According to a GAO report, all existing pools appear to cover AIDS, and four (Indiana, Iowa, Minnesota and Nebraska) specifically include AIDS among the diagnoses that are grounds for presumptive pool eligibility.

Proposed Response/Status

- o HHS has proposed to OMB that the Administration support enactment of S. 1634 proposed by Senator Durenberger which would encourage states to establish risk pools, would establish very limited Federal requirements (which should be further modified), and would provide \$30 million in "seed money" spread over 3 years. We will follow up with OMB.
- o HHS will promote state enactment of risk pools in several forums, including the consensus conferences required in the action plan, and through speeches, letters, and other interactions with the National Governors' Association and the National Conference of State Legislatures.
- o Through the evaluation of existing risk pools and the development of several model risk pool statutes, HHS will act as a resource center to help states wishing to consider enactment of legislation to establish risk pools. We will communicate this to all states.

Issues

None.

COMMENTS ON HIV REPORT RECOMMENDATIONS

11-23 The A.I.D. should increase its support for improved epidemiologic data collection and modeling for a better global understanding of the dynamics of the epidemic in all parts of the world. This work should be coordinated with the WHO's GPA, and the database and modeling should be available to the international assistance community.

Proposed Federal Position

Federal Responsibility

Non-Federal Responsibility

- A = Completed/Ongoing
- X B = Planned
- C = Under Consideration
- D = Disagree
- E = Other

- F = Agree
- G = Disagree
- H = Neutral
- I = Other

Organizations Providing Comments

Federal : A.I.D., HHS (NAPO, Fogarty)
Non-Federal:

Comments

The Agency has an important role to play in improved epidemiologic data collection and modeling and has been working for the past year to foster work in this area. In mid-1987, A.I.D. began systematic data collection through the Bureau of Census. In October 1987, through the National Academy of Sciences, A.I.D. supported an international conference on modeling HIV transmission. In early 1988, making use of the results of this conference, the Agency undertook further support of modeling efforts by the Population Council. Most recently, A.I.D. has worked with the Bureau of Census to conclude an agreement for expanded data collection and modeling of the demographic impact of the epidemic.

A new international AIDS database and impact modeling agreement with the Bureau of the Census should be in place by the end of August 1988.

Staff position: A.I.D. should work closely with NIH and CDC in carrying out this recommendation.

~~We would like to review after CDC has submitted its comments.~~

~~Cooperation essential.~~

~~Disagree primary responsibility should lie with A.I.D. - CDC~~

~~ASPE~~

COMMENTS ON HIV REPORT RECOMMENDATIONS .

11-34 DHHS strategic planning process should develop a five-year plan outlining research priorities and goals of HHS research institutes. This should be done in conjunction with five-year plan of the A.I.D. and the work of the WHO's GPA.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<u> </u> A = Completed/Ongoing	<u> </u> F = Agree
<u> </u> B = Planned	<u> </u> G = Disagree
<u> </u> C = Under Consideration	<u> </u> H = Neutral
<u> </u> D = Disagree	<u> </u> I = Other
<u> X </u> E = Other	

Organizations Providing Comments

Federal : A.I.D., HHS (FDA)
Non-Federal:

Comments

~~Congress has asked the Agency to coordinate U.S. government HIV-related efforts in developing countries. Working through the HHS Federal Coordinating Committee on HIV Information, Education, and Risk Reduction, the Agency undertook this responsibility in April 1988. The Federal Coordinating Committee meets regularly to allow information exchange and program review and planning by those federal agencies involved in developing country HIV-related efforts.~~

Staff position: ~~DHHS should respond to this.~~

This needs to be revised to address the request for a 5 yr plan in conjunction with AID + GPA. Shouldn't NIH be the lead ?

ASPL

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

Recommendation # 11-34 Department/Agency FDA

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

Planned for FY 1990 Further study needed
 Alternative approach Other

Please elaborate on the status below:

No change in status - FDA continues to be involved,
as appropriate in this area.

COMMENTS ON HIV REPORT RECOMMENDATIONS

11-39 Research grants should be awarded for three- to five-year periods at adequate funding levels.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<input type="checkbox"/> A = Completed/Ongoing	<input type="checkbox"/> F = Agree
<input type="checkbox"/> B = Planned	<input type="checkbox"/> G = Disagree
<input checked="" type="checkbox"/> C = Under Consideration	<input type="checkbox"/> H = Neutral
<input type="checkbox"/> D = Disagree	<input type="checkbox"/> I = Other
<input type="checkbox"/> E = Other	

Organizations Providing Comments

Federal : HHS (Fogarty)
Non-Federal:

Comments

~~Current budget amounts (FY 89 & 90) are inadequate to fund the number of good applications received for research training in AIDS and training in epidemiology related to AIDS. Adequate long-term support is essential.~~

~~Staff position: This recommendation should be considered as part of the FY 1990 budget process.~~

- Inconsistent w/ way NIH funds research now. Should also be revised to include FY1990 budget decisions which include increases for AIDS research.
Defer to ASMB comment.

ASPE

COMMENTS ON HIV REPORT RECOMMENDATIONS

11-40 Postdoctoral training fellowships should be established to enable social scientists and biomedical researchers to learn more about the socio-behavioral aspects of the epidemic.

Proposed Federal Position

Federal Responsibility	Non-Federal Responsibility
<input type="checkbox"/> A = Completed/Ongoing	<input type="checkbox"/> F = Agree
<input type="checkbox"/> B = Planned	<input type="checkbox"/> G = Disagree
<input checked="" type="checkbox"/> C = Under Consideration	<input type="checkbox"/> H = Neutral
<input type="checkbox"/> D = Disagree	<input type="checkbox"/> I = Other
<input type="checkbox"/> E = Other	

Organizations Providing Comments

Federal : HHS (Fogarty)
Non-Federal:

Comments

Announcements for the International Postdoctoral Fellowship in AIDS will highlight opportunities for research training in the socio-behavioral aspects of the HIV epidemic.

Staff position: This recommendation should be considered as part of the FY 1990 budget process.

~~SE~~ *Refer to ASMB comment.*

ASPE