THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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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:

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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 to 15 to 20 areas with high prevalence of HIV infection and AIDS.

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

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
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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

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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.

have begun

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.

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THE PRESIDENT'S 10-POINT ACTION PLAN
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8. Directs the Secretary of State to develop a multi-focused international initiative to combat HIV, particularly in less-developed countries; increase U.S. commitment to international technical assistance; and seek development of a three-year plan for international efforts against HIV infection.

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.

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THE PRESIDENT'S 10-POINT ACTION PLAN
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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.

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THE PRESIDENT'S 10-POINT ACTION PLAN
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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) was begun in July, followed in August with a supplemental survey. The Office of Personnel Management reports the following:

- All 22 agencies are putting AIDS policy guidelines in place. 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.

- 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.

- 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."

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THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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

On November 28-29, HHS is sponsoring "The U.S. Health Summit on HIV Infection" in Washington, D.C. This conference will be the kick-off for ensuing consensus conferences to address public health measures to reduce the spread of HIV infection. HHS has already initiated a series of other conferences which partially fulfill this directive:

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

HHS funding already supports over xx community-based organizations. In FY 1989, funding for local HIV prevention programs will be increased from xx to xx, resulting in a substantial increase in the number of CBOs supported by federal funds. In 15-20 metropolitan areas with increased incidence of AIDS or HIV, some CBOs will receive direct funding.

Commission Recommendations Relating to 10-Point Plan

The following recommendations of the President's Commission on the HIV Epidemic relate in whole or in part to the first point: Chapter 1: 2, 3, 4, 7-11, 13-15, 20, 25; Chapter 3: 40, 42-45; Chapter 5: 13-16, 18-20; Chapter 6: 1-20, 28, 33, 37, 38, 40, 41; Chapter 7: 1-3, 5, 6, 18-33, 40; Chapter 8: 13, 36, 46, 53,54, 56, 57, 60, 62-64, 69, 74, 75, 79, 84, 88-93; Chapter 9: 26, 36-42, 44-51, 56, 63-71, 73-76, 83, 84, 100-103.

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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

The FDA is in the process of formulating a plan for the prompt notification of transfusion recipients. The FDA held a meeting on September 8 with the blood community to discuss the best approach to accomplish this. The FDA will submit recommendations later this month.

The FDA is in the process of preparing an integrated strategy to improve laboratory quality that will include| (a) proficiency testing, (b) surveillance of blood bank facilities, (c) enhanced training of FDA investigators who inspect blood banks, and (d) training programs for blood establishment staff.

NIH is conducting research in FY 1989 aimed at the development and evaluation of new tests to detect HIV in infected individuals.

NIH is in the process of developing 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 will include a media campaign to promote autologous donation 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 transfusions.

Commission Recommendations Relating to 10-Point Plan

The following recommendations of the President's Commission on the HIV Epidemic relate in whole or in part to the second point: 6-21 to 6-27, 6-29 to 6-30, 6-32 to 6-39.

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

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Commission Recommendations Relating to 10-Point Plan

The following recommendations of the Presidential Commission on the HIV Epidemic relate in whole or in part to point three: 4-1 to 4-3, 8-1 to 8-51, 9-83, 9-84

THE PRESIDENT'S 10-POINT ACTION PLAN
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4. Begins action in and out of Government that will accelerate development, approval and distribution of vaccines and drugs.

Status

On September 6, the FDA forwarded to OMB a proposal that will expedite approvals for those therapies intended 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 that are capable of providing definitive data on the drug's safety and effectiveness. The use of the 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 intended to treat life-threatening illnesses, and post-marketing studies to gather additional information about the drug's risks and benefits are other key elements of the proposal. Although it was developed in response to a charge from the Vice President, the proposal directly responds to this action plan item.

In response to the President's directive, PHS's Technology Management Advisory Board appointed a Working Group to examine issues such as the Federal role in encouraging reasonable pricing for HIV-related products, such as AZT, developed in part with Federal funds. The Working Group will also consider recommendations that might improve the quality of the technology transfer program generally. The group is on track with the 120 day deadline set by the President for a response.

HHS is also investigating the parameters of the liability issue as it might pose impediments for the development of HIV-related products, in particular vaccines. They 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. HHS plans to report to the President on this matter within the 120 day deadline.

Commission Recommendations Relating to 10-Point Plan

The following recommendations of the Presidential Commission on the HIV Epidemic relate in whole or in part to point four of the President's 10-point action plan: 4-1 to 4-6, 4-23, 4-29, 4-32 to 4-37, 4-42 to 4-64, 4-68, 4-73, 4-75 to 4-100 4-102.

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

Status

HHS reports that OMB is not proposing a formal review of impediments to the efficient use of resources. However, several activities currently under review address this charge:

- An OMB generated budget amendment will allow NIH to use funds appropriated in FY 1988, FY 1989, and FY 1990, along with resources recovered from grant awards made in FY 1988 and FY 1989, for the construction of a consolidated office building on the NIH campus. Resources for this purpose may not exceed $96 million. (Recommendation 4-8).

- OMB expects to address dollar resources for AIDS in the context of the FY 1990 budget.

- OMB intends to continue 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.

Remaining issues which OMB apparently is not addressing which remain impediments for HHS are the inaction on the HHS proposal to create a Senior Biomedical Research Service at NIH and facilitation of lease/purchase agreements for the construction of office and laboratory buildings at CDC. HHS plans to advise OMB of particular HHS resource concerns in this area.

An OMB response on this point is needed.

Commission Recommendations Relating to 10-Point Plan

The following recommendations of the Presidential Commission on the HIV Epidemic relate in whole or in part to point five of the President's 10-point action plan: 1-12, 4-7, 4-8, 4-14, 4-17, 4-19, 4-21, 4-24 to 4-27, 4-33, 4-38, 4-65 to 4-67, 5-1, 5-9 to 5-5-11, 11-37, 11-38.

THE PRESIDENT'S 10-POINT ACTION PLAN
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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

The total Federal funding picture for AIDS is uncertain as this point. The bulk of the funding is in the Labor, HHS and Education, and Related Agencies Appropriations Bill. Conference Action by the House and Senate CommitteeS on that Bill provided $1.29 billion for HIV activities in PHS. (This level assumes funding for FDA, which comes from the Agriculture Appropriations Committee, at the Senate level). The $1.29 billion level represents a 1.2 percent decrease from the President's budget request. The House passed the Labor, HHS and Education Bill on September 9, 1988. The Senate has not set a date for action.

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.

Recommendations Relating to Action Plan

HHS is preparing a document that will identify all FY 1989 and FY 1990 resources devoted to each of the Commission recommendations to which the Department has no disagreement. This will be submitted to Dr. Macdonald for the December report.

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7. The President 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

The evaluation of the health care system is in the planning stage. HHS will use a HCFA team as well as outside contracts both for needed expert information and research support. This process will be established and underway within sixty days. HCFA will coordinate with other executive agencies.

HCFA is also responsible for conducting studies promoting out-of-hospital care. The 1989 research and demonstration project solicitation includes studies of the effectiveness of out-of-hospital and case managed care. The solicitation also encourages studies examining the use of Medicaid waivers, hospice care, home health and other ambulatory services in providing cost-effective alternatives to inpatient care for HIV patients. HCFA will coordinate its activities with PHS service demonstration and research grants activities.

HHS has begun a plan for evaluating existing risk pools and the development of several model risk pool statutes. Their tentative plans are 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.

Specific studies for infants, children and adolescents will be part of implementing recommendations contained in the Secretary's Task Force on Pediatric HIV Infection Report. This report is currently under review with the Department.

HCFA is considering the issue of the response of the health care system to low-income disabled individuals within the context of the overall system evaluation. Disability determination in the SSA's SSI program as it relates to Medicaid eligibility will be included with the involvement of the SSA.

Commission Recommendations Relating to 10-Point Plan

The following recommendations of the President's Commission on AIDS relate in whole or in part to point seven of the President's ten point plan. 1-12, 2-1, 4, 5, 7, 8, 9, 12, 13, 14, 16, 17, 18, 3-4, 5, 6, 8 thru 25, 27, 32, 6-27, 31, 36, 8-,65, 66, 67,

THE PRESIDENT'S 10-POINT ACTION PLAN
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8. Develop a multi-focused international initiative to combat HIV, particularly in less-developed countries; increase U.S. commitment to international technical assistance; and develop three-year plan for international efforts against HIV infection.

Status

The Department of State, with the U. S. Agency on International Development (A.I.D.) taking the lead responsibility, has drafted an outline for the 3-year plan. This process of developing the plan from this outline will be closely coordinated with other Federal agencies through the HHS's Federal Coordinating Committee on AIDS. A.I.D. plans to have a draft plan available for review by mid-October and the final report completed by December 5. This plan will address: (1) multilateral and bilateral activities for the prevention and control of HIV infection; (2) development of new methods of treatment and a vaccine; (3) foreign policy implications of AIDS; and, (4) budgetary implications.

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

Commission Recommendations Relating to 10-Point Plan

The following recommendations of the President's Commission on the HIV Epidemic relate in whole or in part to the eighth point: Chapter 11: 1-15, 16-34, 36-38, 41, 42, 45-47.

THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

9. Requires the Public Health Service 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. It will be a significant background document and will identify over 109 issues, 222 goals, and 554 objectives as priority areas.

This PHS report will be used to develop an HIV Implementation Plan which will identify the major goals to be carried out in FY 1989. It will overlap with the Commission recommendations in many areas.

HHS reports that it plans to use the Charlottesville Report/ HHS Implementation Plan, and the Presidential Commission Report to establish a tracking and monitoring system for HHS activities in combatting HIV infection.

Commission Recommendations Relating to 10-Point Plan

It is not possible at this time to tie the PHS and HHS plans to the recommendations of the Presidential Commission on the HIV Epidemic. PHS should provide for the December report a copy of the plan, a cross walk to show areas of overlap with the Presidential Commission, and information on their tracking and monitoring system.

THE PRESIDENT'S 10-POINT ACTION PLAN
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10. Calls on all sectors of society to respond equitably and compassionately to those with HIV infection and to their families. In addition to directing all Federal agencies to adopt a policy based on OPM guidelines, the President requests that American businesses, unions and schools examine and consider adopting education and personnel policies based on the OPM and Centers for Disease Control guidelines.

Status

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:

- All 22 agencies are putting AIDS policy guidelines in place. Seven agencies have issued AIDS policies. Fourteen others are presently drafting policies/guidelines to be issued by the end of October. One agencies will issue policy guidance no later than December.

- 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.

- All 22 agencies now offer counseling and referral services for AIDS-related issues through their Employee Assistance Programs or medical services facilities.

The Office of Personnel Management will hold a conference September 14, 1988 in the Grand Hyatt Hotel on "AIDS in the Workplace".

On August 17, 1988, the Director, 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".

Commission Recommendations related to 10-Point Plan

The following recommendations of the Presidential Commission on the HIV Epidemic relate in whole or in part to the tenth point: 1-1, 2-1, 2-2, 2-6, 2-7, 3-2, 3-7, 3-28, 3-35, 3-48 to 3-50, 6-2, 6-8, 6-11, 6-12, 6-18, 7-30, 7-32, 7-33, 8-52, 8-54, 8-70 to 8-78, 8-81, 8-82, 8-85, 8-87, 9-1, 9-1, 9-4 to 9-37, 9-39, 9-40,9-48, 9-77, 9-78, 9-80 to 9-83, 9-86 to 9-88, 9-90, 9-92, 9-95 to 9-97, 9-104, 9-105, 11-8.

(10)

SEP 15 1988

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Washington DC 20201

NOTE TO DR. MACDONALD

Subject: Federal Confidentiality Legislation: INFORMATION

You read in the Washington Post yesterday that H.R. 5142, the AIDS Federal Policy Act of 1988, is expected to come to the floor of the House this week for a vote. If Mr. Waxman's and Dannemeyer's staff are able to negotiate on the amendments discussed in the Post article, we believe the bill is likely to pass. If it does, plans are to conference it with S. 1220, an AIDS research bill that was passed by the Senate in the Spring. H.R. 5142 contains a Federal confidentiality provision as well as some protections for the public, similar to the Commission recommendations in areas such as contact tracing, mandatory testing of prostitutes and IV drug abusers, and penalties for knowingly transmitting the disease.

In his July 27 letter to you regarding the Commission's recommendations, Dr. Bowen stated that HHS plans to quickly develop a Federal confidentiality law. This differs from the Secretary's position last September when he testified before Mr. Waxman's subcommittee on the counseling, testing and confidentiality bill, which now in revised form has been folded into H.R. 5142. Last September, the Secretary expressed his concern about "supporting Federal legislation without a better understanding of the optimal solution and some greater certainty that a Federal effort will improve the situation without inadvertently creating additional problems." HHS's change of position is due to several ensuing events:

- The antidiscrimination provisions originally in the bill when the Secretary testified on it were deleted.

- Last October Dr. Bowen wrote to each governor offering the assistance of the Department in dealing with the issues of confidentiality, discrimination and public health protections as they relate to AIDS. He asked them to examine their State laws and seek reforms where necessary. He sent them a copy of the "Uniform Health-Care Information Act" drafted by the National Conference of Commissioners on Uniform State Laws and asked them to consider it as model confidentiality legislation that covers all persons and medical records. Despite this attempt by HHS to encourage States to shore up their confidentiality laws as they relate to AIDS, a minority of States have acted and widespread perception of gaps remains.

- HHS has parsed the confidentiality and public protection provisions of H.R. 5142 and believe, that with some modifications, the Department could support the bill. They have now appointed a working group to develop specific amendments for negotiation with the Congress. The confidentiality and public health protection provisions of H.R. 5142 also appear in H.R. 5210 (Title XXIII, p.307).

Louise Fitzhugh

The Washington Post

AN INDEPENDENT NEWSPAPER

A Federal Response to AIDS

LATER THIS week, an AIDS bill is expected to come to the floor of the House. It is not the kind of comprehensive measure that many AIDS victims and others had hoped for. Nor is it as strong as the legislation recommended by the president's AIDS commission last June. Specifically, the bill does not expand current antidiscrimination laws to cover AIDS bias in housing, public accommodations, schools and jobs that do not receive federal funds. Such provisions remain too controversial and, in the view of the bill's principal sponsor, Rep. Henry Waxman, could not be passed at this time. Nevertheless, the bill that is ready for consideration is a good one and should be passed.

The proposal is in three parts, two of which are not really controversial. The first creates a National Commission on AIDS to advise Congress and the president on AIDS policy matters. The second provides for expedited and expanded research on the epidemic and the development of drugs for treatment and prevention. Except for some opposition by those who oppose mandatory personnel additions in specified federal agencies, this section should be passed without much debate. The final section provides $400 million in grants to the states for expanded testing and counseling programs. With a few exceptions, it mandates confidentiality of records. Disclosure without the tested person's consent can be made, for example, to spouses, sexual partners and those who have shared needles with infected persons. Doctors can also inform blood and organ banks, undertakers and insurers (once the patient has died) and must send information, but not necessarily names, to state public health officials.

There is no opposition to any of these provisions, but attempts will be made to require wider testing and disclosure. Rep. Bill Dannemeyer, for example, wants to require states to offer routine testing to all hospital patients between 15 and 49. He and other conservatives would mandate tests for all prisoners upon entering and leaving confinement, and all marriage-license applicants in states where the rate of infection is more than 0.1 percent. Without these amendments, such decisions would be left to the states. The prison population deserves special concern; society has a special responsibility to protect those in its custody from this terrible disease. But the House Energy and Commerce Committee was right in saying that these policies can be developed at the local level. An impressive number of witnesses representing doctors, hospitals, corrections officials and state governments opposed the Dannemeyer proposals as unnecessary, expensive and intrusive on states' rights. Consideration at a later time may become necessary. But adoption of the amendments now would certainly dim prospects for the passage of this worthwhile legislation. It is best to move forward now on a bill with broad and deserved support.

DRAFT

MEMORANDUM FOR THE SECRETARY OF STATE

SEP 1 9 1988

I have just received and approved the September progress report on my 10-point action plan as part of the response to the Report of the Presidential Commission on the Human Immunodeficiency Virus (HIV) Epidemic. I am pleased with the scope of the activities that have been initiated in just one month.

In particular, your outline of a three year plan for international efforts against HIV infection is encouraging. I look forward to receiving the final plan in December.

DRAFT

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES SEP 1 8 1988

I have just received and approved the September progress report on my 10-point action plan as part of the response to the Report of the Presidential Commission on the Human Immunodeficiency Virus (HIV) Epidemic. I am pleased with the scope of the activities that have been initiated in just one month.

In particular, I am pleased with the many accomplishments of the Department of Health and Human Services. You have taken major strides forward in combatting this disease. I continue to be interested in your progress and look forward to receiving the plan to enhance private incentives for development and marketing of HIV products and a report on the one-year evaluation of the current health care financing system in December.

Although not mentioned in my August 5 memorandum to you, Dr. Macdonald has told me of two additional items you are preparing that would be of interest to me in reporting on the progress we have made toward implementing my Commission's recommendations. Would you please provide Dr. Macdonald copies of the following for his December report to me:

1. A paper discussing the results of your review of the FY 1989 and FY 1990 HHS budget as it relates to relevant recommendations my HIV Commission.

2. A report on how the recommendations of my Presidential Commission relate to those of the HHS Charlottesville Plan.

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DRAFT

MEMORANDUM FOR THE DIRECTOR OF THE OFFICE OF MANAGEMENT AND BUDGET

SEP 1 6 1989

I have just received and approved the September progress report on my 10-point action plan as part of the response to the Report of the Presidential Commission on the Human Immunodeficiency Virus (HIV) Epidemic. I am pleased with the scope of the activities that have been initiated in just one month.

I ask you to continue to work with the Department of Health and Human Services, the General Services Administration, and the Office of Personnel Management to remove any unnecessary administrative and management impediments to the agencies attack on HIV infection.

I ask you to pay particular attention to my FY 1990 budget for HIV-related activities. Please ensure that it is adequate to meet the needs and that it is submitted to the Congress in a timely manner. I ask you to convey again to the Congress a sense of the urgency with which this budget needs to be enacted.

DRAFT

SEP 1 6 1989

MEMORANDUM FOR THE DIRECTOR OF THE OFFICE OF PERSONNEL MANAGEMENT

I have just received and approved the September progress report on my 10-point action plan as part of the response to the Report of the Presidential Commission on the Human Immunodeficiency Virus (HIV) Epidemic. I am pleased with the scope of the activities that have been initiated in just one month.

In particular, I would like to commend you for assuring that Federal agencies adopt a policy based on your Office's "Guidelines for AIDS Information and Education for Personnel Management." Please continue to work with the Federal agencies as well as the private sector to ensure that employees infected with HIV are treated fairly and compassionately in the workplace.

DRAFT

MEMORANDUM FOR THE ATTORNEY GENERAL

SEP 1 8 1988

I have just received and approved the September progress report on my 10-point action plan as part of the response to the Report of the Presidential Commission on the Human Immunodeficiency Virus (HIV) EPidemic. I am pleased with the scope of the activities that have been initiated in just one month.

I remain concerned about fair and compassionate treatment of HIV-infected individuals. Please take the appropriate actions to ensure that the proper mechanisms are in place to protect these individuals against discrimination.

FACSIMILE TRANSMISSION REQUEST

ADDRESSEE: (NAME, ORGANIZATION, CITY, STATE & PHONE#)	FROM: (NAME, ORGANIZATION & PHONE #
Sue Daoulas White House Drug Abuse Policy Office 456-6554 OEOB 220	Lorraine Fishback PHS 245-6135

TOTAL PAGES	FAX MACHINE PHONE NUMBER(IF KNOWN)	DATE	CHARGE SYMBO
23	456-2246	9/19/88	

REMARKS

Sue -

Sue: This responds to Dr. Macdonald's request for more information on #4, first bullet point. It is not an issue of more FTE's or more funding for FDA. That is being handled through the budget process. This is more of a regulatory issue. We were told no adjustments are needed on people or money.

We are gathering more on the other questions.

Lorraine

IF RETRANSMISSION IS NECESSARY CALL: HQS COMMCEN FTS 8-245-6277 (AC 202) WA

INSTRUCTIONS TO COMMCEN: (CHECK ONE)

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

988

Honorable Otis Bowen, M.D.
Secretary
Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

At the meeting of the Presidential Task Force on Regulatory Relief held on Friday, July 29th, Commissioner Frank Young gave an excellent presentation on the current state of the new drug and Investigational New Drug (IND) approval processes. At the end of the discussion, the Vice President charged Commissioner Young, working under your guidance, with developing for Administration consideration, new administrative and statutory proposals designed to improve these processes.

These proposals are to enhance expeditious approval of new drug applications and treatment IND's, and should:

1) Permit FDA to balance the risks of not treating a life threatening illness against both the potential benefits and the risks of the drug itself in making decisions to approve drugs,

2) Ensure that American drug makers can compete with foreign suppliers, and

3) Allow, to the maximum extent possible, patients and their physicians to make the difficult choices among risks.

The Vice President asked that these proposals be forwarded for Administration review and transmitted to the Congress in time for legislation to be considered by Congress when it returns in September. I am confident that Commissioner Young is giving this matter the highest priority. In order to meet this schedule, we will need your proposals for Administration review no later than the 26th of August.

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THE UNDER SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

SEP 2 1988

Mr. S. Jay Plager
Administrator
Office of Information and Regulatory Affairs
Room 246 Old Executive Office Building
Washington, D.C. 20503

Dear Mr. Plager:

I am enclosing for your review and further discussion, FDA's proposal for expediting approvals for drugs intended to treat life-threatening diseases for which there is no other treatment. The FDA proposal is innovative and likely to speed the availability of life-saving therapies. We plan to implement the proposal as soon as possible.

The proposal's principal features include:

- Early consultation with drug sponsors to design definitive phase 2 studies;
- Marketing approval after phase 2 research, if data is favorable, utilizing risk/benefit analysis appropriate for drugs intended to treat life-threatening illnesses;
- Use of the Treatment IND as a bridge between the completion of phase 2 studies and the point of marketing approval; and
- Phase 4 (postmarketing) studies requested of the sponsor to gain additional information, as appropriate.

PHS will continue to refine this proposal over the next few weeks and will consider additional reforms within existing laws. One would be to extend our successful clearinghouses to include information on investigational products for extreme disease states.

In light of what we can accomplish through this proposal, we have serious concerns about the wisdom of proposing legislation at this time.

We look forward to working with you to refine and implement this proposal as soon as possible.

Sincerely,

Don

Don M. Newman
Under Secretary

Enclosure A/S

The three phases describe the usual process of drug development, but they are not statutory requirements. The basis for marketing approval is the adequacy of the data available; progression through the particular phases is simply the usual means the sponsor uses to collect the data needed for approval. The statute itself focuses on the standard of evidence needed for approval, as derived from adequate and well-controlled clinical investigations, with no mention of phases 1, 2 and 3. FDA believes that if sufficient attention is paid to the quality and amount of data obtained in phase 2, it should be possible to identify early those drugs that represent safe and effective treatments for life-threatening diseases -- and to develop the evidence needed for marketing approval -- in the course of carrying out the first controlled trials.

This proposed program is based on that premise. For drugs intended to treat life-threatening illnesses, it should be possible to compress the total premarket drug development time by designing and conducting phase 2 controlled trials that are capable of providing definitive data on the drug's safety and effectiveness. FDA would analyze data from such studies utilizing risk-benefit considerations appropriate for drugs intended to treat life-threatening illnesses. The Treatment IND would continue to serve as a bridge between the completion of promising phase 2 trials and the point of marketing approval.

6

Drug sponsors might also be asked to conduct postmarketing (phase 4) studies to delineate additional information about the drug's risks and benefits. (See Figure 2.) The FDA Commissioner and other Agency officials would be proactive during the entire drug development process to ensure that such drugs are developed by the sponsor and analyzed by the Agency as expeditiously as possible. FDA believes that this proposed program would establish a new and innovative approach to drug development and data review, while at the same time building on past practices that have proven to be successful.

SCOPE

This program would apply to drugs and biologics intended to treat life-threatening diseases, especially those for which there is no satisfactory alternative therapy. A life-threatening disease is one where the likelihood of death is certain unless the unrelenting course of the disease is interrupted (e.g., progression from asymptomatic HIV infection to symptomatic HIV infection, or further progression to a later stage of AIDS). Thus, the term "life-threatening" would apply to diseases likely to lead to death in a short period of time (e.g., 6 months to 1 year). This approach is also appropriate for conditions where the end point of clinical analysis is survival (e.g., increased survival after a heart attack), or where the drug is being studied to treat major irreversible morbidity (e.g., prevention

of recurrence of breast cancer after surgery; blindness due to CMV infection in AIDS patients).

In all of these cases the end points of the study are of such great importance that it is imperative that the first controlled clinical trials be designed and conducted as well as possible. Preliminary reports of success from poorly designed studies might make it difficult ever to carry out the proper trials. FDA believes it is clearly in the public interest to assure in such situations, to the extent possible, that the first clinical trials be definitive so that the true merit of the drug or biologic is discovered early.

The Agency recognizes that this definition is subject to interpretation. However, the Agency intends to be flexible in its implementation of this program and encourages sponsors to consult with FDA on the program's applicability to particular products.

ELEMENTS OF THE PROGRAM

1. Early Consultation

The most important problem to be addressed is early consultation. Under current practice, upon request of a drug's sponsor, FDA medical staff hold a conference with the sponsor at the end of

phase 2 testing. The goal of this conference is to reach agreement on a plan of phase 3 testing that will provide the needed remaining evidence of the drug's safety and efficacy to gain marketing approval. If, however, the evidence obtained from well-planned and well-executed phase 2 research is definitive, there may be no need for additional data before approval, and the drug can become available much more rapidly than usual. This is most likely to occur for drugs to treat life-threatening illnesses where the relatively small amount of data available at this stage may nevertheless be sufficient for approval. For example, phase 2 research was sufficient for approval of AZT, the only drug approved thus far to treat the AIDS virus. AZT was developed and approved in record time, largely because phase 3 studies were not needed to support safety and effectiveness following completion of a highly successful well-controlled multi-center phase 2 study.

There have been other circumstances, particularly in the oncology area, where early (phase 2) results were so definitive that additional studies were not needed to conclude that the drug was effective and that its benefits outweighed its risks. For example, the licensing of alpha interferons to treat hairy cell leukemia was based on phase 2 trials that showed partial or complete remission of the disease in 75 to 90 percent of patients.

To build upon these successes, FDA proposes to institute a process in which conferences will be held at the end of phase 1 (rather than waiting until the end of phase 2) with the sponsors of drugs and biologics intended to treat life-threatening illnesses, especially where there are no satisfactory alternative therapies. The purpose of these conferences would be to review the product's phase 1 test results and to plan phase 2 testing. If enough is known about the drug at that time, agreement would be reached on a phase 2 testing program (e.g., the design of the studies, the number of patients to be tested, the endpoints to be used, and the proposed mode of replication), that would have the potential for establishing the drug's safety and effectiveness. Where the data resulting from these phase 2 studies prove sufficient to allow a determination that the drug is safe and effective, using risk-benefit considerations detailed further below, FDA will approve the drug without further preapproval studies. The scope of the phase 2 clinical trials is thus expanded to preclude the need for further research in phase 3, if the phase 2 trials prove successful. Of course, when the phase 2 research is not definitive, further preapproval studies will be necessary.

With respect to study design, the Agency recognizes that there has been some confusion about the role of placebo-controlled studies in patients with a life-threatening disease. FDA believes that placebo-controlled studies are not appropriate in

those situations where there is known to be an effective therapy, for the stage of disease or condition under investigation, that can improve survival or prevent irreversible morbidity. For example, in the case of symptomatic AIDS or advanced ARC, where AZT is known to improve survival, it would not be appropriate to compare a new drug with placebo. Rather, the new drug should be compared with AZT. It would also be possible to compare the new drug plus AZT with AZT alone, but in neither case would it be necessary to deny patients therapy with AZT, which is known to improve survival. In contrast, where no therapy has been shown to be effective, it is scientifically appropriate to randomize patients to test drug and placebo. This was done with AZT and, by providing early and clear evidence of benefit in terms of improved survival, enabled FDA to confer the rapid approval that made the drug widely available to AIDS patients.

The Institute of Medicine, in its recent report entitled, "Confronting AIDS: Update 1988," emphasized the importance of controlled clinical trials as the "fastest, most efficient way to determine what treatments work" (Executive Summary at page 19; Report at page 139). As the report continues, "Conducting well-designed trials from the beginning will benefit more patients, sooner, than any other approach. Poorly designed trials, or administering drugs without controls and 'observing' the course of the disease, risk being inconclusive or drawing incorrect conclusions." (Report at page 139.) FDA fully supports the

early initiation of well-designed phase 2 controlled clinical trials as the most efficient mechanism of evaluating treatments for the desperately ill.

FDA can also make the drug development process more efficient by interacting with the drug sponsor, even before Phase 1 testing begins, to help identify the animal studies necessary to assess the toxicity of the new drug and assure that clinical studies can be initiated with reasonable assurance of safety. In consulting with sponsors on animal studies, FDA takes into account the seriousness of the disease to be treated and the nature of the clinical studies planned. In this way, FDA involvement can facilitate the initiation of trials in human patients as early as the safety studies in animals permit, thereby reducing potential barriers to innovation at this early but important stage of new pharmaceutical development.

For example, using this process, some new AIDS drugs have been able to enter clinical testing after animal studies that were 4 weeks long or less in duration. The preclinical animal studies completed before initial human use of AZT were 2-4 weeks long, and the short-term clinical studies of a recent new AIDS drug from the National Cancer Institute (NCI) were able to begin after animal studies lasting only 2 weeks. By working closely with the sponsor, FDA can suggest the minimum amount of preclinical testing needed to go forward without compromising the safety of

clinical study participants. Unnecessary animal studies can be avoided, and the sponsor can move the drug into clinical testing in the shortest possible time.

Moreover, early FDA involvement can also shorten the time it takes the Agency to review an IND submission and lessen the likelihood of FDA placing the application on clinical hold.

2. Focused FDA Regulatory Research

In certain circumstances, FDA may undertake research on critical rate-limiting aspects of the preclinical, chemical/manufacturing, and clinical phases of drug development and evaluation. For example, FDA often needs specific information upon which critical regulatory decisions are made--e.g., manufacturing standards and assays for vaccine or biotechnology products. Recent examples include FDA potency testing of vaccines and development of assay methods for drug bioavailability. FDA is prepared to intensify this practice.

3. Risk-Benefit Analysis

The Vice President's charge includes a provision that FDA be permitted, in making decisions to approve new drugs, to consider the risks of the disease to be treated in balancing the

identified benefits and risks of the drug. While the statute uses the terms safety and effectiveness, rather than risks and benefits, the statutory safety standard (that all tests "reasonably applicable" be carried out and that they show the drug to be safe for its intended use) inherently represents a risk-benefit judgment. The Agency recognizes that safety is not absolute (i.e., no drug is free of risk), but must be assessed in light of what condition the drug treats. This is particularly true in the case of drugs to treat life-threatening diseases, where drugs that are quite toxic may nevertheless be considered safe under the circumstances.

In carrying out the statutory mandate, FDA will consider the seriousness of the disease being treated in balancing risks and benefits. For example, as a class, oncologic drugs are highly toxic, but this is acceptable when they are used to treat illnesses for which they represent the only available method of treatment and when they can have a favorable influence on survival or on intractable symptoms. Moreover, dramatic responses (i.e., great benefit), especially on "bottom line" endpoints like survival or progression to an inevitably fatal stage of illness, make it easier to conclude that the benefits of treatment outweigh its risks, even if not all important questions about the drug are answered. Clearly, for a life-threatening illness, a relatively high level of known risk and some uncertainty about potential risk from the drug can be acceptable

in exchange for the improved survival provided by effective drug treatment for a condition that, left untreated, would result in death.

In seeking to utilize phase 2 data for final decisionmaking, FDA would be trying to increase the likelihood that a safe and effective drug, especially one that affects mortality or major irreversible morbidity, would be shown safe and effective in the shortest possible time by assuring that the initial studies are adequate to do this -- i.e., to provide evidence, even though derived from a limited data base, that would be sufficient to reach a benefit-risk judgment. FDA's goal is to be able to reach a scientifically defensible decision based on the results of well-designed phase 2 controlled clinical trials. If a therapy is found to effectively treat a life-threatening disease for which no other therapy exists, it would not be appropriate to continue research into phase 3, once phase 2 testing is found to be definitive. However, poorly designed phase 2 studies serve to retard the drug development process, as even equivocal results from such studies make it difficult to carry out the additional research needed to fully evaluate the drug.

In order to increase the likelihood that Phase 2 testing can provide definitive results, sponsors would plan phase 2 studies that are somewhat larger and more extensive than is currently the norm, including a mode for replication of key findings.

Moreover, to avoid missing an effect by using too little drug, or to avoid studying a dose that proves toxic, it may be necessary to study several doses in the first formal trials, an approach that may require a larger study but can plainly save time. However, it should be appreciated that if a drug has only minor or inconsistent effects, these limited beneficial results may be missed in this stage of clinical testing, even if the drug ultimately proves to be beneficial following more extensive phase 3 trials.

When planning phase 2 studies, it will be particularly important to make optimal use of pharmacokinetic/pharmacodynamic studies carried out in phase 1. Such phase 1 data are particularly useful in selecting the best dose(s) and dosing intervals for phase 2 testing. Therefore, FDA input should be helpful in the design of phase 1 studies also.

While FDA can contribute to the design of the controlled clinical trials, and be proactive in urging that such trials be pursued, the Agency has no direct control over the pace at which trials are initiated and completed. Success of drug development depends on the willingness of the commercial sponsor and clinical investigators to devote the necessary time and resources to complete the studies expeditiously.

4. Treatment INDs

Treatment INDs are intended to permit the wider use of promising experimental drugs for serious and immediately life-threatening illnesses in patients who lack satisfactory alternative therapy.

Within the drug development process, treatment INDs can provide a bridge between the completion and initial analysis of promising phase 2 studies and the point of marketing approval. Thus, when evidence from phase 2 indicates that a drug for a life-threatening illness is promising and the data are potentially sufficient for approval, FDA will actively work with the sponsor to evaluate the appropriateness of a treatment IND while the phase 2 data are being assembled and analyzed. This approach was used during the development of AZT, and allowed wide availability of the drug to over 4,000 patients while the marketing application was being assembled by the sponsor and reviewed by FDA. In addition, FDA will continue to work actively to educate physicians and drug sponsors on how to utilize the Treatment IND process most effectively.

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5. Phase IV Studies

If FDA approval is gained on the basis of limited, but sufficient, clinical trials, it will usually be important to conduct postmarketing (phase 4) clinical studies that will extend the knowledge about the drug's safety and efficacy and allow physicians to optimize its use. For example, in the case of AZT, early appearance of a dramatic improvement in survival of the treated patients was taken as clear evidence that, for the relatively advanced HIV-infected patients treated, the benefits clearly outweighed the risks. Although significant side effects of AZT were found, the clinically demonstrated benefit of prolonged survival clearly outweighed those risks.

This does not mean that all important questions were answered at the time of approval of AZT and that research into its use could end. It was critical to examine--after marketing--its use in earlier stages of the disease, where its toxicity might outweigh its benefit (i.e., in earlier stages of the disease, survival is much greater without treatment so that there is less improvement possible, but toxicity might be just as severe). It was also important to explore dosing regimens that might be less toxic and equally effective. In addition, as with any drug, it is important to consider whether there are longer-term adverse effects that might "take away" the early gain. As with AZT, FDA

has generally been able to persuade drug sponsors to do such follow-up studies voluntarily, because sponsors also recognize important gaps in the data base and believe they need to be filled.

6. Active Monitoring of Conduct and Evaluation of Clinical Trials

Recognizing that people with life-threatening diseases face a catastrophic condition that requires special attention, it is imperative that the conduct of clinical trials and FDA's evaluation of them proceed as expeditiously as possible. Accordingly, the Commissioner and other Agency officials will monitor the progress of the clinical trials and be involved in stimulating their appropriate progress. This would include, for example, contacting the sponsor directly when clinical trials are not proceeding on schedule.

Additionally, the Commissioner and Agency officials will monitor closely any safety considerations that occur during the clinical research phases, as well as monitor the progress of the evaluation of these therapies within FDA to ensure that maximal expeditious attention is devoted to evaluating therapies for life-threatening diseases. For example, FDA may convene special meetings of its Advisory committees, as necessary, rather than waiting for the next scheduled periodic meeting.

Finally, FDA, in conjunction with other PHS agencies, will utilize, to the extent possible, clearinghouse mechanisms for informing physicians and patients of investigational therapies for life-threatening illnesses. Existing mechanisms of this type will be augmented, as appropriate.

7. Safeguards

If successfully implemented, this approach would expedite the availability and approval of drugs for life-threatening illnesses while assuring that the drugs are shown safe and effective under the law:

- Patient Safety: FDA will carefully monitor the safety of drugs throughout the drug development and marketing process.

  This includes review of: animal studies to assure the reasonable safety of initial human testing; IND safety reports during the conduct of clinical trials and Treatment IND protocols; safety update reports during the review of marketing applications; and adverse drug reaction reports after products are approved for marketing.

- Study Design: FDA will take great care in the design and monitoring of phase 2 clinical trials so that they will be able to show the safety and effectiveness of the drugs under investigation (if indeed the drugs are effective and safe).

- Study Audits: FDA will work closely with clinical investigators prior to and during their studies to avoid delays and ensure that studies are done correctly, according to accepted practices that permit successful audits of investigations.

- Facility Inspections: FDA will inspect manufacturing facilities to ensure that manufacturers are ready and able to produce properly formulated compounds as soon as approval is granted.

SUCCESS OF CLINICAL RESEARCH
(NCEs SUBMITTING FIRST INDs IN 1976-1978)

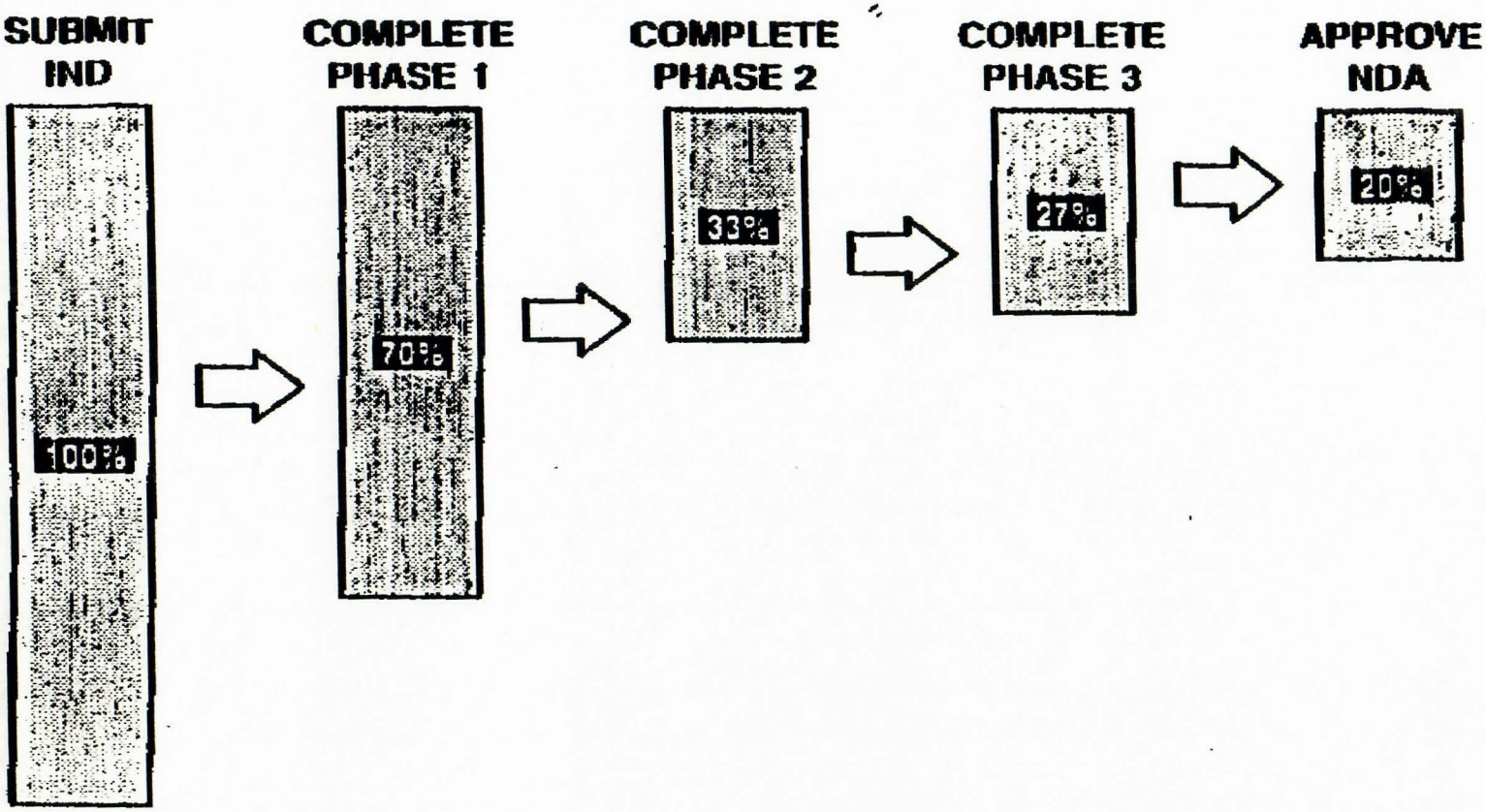

FIGURE 1

DRUG DEVELOPMENT PROCESS:

PRODUCTS FOR LIFE-THREATENING ILLNESSES

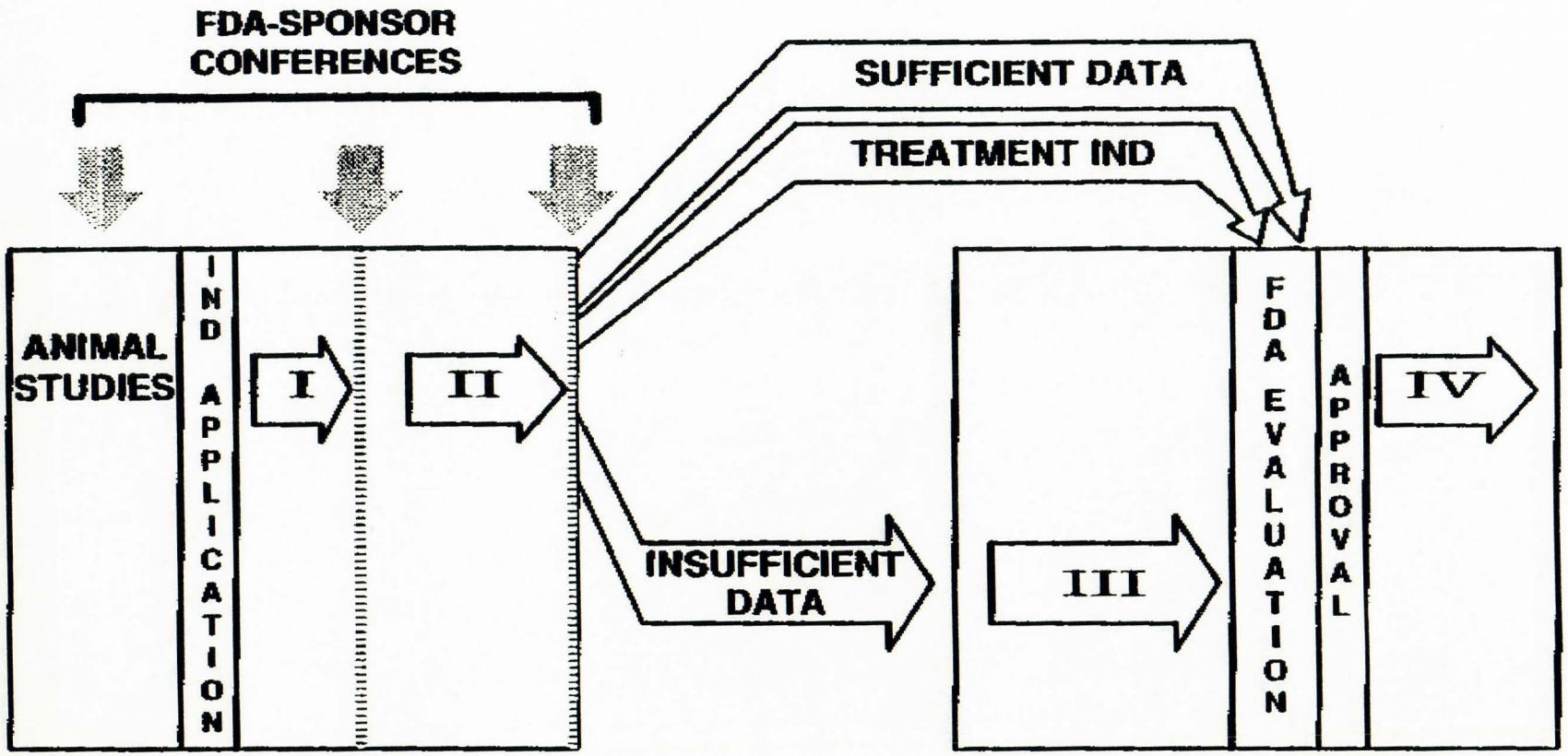

FIGURE 2

9/19
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:

- 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.

- 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.

- 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).

- 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

DRAFT

HHS

THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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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;
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- o Developing appropriate services for adolescents and youth at risk of HIV infection, FY 1989;
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- o Federal-State strategies to overcome neighborhood resistance to drug abuse treatment facilities, FY 1989.

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which ones

from what level over what period

DRAFT

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

FY 88 - 89

CDC → 11.5m 16.9m
minority PFA
US Conf of Mayors 384 412
Direct $ — 5.4m
12m 23m

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THE PRESIDENT'S 10-POINT ACTION PLAN
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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).

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THE PRESIDENT'S 10-POINT ACTION PLAN
September Update

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.

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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.]

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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.

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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.

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THE PRESIDENT'S 10-POINT ACTION PLAN
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5. Reaffirms his commitment to provide adequate resources (dollars, staff, office and laboratory space) to combat the HIV epidemic and directs the Office of Management and Budget to make certain there are no impediments to efficient use of these resources.

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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.

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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
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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.

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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 ?

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Rich Soeb 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.

insured & uninsured

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

Promotes model statutes
Durenberger Bill
HHS vs. OMB

Nat Gov Assn
Nat Conf St Leg's
Nat Assn of Insurance Commissioners

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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.

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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:

- 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.

- 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.

- 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 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]

DRAFT

9/19
2:30pm

(date)

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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:

- 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.

- 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.

- 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).

- 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.

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September Update

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