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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.

- In response to your directive to promote fairness and compassion, the 22 largest Federal agencies will have OPM guidelines in place by December.

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

- The Attorney General is working on issues related to anti-discrimination laws -- a most sensitive and important issue.

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

THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

September Progress Report

29 September 1988

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

Status

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

- A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989. ISSUES: counseling, testing, and partner notification, reporting of HIV infection, and health care worker safety.

- Five regional "mini-summits" will be held from January to May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

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

  -- "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety, and liability.

  -- "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.

  -- "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in behaviors that transmit the infection and other legal issues.

  -- "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

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

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

Status

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

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

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

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

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

Status

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

Several important HIV-related issues:

- **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.

- **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on Congressional action ~~on your budget request~~. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. NIDA has developed model demonstration projects for IV drug users at risk for HIV/AIDS, ~~however administration of~~ these grants is dependent upon increased funding for treatment.

- **High-Risk Populations** HHS and DoJ are developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. HHS and DoJ are providing technical assistance to major metropolitan areas working with high-risk youth.

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HHS is investigating with DOD possible use of unused or underused military facilities to

~~HHS~~ One of the new HHS consensus conference will address the issue of personnel. ~~The facilities issue problem is being~~ To alleviate the facilities problem HHS is investigating with DOD the possible use of ~~an~~ unused or underused federal facilities.

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

Status

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

- o Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.

- o Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).

- o Appropriate drugs will be made available for treatment as Investigational New Drugs ~~between~~ after completion of the expedited testing process and marketing approval.

- o Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.

- o Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

Prior to full

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

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

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

Status

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

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

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

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If so should read In addition Congress the Labor, Health & Human Services, and Education Bill you signed in September so calls for a lease . . . .

If we use the bill name here needed say when signed on next page

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

Status

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

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

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

Status

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

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

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

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

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

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

Status

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

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

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

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

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

Status

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

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

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

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

Status

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

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

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

OPM AIDS Clearinghouse Established A ~~clearinghouse~~ T to make AIDS information available to agencies seeking assistance contains ~~the~~ your ~~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 your ~~the President~~'s ten point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines." Positive response has been received from a number of companies thanking OPM for mailing and announcing plans to implement the guidelines.

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TITLE XI—DRUG INTERDICTION AND LAW ENFORCEMENT SUPPORT

SEC. 1101. ANNUAL GUIDELINES TO THE MILITARY DEPARTMENTS

Section 113 of title 10, United States Code, is amended by adding to the end the following new subsection:

"(1) The Secretary of Defense, with the advice and assistance of the Chairman of the Joint Chiefs of Staff, shall provide annually to the Secretaries of the military departments and to the commanders of the combatant commands written guidelines to direct the effective detection and monitoring of all potential aerial and maritime threats to the national security of the United States. Those guidelines shall include guidance on the specific force levels and specific supporting resources to be made available for the period of time for which the guidelines are to be in effect.".

SEC. 1102. LEAD AGENCY FOR DETECTION

(a) DEPARTMENT OF DEFENSE TO SERVE AS LEAD AGENCY.—The Department of Defense shall serve as the single lead agency of the Federal Government for the detection and monitoring of aerial and maritime transit of illegal drugs into the United States.

(b) PRESIDENTIAL DETERMINATION.—Not later than 15 days after the date of the enactment of this Act, the President may designate an agency other than the Department of Defense as the single lead agency for the purpose stated in subsection (a). Before making such a designation, the President shall notify the Committees on Armed Services of the Senate and House of Representatives of the proposed designation and shall submit to those committees a detailed report setting forth the reasons for such designation.

SEC. 1103. COMMUNICATIONS NETWORK

(a) INTEGRATION OF C3I ASSETS.—(1) The President shall direct that command, control, communications, and technical intelligence assets of the United States that are dedicated to the interdiction of illegal drugs be integrated by the Secretary of Defense into an effective communications network.

(2) Not later than 90 days after the date of the enactment of this Act, the President shall submit to Congress a report setting forth the plan of the President for the integration of assets by the Secretary of Defense under paragraph (1).

(b) PLAN FOR RESPONSIBILITY FOR OPERATING C3I NETWORK.—Not later than 120 days after submission of the report required by subsection (a)(2), the President shall develop a plan for the assignment of responsibility for operating the communications network described in subsection (a)(1) and shall submit to Congress a report on such plan. The plan shall ensure that assignment of the responsibility for operating the communications network referred to in subsection (a)(1) is made not later than 60 days after the date on which the report required by this subsection is submitted to Congress.

SEC. 1104. ENHANCED DRUG INTERDICTION AND LAW ENFORCEMENT SUPPORT BY THE DEPARTMENT OF DEFENSE

(a) REVISION OF SUPPORT FOR CIVILIAN LAW ENFORCEMENT AGENCIES.—Chapter 18 of title 10, United States Code, is amended to read as follows:

"CHAPTER 8—MILITARY SUPPORT FOR CIVILIAN LAW ENFORCEMENT AGENCIES

"§ 371. Use of information collected during military operations

"(a) The Secretary of Defense may, in accordance with other applicable law, provide to Federal, State, or local civilian law enforcement officials any information collected during the normal course of military training or operations that may be relevant to a violation of any Federal or State law within the jurisdiction of such officials.

"(b) The needs of civilian law enforcement officials for information shall, to the maximum extent practicable, be taken into account in the planning and execution of military training or operations.

"(c) The Secretary of Defense shall ensure, to the extent consistent with national security, that intelligence information held by the Department of Defense and relevant to drug interdiction or other civilian law enforcement matters is provided promptly to appropriate civilian law enforcement officials.

"§ 372. Use of military equipment and facilities

"The Secretary of Defense may, in accordance with other applicable law, make available any equipment (including associated supplies or spare parts), base facility, or research facility of the Department of Defense to any Federal, State, or local civilian law enforcement official for law enforcement purposes.

"§ 373. Training and advising civilian law enforcement officials

"The Secretary of Defense may, in accordance with other applicable law, make Department of Defense personnel available—

"(1) to train Federal, State, and local civilian law enforcement officials in the operation and maintenance of equipment, including equipment made available under section 372 of this title; and

"(2) to provide such law enforcement officials with expert advice relevant to the purposes of this chapter.

"§ 374. Maintenance and operation of equipment

"(a) The Secretary of Defense may, in accordance with other applicable law, make Department of Defense personnel available for the maintenance of equipment for Federal, State, and local civilian law enforcement officials, including equipment made available under section 372 of this title.

"(b)(1) Subject to paragraph (2) and in accordance with other applicable law, the Secretary of Defense may, upon request from the head of a Federal law enforcement agency, make Department of

Defense personnel available to operate equipment (including equipment made available under section 372 of this title) with respect to—

"(A) a criminal violation of a provision of law specified in paragraph (4)(A); or

"(B) assistance that such agency is authorized to furnish to a State, local, or foreign government which is involved in the enforcement of similar laws.

"(2) Department of Defense personnel made available to a civilian law enforcement agency under this subsection may operate equipment for the following purposes:

"(A) Detection, monitoring, and communication of the movement of air and sea traffic.

"(B) Aerial reconnaissance.

"(C) Interception of vessels or aircraft detected outside the land area of the United States for the purposes of communicating with such vessels and aircraft to direct such vessels and aircraft to go to a location designated by appropriate civilian officials.

"(D) Operation of equipment to facilitate communications in connection with law enforcement programs specified in paragraph (4)(A).

"(E) Subject to joint approval by the Secretary of Defense, the Attorney General, and the Secretary of State, in connection with a law enforcement operation outside the land area of the United States—

"(i) the transportation of civilian law enforcement personnel; and

"(ii) the operation of a base of operations for civilian law enforcement personnel.

"(3) Department of Defense personnel made available to operate equipment for the purpose stated in paragraph (2)(C) may continue to operate such equipment into the land area of the United States in cases involving the pursuit of vessels or aircraft where the detection began outside such land area.

"(4) In this subsection:

"(A) The term 'Federal law enforcement agency' means an agency with jurisdiction to enforce any of the following:

"(i) The Controlled Substances Act (21 U.S.C. 801 et seq.) or the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.).

"(ii) Any of sections 274 through 278 of the Immigration and Nationality Act (8 U.S.C. 1324–1328).

"(iii) A law relating to the arrival or departure of merchandise (as defined in section 401 of the Tariff Act of 1930 (19 U.S.C. 1401) into or out of the customs territory of the United States (as defined in general headnote 2 of the Tariff Schedules of the United States) or any other territory or possession of the United States.

"(iv) The Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 et seq.).

"(B) The term 'land area of the United States' includes the land area of any territory, commonwealth, or possession of the United States.

"(c) The Secretary of Defense may, in accordance with other applicable law, make Department of Defense personnel available to any Federal, State, or local civilian law enforcement agency to

operate equipment for purposes other than described in paragraph (2) only to the extent that such support does not involve direct participation by such personnel in a civilian law enforcement operation unless such direct participation is otherwise authorized by law.

"§ 375. Restriction on direct participation by military personnel

"The Secretary of Defense shall prescribe such regulations as may be necessary to ensure that the provision of any support (including the provision of any equipment or facility or the assignment or detail of any personnel) to any civilian law enforcement official under this chapter does not include or permit direct participation by a member of the Army, Navy, Air Force, or Marine Corps in a search and seizure, an arrest, or other similar activity unless participation in such activity by such member is otherwise authorized by law.

"§ 376. Support not to affect adversely military preparedness

"Support (including the provision of any equipment or facility or the assignment or detail of any personnel) may not be provided to any civilian law enforcement official under this chapter if the provision of such support will adversely affect the military preparedness of the United States. The Secretary of Defense shall prescribe such regulations as may be necessary to ensure that the provision of any such support does not adversely affect the military preparedness of the United States.

"§ 377. Reimbursement

"(a) To the extent otherwise required by section 1535 of title 31 (popularly known as the 'Economy Act') or other applicable law, the Secretary of Defense shall require a civilian law enforcement agency to which support is provided under this chapter to reimburse the Department of Defense for that support.

"(b) An agency to which support is provided under this chapter is not required to reimburse the Department of Defense for such support if such support—

"(1) is provided in the normal course of military training or operations; or

"(2) results in a benefit to the element of the Department of Defense providing the support that is substantially equivalent to that which would otherwise be obtained from military operations or training.

"§ 378. Nonpreemption of other law

"Nothing in this chapter shall be construed to limit the authority of the executive branch in the use of military personnel or equipment for civilian law enforcement purposes beyond that provided by law before December 1, 1981.

"§ 379. Assignment of Coast Guard personnel to naval vessels for law enforcement purposes

"(a) The Secretary of Defense and the Secretary of Transportation shall provide that there be assigned on board every appropriate surface naval vessel at sea in a drug-interdiction area members of the Coast Guard who are trained in law enforcement and have powers of the Coast Guard under title 14, including the power to make arrests and to carry out searches and seizures.

"(b) Members of the Coast Guard assigned to duty on board naval vessels under this section shall perform such law enforcement functions (including drug-interdiction functions)—

"(1) as may be agreed upon by the Secretary of Defense and the Secretary of Transportation; and

"(2) as are otherwise within the jurisdiction of the Coast Guard.

"(c) No fewer than 500 active duty personnel of the Coast Guard shall be assigned each fiscal year to duty under this section. However, if at any time the Secretary of Transportation, after consultation with the Secretary of Defense, determines that there are insufficient naval vessels available for purposes of this section, such personnel may be assigned other duty involving enforcement of laws listed in section 374(b)(4)(A) of this title.

"(d) In this section, the term 'drug-interdiction area' means an area outside the land area of the United States (as defined in section 374(b)(4)(B) of this title) in which the Secretary of Defense (in consultation with the Attorney General) determines that activities involving smuggling of drugs into the United States are ongoing.

"§ 380. Enhancement of cooperation with civilian law enforcement officials

"(a) The Secretary of Defense, in cooperation with the Attorney General, shall conduct an annual briefing of law enforcement personnel of each State (including law enforcement personnel of the political subdivisions of each State) regarding information, training, technical support, and equipment and facilities available to civilian law enforcement personnel from the Department of Defense.

"(b) Each briefing conducted under subsection (a) shall include the following:

"(1) An explanation of the procedures for civilian law enforcement officials—

"(A) to obtain information, equipment, training, expert advice, and other personnel support under this chapter; and

"(B) to obtain surplus military equipment.

"(2) A description of the types of information, equipment and facilities, and training and advice available to civilian law enforcement officials from the Department of Defense.

"(3) A current, comprehensive list of military equipment which is suitable for law enforcement officials from the Department of Defense or available as surplus property from the Administrator of General Services.

"(c) The Attorney General and the Administrator of General Services shall—

"(1) establish or designate an appropriate office or offices to maintain the list described in subsection (b)(3) and to furnish information to civilian law enforcement officials on the availability of surplus military equipment; and

"(2) make available to civilian law enforcement personnel nationwide, tollfree telephone communication with such office or offices.".

(b) CLERICAL AMENDMENT.—The item relating to such chapter in the tables of chapters at the beginning of subtitle A, and at the beginning of part I of subtitle A, of title 10, United States Code, is amended to read as follows:

"18. Military Support for Civilian Law Enforcement Agencies ..... 371".

SEC. 1105. ENHANCED DRUG INTERDICTION AND ENFORCEMENT ROLE FOR THE NATIONAL GUARD

(a) FUNDING ASSISTANCE.—(1) The Secretary of Defense may provide to the Governor of a State who submits a plan to the Secretary under paragraph (2) sufficient funds for the pay, allowances, clothing, subsistence, gratuities, travel, and related expenses of personnel of the National Guard of such State used—

(A) for the purpose of drug interdiction and enforcement operations; and

(B) for the operation and maintenance of the equipment and facilities of the National Guard of such State used for such purposes.

(2) The Secretary may provide funds under paragraph (1) to the Governor of a State who submits to the Secretary a plan specifying how personnel of the National Guard of that State are to be used in drug enforcement and interdiction operation by a National Guard of a State if—

(A) such operations are conducted at a time when personnel of the National Guard of the State are under the command and control of State authority and are not in Federal service; and

(B) participation by a National Guard personnel in such operations is service in addition to annual training required under section 502 of title 32, United States Code.

(3) Before funds are provided to the Governor of a State under this section, the Secretary of Defense shall consult with the Attorney General of the United States regarding the adequacy of the plan submitted by the Governor to the Secretary.

(4) Of the amounts appropriated pursuant to section 1106, the Secretary shall, for the purposes of paragraph (1), make available—

(A) not more than $30,000,000 for operations and maintenance for the National Guard, and

(B) not more than $30,000,000 for National Guard personnel.

(5) Nothing in this subsection shall be construed as a limitation on the authority of any unit of the National Guard of a State, when such unit is not in Federal service, to perform law enforcement functions authorized to be performed by the National Guard by the laws of the State concerned.

(b) TRAINING CRITERIA.—The Secretary of Defense shall prescribe and enforce training criteria for the National Guard to enhance the capability of the National Guard to assist in drug abuse control activities.

(c) PRESIDENTIAL REPORT.—Not later than 120 days after the date of the enactment of this Act, the President shall submit to Congress a report on the past effectiveness of using members of the National Guard for drug interdiction efforts, consistent with applicable law, along the borders and at the ports of entry of the United States and on the potential for the effective use of such members for such purpose in the future.

SEC. 1106. FUNDING OF ACTIVITIES RELATED TO DRUG INTERDICTION

(a) AUTHORIZATION OF APPROPRIATIONS.—(1) In addition to the amounts otherwise authorized to be appropriated by this Act, there is hereby authorized to be appropriated to the Department of Defense for fiscal year 1989 the sum of $210,000,000. Amounts appropriated pursuant to the preceding sentence shall be available only for transfer to other appropriations available to the Department of

Defense and may be used only for the purposes stated in paragraph (2).

(2) Funds transferred under paragraph (1) may be used only for the mission of the Department of Defense set forth in section 113(1) of title 10, United States Code, as added by section 1101, for the activities of the Department of Defense under section 1103, and for National Guard drug interdiction activities described in section 1105. Such funds shall be available for obligation for the same period, and for the same purpose, as the appropriation to which transferred.

(b) TRANSFER OF FISCAL YEAR 1987 FUNDS.—Of the amounts appropriated for the Navy for procurement of aircraft for fiscal year 1987, and which remain unobligated on the date of the enactment of this Act, the sum of $90,000,000 shall be available only for the purposes set forth in subsection (a)(2). Such amount may be transferred to any appropriation made for the Department of Defense for fiscal year 1989 and shall be merged with, and be available for the same purpose as, the appropriation to which transferred. The period of the availability for obligation of any amount so transferred shall not be extended as a result of such transfer.

(c) NOTICE TO CONGRESS.—(1) The Secretary of Defense may not transfer any funds appropriated pursuant to subsection (a) to another appropriation for obligation pursuant to this section and may not transfer or obligate any funds made available under subsection (b) until—

(A) the Secretary submits to the Committees on Armed Services of the Senate and the House of Representatives a report with respect to that transfer described in paragraph (2); and

(B) a period of 60 days elapses after the report is received by those committees.

(2) A report under paragraph (1) with respect to a transfer of funds shall set forth in detail the Secretary's proposal for the obligation of such funds, including a statement of the following:

(A) The appropriation account or accounts to which the funds are proposed to be transferred.

(B) The activities proposed to be undertaken using those funds.

(C) The relationship between those activities and the drug interdiction strategy of the United States.

SEC. 1107. REPORTS

(a) PROPOSALS.—Not later than December 1, 1988, the President shall submit to Congress a report containing—

(1) legislative proposals to enhance the capability of the Department of Defense to perform the functions provided for in this title and in the amendments made by this title; and

(2) estimates of the amounts necessary to carry out such proposals.

(b) RADAR COVERAGE AND SOUTHERN BORDER.—(1) The President shall submit to the Committees on Armed Services of the Senate and the House of Representatives a report assessing the potential effect on drug interdiction and on the drug abuse problem in the United States of—

(A) carrying out radar coverage along the southern border of the United States; and

(B) pursuing drug smugglers detected by such radar coverage with rotor-wing and fixed-wing aircraft of the Department of Defense and of civilian law enforcement agencies.

(2) The President shall include in such report an assessment of the relative effectiveness—

(A) of carrying out the operations described in clauses (A) and (B) of paragraph (1) on a full-time basis;

(B) of carrying out such operations only during the hours of darkness; and

(C) the feasibility and cost of carrying out such operations under each of the conditions specified in clauses (A) and (B).

(3) The report under paragraph (1) shall be submitted not later than 30 days after the date of the enactment of this Act.

(c) PURSUIT BY AIRCRAFT.—(1) Not later than 15 days after the date of the enactment of this Act, the Secretary of Defense shall submit to the Committees on Armed Services of the Senate and the House of Representatives a report containing the following information:

(A) The total number of times suspected drug smugglers flying aircraft into the United States have been pursued by aircraft operated by or with the support of personnel of the Department of Defense under the authority of section 374(c)(2)(B) of title 10, United States Code, as in effect on the day before the date of the enactment of this Act.

(B) The number of times civilian law enforcement officials were present at the location and at the time the suspected drug smugglers were forced to land their aircraft in the United States as a result of the pursuit of the aircraft operated by or with the support of Department of Defense personnel.

(C) The number of times such officials were not present at the location and at the time such suspected smugglers were forced to land their aircraft in the United States.

(2) Not later than one year after the date of the enactment of this Act, the Secretary of Defense shall submit to such committees a report containing the following information:

(A) The total number of times suspected drug smugglers described in paragraph (1) have been pursued into the United States by aircraft operated by or with the support of Department of Defense personnel under the authority of section 374(b)(2)(C) of title 10, as amended by section 1104.

(B) The number of times civilian law enforcement officials were present at the location and at the time the suspected drug smugglers were forced to land their aircraft in the United States as a result of the pursuit of the aircraft operated by or with the support of Department of Defense personnel.

(C) The number of times such officials were not present at the location and at the time such suspected smugglers were forced to land their aircraft in the United States as a result of the pursuit of the aircraft operated by or with the support of Department of Defense personnel.

(D) Such other information and such recommendations as the Secretary considers appropriate regarding the use of Department of Defense personnel for purposes authorized in section 374(b) of title 10, United States Code, as amended by section 1104.

D R A F T -- 9/29/88 5:00pm

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

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

D R A F T -- 9/29/88 5:00pm

THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

September Progress Report

29 September 1988

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

Status

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

- o A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989. ISSUES: counseling, testing, partner notification, reporting of HIV infection, and health care worker safety.

- o Five regional "mini-summits" will be held from January to May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

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

  - -- "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety, and liability.

  - -- "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.

  - -- "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in behaviors that transmit the infection and other legal issues.

  - -- "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

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

9/29

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

Status

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

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

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

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9/29

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9/29

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

Status

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

Several important HIV-related issues:

- **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.

- **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on Congressional action. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. One of the new HHS consensus conferences will address the issue of personnel. To alleviate the facilities problem, HHS is investigating with DOD the possible use of unused or under-used federal facilities.

- **High-Risk Populations** HHS and DOJ are developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. HHS and DOJ are providing technical assistance to major metropolitan areas working with high-risk youth. 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.

9/29

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

Status

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

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

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

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

9/29

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, a lease-purchase acquisition has been approved in the FY 1989 budget for the Centers for Disease Control to provide additional laboratory and office space.

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

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

DRAFT

9/29

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

Status

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

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

DRAFT

9/29

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

Status

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

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

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

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

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

9/29

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

Status

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

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

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

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

DRAFT

9/29

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

Status

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

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

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

DRAFT

9/29

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

Status

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

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

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

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

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

9/29

Dr. Mac:

Jay Plager called (6:15pm) -- his people have worked up some additional/alternate language for #4 of the ten-point plan (based on the draft which you gave him last week) attached is the revised!

Hope you enjoy all your reading pleasure!

Sue

OFFICE OF MANAGEMENT AND BUDGET
ROUTE SLIP

TO Ian MacDonald

Take necessary action	☐
Approval or signature	☐
Comment	☐
Prepare reply	☐
Discuss with me	☐
For your information	☐
See remarks below	☐

FROM Jay Plager

DATE 9/29/88

REMARKS

Here is our mark up of the status of FDA's drug approval initiative. It reflects our understanding of FDA's intentions. You should, however, check with Commissioner Young to see if he agrees. Let me know if Frank has any problems with our revisions.

OMB FORM 4

Jeremy — Status?

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 12, FDA ~~released a~~ submitted a draft proposal designed to expedite approval for therapies to treat life-threatening illnesses. The proposal was ~~developed in coordination with~~ pursuant to a request from the Vice President and the Presidential Task Force on Regulatory Relief. It is designed to reduce the total premarket development time of ~~most~~ this class of drugs ~~should be shortened~~ by 25 percent. The FDA ~~will~~ proposes to work with the drug sponsor early in the course of the approval process ~~to~~ design and conduct expedited so that the controlled clinical trials ~~which provide definitive data~~ sponsor may regarding safety and effectiveness. Some key components of the proposal are:

- ~~Providing patients with clinically tested yet experimental drugs prior to marketing approval.~~
- ~~Exceptions for the use of possible, yet unproven,~~ Permitting the marketing of drugs for treating life-threatening illnesses for which some clinical evidence demonstrates the drug may be effective
- Permitting FDA to request ~~Post-marketing~~ studies to gather additional information about the drug's risks and benefits for approved

Incentives for Drug Development At HHS, a working group was appointed on _____ to consider incentives for private development and marketing of HIV products, including issues such as granting marketing rights and waivers of royalty or patent licensing rights. The group has also been charged with examining the Federal role in encouraging reasonable pricing for HIV-related products which are developed in part with Federal grants. A report is due in December.

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.

[Flush cont. ¶3]

As part of this proposal, FDA is ~~going to~~ developing a draft ~~rule~~ regulations that would detail the expedited review process and the criteria for the review and approval of these drugs.

Incorporating a risk-benefit analysis in to the drug evaluation process for this class of drugs

FACSIMILE TRANSMISSION REQUEST

ADDRESSEE: (NAME, ORGANIZATION, CITY, STATE & PHONE#)	FROM: (NAME, ORGANIZATION & PHONE #)
Sue Deolis The White House Wash., DC / Old Exec Office Bldg.	Jerry Bitter ASPE/HHS 245-9774

TOTAL PAGES	FAX MACHINE PHONE NUMBER (IF KNOWN)	DATE	CHARGE SYMBOL
9	456-2246	9/30/88	ASPE

REMARKS

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Room 220
HHS UP

Addendum to
FDA'S RESPONSE TO PRESIDENT REAGAN'S 10-POINT ACTION PLAN FOR AIDS

Timetable for FDA Action Items

I. Prompt Notification of Transfusion Recipients

A. Transfusion Recipients from a Donor Subsequently Found to be Infected with HIV

1. FDA will prepare draft proposed regulations by mid-1989 to make the current voluntary look-back program mandatory. This timeframe reflects a high FDA priority and FDA resource commitment for this action as well as the high complexity of the subject matter being addressed. Further action on draft proposed regulations will depend upon the priority given this action by PHS and DHHS.

2. Action by HCFA. FDA has discussed this issue with HCFA and will continue to provide assistance.

3. Action by AMA. FDA will discuss and provide assistance to AMA by end of 1988.

B. Recipients of Transfusions from Infected Donors Who Remain Undetected

1. FDA will place this issue on the agenda of the October 1988 PHS Blood Subgroup meeting. Meeting with CDC to determine need for revised guidelines will be held subsequent to the PHS Blood Subgroup meeting.

2. Action by AMA. FDA will discuss and provide assistance to AMA by the end of 1988.

3. Action will be determined based on results of #1 above.

4. In progress.

5. Initial meeting with AHA scheduled for September 28, 1988 in Chicago.

6. FDA will develop appropriate PHS communication by the end of 1989.

II. Steps to Improve Laboratory Quality and HIV Screening Tests

1. In progress.

2. FDA will prepare draft proposed regulations by the end of January 1989 that will require blood establishments to demonstrate satisfactory performance in a proficiency testing program that meets HCFA standards. These regulations will rely heavily on already existing HCFA regulations; therefore, preparation of these draft regulations is much simpler than those described in I.A.1 above.

3. In progress.

4. In progress.

5. In progress.

6. Pilot program in progress.

III. Encourage the Use of Autologous Transfusions in Appropriate Circumstances

1. In progress.

2. Action by NIH/NHLBI. Position paper completion anticipated by mid-1989.

3. Action by AHA. FDA/NIH meeting with AHA scheduled for September 28, 1988 in Chicago.

Drafted D.Henderson 9/26
Revised P.Parkman 9/26
Revised J.Lavitt 9/26
Approved P.Parkman 9/26

DRAFT 9/23/ PM

RESPONSE TO PRESIDENT REAGAN'S DIRECTIVE TO HHS FOR AIDS

Point 4 of the President's directive to HHS for AIDS calls for the implementation of actions which address the blood safety issues raised by the Presidential Commission on the HIV Epidemic. The Secretary, Health and Human Services, is asked to address three areas: (I) the prompt notification of transfusion recipients who are at increased risk of HIV infection; (II) steps to improve HIV laboratory quality and HIV screening tests; and, (III) ways to encourage the use of autologous transfusions in appropriate circumstances.

On September 8, 1988, the Food and Drug Administration (FDA) held a meeting to discuss appropriate action to respond to the President's charge. Attendees of the meeting included members of the blood subgroup of the PHS AIDS Executive Task Force (representatives attended from FDA, NIH and CDC), representatives of the major blood organizations (American Association of Blood Banks, Council of Community Blood Centers, and American Red Cross), and representatives from the American Hospital Association and the American Medical Association. A follow-up meeting was held with the Commissioner and a representative of the Health Care Financing Administration (HCFA). As a result of these meetings, the FDA proposes the following plan to address the blood safety issues raised above.

Currently, a three-tiered system is in place to ensure that contaminated blood or blood products are not transfused. First, since 1983, when blood-borne transmission of AIDS seemed likely, the Public Health Service (PHS) issued recommendations that individuals who practiced recognized high risk behaviors for AIDS voluntarily refrain from donating blood or plasma. These recommendations have been modified over time as our knowledge of the epidemiology of the disease has expanded. The application of these guidelines has proven to be very effective in eliminating at-risk donors from the donor pool. Second, in 1986, methods earlier adopted in several blood collection establishments[1] for donors at risk for HIV infection to exclude their units from the blood supply in a confidential manner were instituted nationwide. Finally, the third level of protection, which was initiated in 1985, is testing of all units of blood and plasma for antibodies to HIV. By implementing all three levels of protection, the risk of HIV transmission by blood transfusion is exceedingly small. The small number of transfusion-associated infections which have been reported since 1985 probably occurred because HIV antibodies had not yet formed in infected donors when the screening was done and thus were not detectable by the screening tests used. This is a rare event, with published estimates of risk ranging from a high of 1 in 40,000 to a low of 1 in 250,000.

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[1] Blood establishments include those facilities that collect, process, store or distribute blood products. The Code of Federal Regulations (21 CFR Part 607) requires that these establishments register annually with the FDA. Facilities engaged only in transfusion of blood products prepared by an outside laboratory are not under the jurisdiction of the FDA and are usually known as "transfusion services".

7. PROMPT NOTIFICATION OF TRANSFUSION RECIPIENTS

Transfusion recipients who are at increased risk for HIV infection can be defined as those who have received blood from a donor who is infected with HIV. Such recipients fall into two categories: A) those who received blood from a donor later found to be infected and B) those who received blood from an infected donor who was not subsequently identified.

A. Transfusion Recipients from a Donor Subsequently Found to be Infected with HIV

In instances in which a blood donor is known to be infected (detected during routine screening for antibodies to HIV at the time of a later donation), most blood collection establishments have initiated a program of voluntary "look-back". In this program, recipients of blood or blood products obtained from the infected donor's prior donation(s) are traced and tested. Recipient tracing is continued retrospectively until two recipients are found to test negative for HIV antibodies. The look-back program provides an effective mechanism for identifying, testing and counseling transfusion recipients who are at the highest risk for HIV infection -- those who received blood from a donor later found to be infected with HIV.

FDA believes that the look-back program is the most important initiative to address the President's directive to notify blood recipients at increased risk for HIV infection. Two problems have been identified with the current program. First, at this time, look-back is voluntary and the degree of compliance by blood establishments with the voluntary program has not been ascertained. Second, the chain of responsibility for notification of transfusion recipients once an infected donor has been identified is not precisely delineated.

Patient notification now depends upon the efforts of those who have the patient records, i.e., the transfusion services and health care providers, to locate the patients. The FDA believes that direct notification should continue to be performed in this way. However, the ultimate responsibility to document that notification has occurred, where possible, should rest with the blood collection establishment which collected the potentially contaminated product(s). Under the provisions of the Public Health Service Act (42 U.S.C. 262-64) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351-360k, 374), FDA has adequate legal authority to require blood establishments to undertake or ensure recipient notification.

The following actions are recommended to enhance the effectiveness of look-back:

1. FDA will promulgate regulations to make the current voluntary look-back program mandatory. Such regulations would require that blood collection establishments notify the appropriate transfusion establishments as soon as an infected donor is identified and implement a system of follow-up to ensure that either recipients are notified or that the physician of record determined that notification

was inappropriate or was not possible. Since the systems of follow-up will vary, details of follow-up methods will be developed in the course of preparing the regulation.

2. The Health Care Financing Administration (HCFA), through the Joint Commission for Accreditation of Health Care Organizations (JCAHO), should promulgate and enforce requirements that blood transfusion services (most often hospital-based blood banks) notify the appropriate physicians that potentially contaminated units have been released and look-back notification should be initiated. The requirements will include provisions that enable implementation of the follow-up system required of the blood collection establishments.

3. The American Medical Association should initiate programs to educate physicians to ensure that, when possible, transfusion recipients who become part of a look-back effort are appropriately notified, tested and counseled.

b. Recipients of Transfusions From Infected Donors Who Remain Undetected

Look-back programs cannot identify all infected donors because after HIV antibody screening of donors began 1) many infected donors have refrained from donating or 2) become too ill to continue to donate. Therefore, some additional notification effort is warranted.

As noted above, since the uniform implementation in blood establishments of screening for antibodies to HIV, the risk of transfusion-associated HIV infection is extremely small. Therefore, the PHS believes strongly that any effort to notify transfusion recipients of their risk for HIV infection should be limited to those who received transfusions between 1977 and mid-1985.

Notification of these transfusion recipients can be classified in two ways: direct, individual notification (such as by letter) and general, widespread notification (such as through various media).

o Direct, Individual Notification

Under certain defined circumstances, the PHS has already encouraged direct notification of transfusion recipients at increased risk for HIV infection. The Morbidity and Mortality Weekly Report (MMWR) of March 20, 1987, recommended testing and counseling for individuals who received multiple transfusions of unscreened blood in areas with a high incidence of AIDS.

Direct notification by letter of all transfusion recipients between 1977 and 1985 has been attempted by a number of centers in the United States. Data from these efforts indicates that the process is both ineffective in detecting potential carriers of HIV infection as well as extremely resource-intensive. With a rate of infection in this population

estimated to be as low as 1 in 1000 and mortality over 4 years to be greater than 50% due to the severity of underlying illness, individual tracing for those transfused in 1985 and earlier would be nearly impossible. The PHS therefore believes that widespread, individual notification of all transfusion recipients is not the optimum mechanism for notifying these individuals of their potential risk.

c. General notification.

The March 1987 Centers for Disease Control (CDC) recommendations described above received widespread media coverage, prompting thousands of phone calls by previous recipients to blood centers and physicians. More recently, the Surgeon General's mailing to all United States' households advised that individuals who received blood prior to the implementation of screening may be at increased risk for infection.

Additional efforts to increase awareness of the risk of transfusion-associated HIV infection need to be targeted at two groups: the medical community and the general public. Physicians should routinely obtain, during medical history taking, information regarding risk behavior for HIV infection, which includes prior transfusions. Testing and counseling can then be appropriately offered to those at increased risk. An information campaign targeted at the general public should be designed to inform individuals who were transfused prior to 1985 of their potential exposure to HIV. Such a campaign, while generally addressing all HIV-related risks and the need for testing and counseling of those at risk, would be designed to spotlight the transfusion-associated risk. An additional benefit of a public information campaign versus individual notification by letter would be its ability to reach not only transfusion recipients but their sexual partners as well.

To achieve optimum notification, testing and counseling of individuals at increased risk for transfusion-associated HIV infection, PHS will implement the following actions:

1. FDA and CDC will work together to develop criteria to define populations at increased risk for transfusion-related HIV infection and will update, if necessary, the March 1987 recommendations. CDC will publish revised recommendations in the MMWR.

2. CDC and FDA will work with the AMA to develop educational materials designed to educate physicians about appropriate use of blood and blood products and to help physicians to identify and notify individuals at increased risk for transfusion-associated HIV infection.

3. FDA will publish an article in the Drug Bulletin. This article will reiterate CDC recommendations for individual notification of transfusion recipients as well as provide updated information on the general risk for transfusion-associated HIV infection.

4. The National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and the Health Resources and Services Administration (HRSA) will continue to support the development of medical school curricula to include risk assessment for HIV infection, including transfusion-associated risk.

5. FDA, CDC, and NIH will work with the American Hospital Association to develop an appropriate education strategy for transfusion recipients. AHA currently plans to develop and provide education to health care personnel, technical assistance to hospitals, and a national public awareness campaign to address HIV-related risks and strategies for prevention. Representatives from FDA and NIH will participate as part of a national AHA task force to develop this strategy. The first meeting is to be held September 28, 1988 in Chicago.

6. FDA will develop a Public Health Service communication, either in the form of a video news release or PHS announcement which will address the risk for transfusion-associated HIV infection and the benefits of testing and counseling. This communication will be carefully worded so as to describe the magnitude of transfusion-associated risk.

II. STEPS TO IMPROVE LABORATORY QUALITY AND HIV SCREENING TESTS

Tests to measure the development of antibodies to HIV have been commercially available since the spring of 1985. Currently, eight different test kits have been licensed by FDA -- seven enzyme-linked immunoassay (ELISA) test kits and one Western blot test kit. These tests, especially used in combination, are extremely sensitive and specific in detecting HIV infection. However, to ensure that new and/or refined tests for HIV infection are available as rapidly as possible, FDA continues to place high priority on their expeditious review.

FDA is expanding its program for ensuring that blood products are safe and effective to include new initiatives directly related to increasing the accuracy of laboratory tests for anti-HIV. This laboratory quality program will be coordinated by the Center for Biologics Evaluation and Research and will encompass proficiency testing, surveillance and compliance actions, education and training as follows:

1. The FDA will assist CDC and HCFA in developing: 1) proficiency testing requirements for anti-HIV (developing a final rule based on the Notice of Proposed Rule Making published on August 5, 1988); and 2) will develop standards for laboratory quality audit programs.

2. FDA will publish a requirement for blood establishments to demonstrate satisfactory performance in a proficiency testing program that meets the HCFA standards. FDA will ensure through annual inspections of blood establishments that all laboratories are enrolled in the CDC proficiency testing program for anti-HIV or an equivalent private sector program meeting the requirements of 42 CFR, Part 493 (proposed rule, August 5, 1988).

3. The effectiveness of FDA laboratory surveillance activities will be increased by additional training for all FDA investigators and a revised inspection checklist. All Reference Laboratories performing anti-HIV tests will be added to the FDA work plan for FY 1989.

4. The accident and error reporting requirements will be revised to provide a uniform procedure for reporting errors and accidents and FDA will continue to monitor incidents to ensure aggressive corrective action.

5. The public's awareness of FDA's concern for laboratory quality will be heightened by publication of data, registration of proficiency testing program participation and notification of FDA's recommendation for periodic personnel competency evaluation.

6. The FDA will provide training to ensure understanding of the critical elements of accurate test performance for anti-HIV. A pilot program is already underway to rapidly produce a video instruction program that will be widely available to both FDA staff and all laboratory workers.

III. ENCOURAGE THE USE OF AUTOLOGOUS TRANSFUSIONS IN APPROPRIATE CIRCUMSTANCES

Whereas the use of autologous donated blood has been common in certain types of surgery (such as orthopedic surgery) for many years, the recent alarm about transfusion transmitted disease has stimulated wider interest in the practice.

1. The FDA, in cooperation with the NHLBI is exploring modes of public education to explain the benefits as well as the limitations of autologous use programs.

2. The NHLBI, through its National Blood Resource Education Program will convene an Expert Panel on Autologous Transfusion in early October. Like other such panels, this one will prepare a position paper which will include designing, testing and distributing public messages aimed at encouraging the use of autologous donations by patients and physicians. This position paper, expected in mid-1989, will be widely disseminated to professional audiences; modified materials will be available for lay audiences.

3. FDA and CDC will work with the AHA to develop educational materials for health care personnal concerning appropriate use of blood and blood products and alternatives to homologous transfusion.

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(date)

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

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

I am pleased to report that 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 ten consensus conferences to intensify public/private sector collaboration on public health measures to reduce the spread of AIDS.
- In response to your directive to promote fairness and compassion, the 22 largest Federal agencies will have OPM guidelines in place by December.
- FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has announced a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- The Attorney General is working on issues related to anti-discrimination law -- a most sensitive and important issue.

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

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THE PRESIDENT'S 10-POINT ACTION PLAN

AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

September Progress Report

3 October 1988

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

- o A "U.S. Health Summit" will kick-off the series in Washington, D.C., on November 28-29, 1989. ISSUES: counseling, testing, partner notification, reporting of HIV infection, and health care worker safety.

- o Five regional "mini-summits" will be held from January to May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

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

  - -- "AIDS: Frontline Health Care" (January 8-10, 1989). ISSUES: prevention, treatment, safety, and liability.

  - -- "Federal-State Strategies" (February 1989) with the National Governor's Association meeting. ISSUES: neighborhood resistance to drug abuse treatment facilities; alternative drug abuse service facilities; integrating drug abuse care with primary care; and, training alcohol, drug abuse, mental health workers.

  - -- "Legal Issues" (tentative) (May 1989). ISSUES: restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in behaviors that transmit the infection and other legal issues.

  - -- "Reporting HIV Infection" (tentative) -- Atlanta; June 1989.

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

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

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

Status

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

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

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

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

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

Status

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

Several important HIV-related issues:

- **Evaluation of Effective Treatment** Your legislative package emphasizes increased evaluation of "what works" in drug treatment. Both the House and Senate bills contain provisions for increased evaluation.

- **Increased Drug Treatment Capacity** The availability of additional funds for drug treatment hinges on Congressional action. However, money is not the only constraint to increasing treatment capacity -- availability of trained personnel and treatment facilities will slow any expansion. One of the new HHS consensus conferences will address the issue of personnel. To alleviate the facilities problem, HHS is investigating with DOD the possible use of unused or under-used federal facilities.

- **High-Risk Populations** HHS and DOJ are developing demonstration projects which target populations at high-risk for HIV/AIDS, including women of child-bearing age, infants born with HIV/AIDS, and high-risk youth. HHS and DOJ are providing technical assistance to major metropolitan areas working with high-risk youth. 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.

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

Status

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

- Early consultation between FDA and drug sponsors to develop studies which provide definitive data on safety and effectiveness earlier in the approval process, thereby compressing two phases of the present process into one and shortening the approval time.

- Focused FDA research when the sponsor is unable to conduct all necessary research or when FDA can contribute special research expertise (e.g. pharmacokinetics).

- Appropriate drugs will be made available for treatment as Investigational New Drugs after completion of the expedited testing process and prior to full marketing approval.

- Risk-benefit analysis to assess the risks of the disease against the identified benefits and risks of the products.

- Proactive involvement of the FDA Commissioner and other agency officials with sponsors to assure that product review is proceeding on schedule.

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

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

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

Status

Space Needs 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, a lease-purchase acquisition has been approved in the FY 1989 budget for the Centers for Disease Control to provide additional laboratory and office space.

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

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

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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

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

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

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	65.4
OASH	0.0	0.0	0.0	0.0	0.0	0.2	3.7	13.4
IHS	0.0	0.0	0.0	0.0	0.0	0.1	0.6	0.8
SUB-TOTAL PHS	5.6	28.7	61.5	108.6	233.8	502.5	951.0	1289.8
Hlth Care Finc. Admin.								
Medicaid (Fed Share)	0.0	10.0	30.0	70.0	130.0	200.0	330.0	490.0
Medicare	0.0	0.0	0.0	5.0	5.0	10.0	15.0	30.0
SUB-TOTAL HCFA	0.0	10.0	30.0	75.0	135.0	210.0	345.0	520.0
Social Security Admin.								
Disability Income	0.0	0.0	5.0	10.0	25.0	40.0	70.0	110.0
Supp.Security Income	0.0	0.0	1.0	3.0	8.0	11.0	18.0	28.0
SUB-TOTAL SSA	0.0	0.0	6.0	13.0	33.0	51.0	88.0	138.0
Human Development Serv.	0.0	0.0	0.0	0.0	0.0	0.0	5.7	5.2
SUB-TOTAL HHS	5.6	38.7	97.5	196.6	401.8	763.5	1389.7	1947.8
Veterans Admin.	2.0	5.0	6.1	10.1	22.9	52.6	82.9	99.3
Dept. of Defense	0.0	0.0	0.0	0.0	79.0	74.0	52.0	52.0
Dept. of Justice	0.0	0.0	0.0	0.0	1.0	3.0	6.0	6.0
Dept. of Labor	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
Dept. of State	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
Dept. of Education	0.0	0.0	0.0	0.0	0.0	0.0	1.2	0.0
Dept. of Agriculture	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3
SUB-TOTAL NON HHS	2.0	5.0	6.1	10.1	102.9	131.6	144.3	159.6
* * * GRAND TOTAL	7.6	43.7	103.6	206.7	504.7	895.0	1534.0	2107.4

Detail may not add to total due to rounding.

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

Status

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

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

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

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

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

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

Status

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

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

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

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

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

Status

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

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

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

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

Status

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

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

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

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

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

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

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

Detail may not add to total due to rounding.