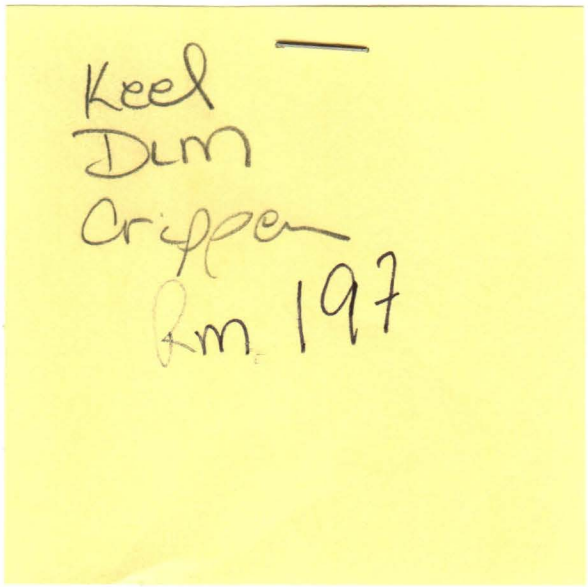
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THE WHITE HOUSE

WASHINGTON

January 9, 1989

MEMORANDUM FOR GOVERNOR JOHN H. SUNUNU

FROM: DONALD IAN MACDONALD, M.D.
DIRECTOR, DRUG ABUSE POLICY OFFICE

SUBJECT: Federal Response to the HIV/AIDS Epidemic

The HIV/AIDS epidemic will continue to be a matter for crisis management during the Bush Administration. In 1992, an estimated 65,000 people will die because of the Human Immunodeficiency Virus (HIV). Regardless of any action we may take, the predicted consequences of this epidemic will place increasing demands on the Nation's health and science resources.

In June 1988, President Reagan received the report of the Presidential Commission appointed to advise him on the complex medical, legal, ethical, social, and economic aspects of the HIV epidemic. The President asked me to review the Commission's report and present him with "a course of action that takes us forward" in the fight against HIV infection.

The resulting 10-point action plan directed immediate implementation of the majority of the Commission's 597 recommendations. There has been significant accomplishments by the Government, the private sector, and the international community. Our knowledge of the HIV and our response to the epidemic have come further faster than with any disease in history. I hope that you will reinforce the existing efforts, including continued Presidential attention.

The attached documents provide background information on the status of the 10-point action plan (Tab A), major unresolved issues with recommendations (Tab B), and major accomplishments (Tab C).

I would be happy to meet with you to share my views and to facilitate transfer of this issue to your staff. I will assist in any way I can. Good luck.

TAB A

History In June 1987, President Reagan issued an Executive Order that created a Commission to advise him on medical, legal, ethical, social and economic issues raised by the HIV epidemic. Admiral James D. Watkins chaired the Commission for most of the year it was in existence. During that time, the Presidential Commission on the HIV Epidemic held a series of about 40 hearings and heard testimony from more than 600 witnesses. On June 27, 1988, Admiral Watkins submitted the Commission's report to the President. The President asked me to review the Commission's report and its 597 recommendations and present him with "a course of action that takes us forward" against HIV infection.

A 10-point action plan was established, based on recommendations of the Presidential Commission on the HIV Epidemic, to advance the U.S. battle against AIDS and HIV. The Plan called for actions to assure compassion towards those with HIV infection, to allow for their care with dignity and kindness, and to inform and educate citizens to prevent further spread of the disease. The President further instructed the Federal government to take the lead in protecting HIV-infected persons against discrimination in the Federal workplace.

Implementation status reports on the 10-point plan were submitted to the President in September and December. In my December report to the President, I was pleased to state that most of the 354 recommendations which fall within the Federal purview have been completed or will be implemented with FY89 funds. Additionally, Federal leadership has stimulated action on most of the 243 recommendations that fall beyond Federal jurisdiction.

Status Report The 10-Point Action Plan Against the Human Immunodeficiency Virus (HIV) Epidemic

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

   Point one responds to 129 of Commission's recommendations.

   Consensus Conferences In response to this point, HHS has planned a series of 10 consensus conferences. The first of this series, "The U.S. Health Summit on HIV Infection", was held in Washington, D.C., November 28-29. Key state and local public health officials discussed issues such as outreach programs to get IV drug users in treatment, management of public health agencies, testing issues such as counseling, reporting and partner notification, and health care worker safety and education. A series of 5 regional mini-Summits will be held between January and May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

The other 4 conferences will address specific issues the President raised in his directive to HHS:

1. "AIDS: Frontline Health Care" is a conference for health care workers jointly sponsored by the Department of Labor, the Department of Health and Human Services, and the National AIDS Network. It will be held in Washington, D.C., January 8, 9, and 10th.

2. A Gubernatorial Consensus Conference on Federal-State strategies to address topics such as neighborhood resistance to drug abuse treatment facilities, alternative drug abuse service facilities, and mainstreaming drug abuse care with primary care is planned during the National Governor's Association meeting in February 1989.

3. The Department of Health and Human Services and the Department of Justice are planning a meeting (tentatively scheduled for May) that will address restrictive measures and criminal statues directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit their infection and other legal issues.

4. The Department of Health and Human Services is planning a consensus conference in May on reporting of HIV infection.

Community-Based Education Programs: In response to the President's 10-point action plan and in recognition of the importance of racial/ethnic minority community-based educational programs, funds for community based programs will double in FY 1989. This will include the direct funding of 15 to 20 community-based organizations in areas with the highest prevalence of AIDS.

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

Point 2 responds to 19 of the Commission's recommendations.

In September, HHS submitted a plan in response to this item. Key elements include:

Notification of transfusion recipients: HHS has intensified efforts for the prompt notification of transfusion recipients at increased risk of HIV infection. These efforts include strengthening existing "look-back" programs by:

a) promulgating regulations to make "look-back" mandatory rather than voluntary when a donor is seropositive;

b) promulgating requirements to ensure that the blood industry and hospitals must notify either each recipient or the physician of each recipient that potentially infectious blood has been administered, ultimately ensuring that each recipient is offered appropriate testing and counseling; and

c) for those individuals who live in high AIDS incidence areas and received multiple blood transfusion between 1977 and 1985 (before the HIV antibody screening test was available), HHS will intensify its efforts to encourage them to seek counseling and testing.

Improving laboratory quality: HHS has begun an intensified strategy to improve the accuracy of laboratory tests for HIV antibody that will include: (a) proficiency testing requirements and development of standards for laboratory quality, (b) inspections of blood bank facilities annually rather than every other year, (c) enhanced training of FDA investigators who inspect blood banks, and (d) training programs for blood establishment staff.

Encouraging the Use of Self-Donated Blood Before Surgery: HHS has begun to implement a public education campaign that will include a public service message campaign. HHS will also work with health professionals to encourage the appropriate use of autologous transfusions.

3. Enact the President's anti-drug proposals in recognition of concern about drug abuse and its relation to HIV infection.

Point 3 responds to 52 of the Commission's recommendations.

This point was largely implemented by the Omnibus Drug Act of 1988, which contains the single largest expansion of funding for drug abuse treatment and authorizes the following activities which are being implemented:

- Prevention and Treatment of Intravenous (IV) Drug Abuse Funds go to states for development, implementation, and operation of IV drug abuse treatment programs, training of drug abuse counselors, and outreach activities to bring persons into treatment.

- Expansion of Demonstration Programs Three-year demonstration projects will be funded to: (1) study efficacy of providing drug treatment and vocational training in exchange for public service; (2) conduct outreach activities to IV drug users to prevent the spread of HIV, and (3) provide drug treatment services to pregnant and postpartum women, and their infants.

4. Begin action in and out of Government to accelerate development, approval and distribution of vaccines and drugs.

Point 4 responds to 67 of the Commission's recommendations.

Acceleration of the Drug Approval Process: At the direction of Vice President Bush and the Presidential Task Force on Regulatory Relief, the FDA has implemented a proposal that will expedite approvals for therapies intended to treat life-threatening illnesses such as AIDS. The proposal compresses the total pre-market drug development time by having FDA work with the drug sponsor early in the course of the approval process to design and conduct controlled clinical trials that are capable of providing definitive data on the drug's safety and effectiveness.

Other key elements of the proposal are:

a) a means to provide patients with experimental drugs between the completion of promising clinical trials and the point of marketing approval;

b) risk-benefit considerations appropriate for drugs intended to treat life-threatening illnesses; and

c) post-marketing studies to gather additional information about the drug's risks and benefits.

Incentives for Drug Development PHS surveyed existing Federal incentives to the private sector for developing HIV-related products and made recommendations to strengthen these incentives. The recommendations include a legislative proposal to assure that the important research and development incentives under the Orphan Drug Act (i.e. market exclusivity and R&D tax credits) will be available after the number of AIDS patients exceeds the 200,000 ceiling applied by the act. In order to assure that new products will be affordable to AIDS patients, PHS has recommended negotiation of equitable pricing assurances in cooperative R&D agreements when exclusive licenses are granted to industrial partners.

Liability Issues In an analysis of the issue, HHS has found no indication that promising research on an AIDS vaccine has been delayed or foregone in the public or private sector because of fears about liability. HHS has, however, identified a series of options for continued attention to possible liability problems.

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

Point 5 responds to 41 of the Commission's recommendations. Space Needs In September, the National Institutes of Health was granted authority to construct a consolidated office building on their Maryland campus. The Commission recommended construction of such a building to remove "one of the most serious research administrative obstacles . . . encountered." Also, the Centers for Disease Control will begin construction of additional laboratory and office space in FY 1989. These buildings will provide room for the expansion necessitated by the AIDS programs of these PHS agencies.

Resource Needs Because of the urgent need, additional FTEs for HHS were approved for FY89. The FY90 budget includes $1.6 billion for Public Health Service programs to combat the HIV epidemic. This is a 24 percent increase over the FY89 appropriation. For FY90, OMB has recommended an HHS allocation of 355 more FTEs than HHS proposed to allocate to PHS for HIV activities. These FTEs are to be reprogrammed from other HHS programs.

Science Personnel The recruitment and retention of science personnel remains a problem for HHS. A recent Institute of Medicine report on retention of NIH intramural health professionals made two major recommendations that address this issue. (See Tab B)

6. Accelerate enactment of the FY89 HIV appropriations request and adopt the FY90 budget request for HIV activities as early as possible after the budget is submitted. Seek a special HIV emergency fund for unanticipated problems and opportunities in the FY90 budget request.

On August 5, the President sent a letter to the Congress announcing his 10-point action plan against HIV and asked Congress to take the important step of enacting the FY 1989 appropriations for HIV activities as expeditiously as possible and to adopt the FY 1990 request as soon as possible after the budget is submitted.

Much of the FY89 HIV appropriation request was contained in the Labor, Health and Human Services and Education Bill which the President signed on September 20. It included a $1.29 billion appropriation to combat HIV infection, which was approximately the amount requested in the President's budget for the Public Health Service.

Status of FY 1990 Request: The following chart lists the government wide spending for HIV activities, including the FY90 request. The PHS budget for FY90 totals $1.6 billion for HIV-related research, education and prevention (a 24 percent increase over FY89). It is estimated that $925 million will be spent in FY90 to provide treatment and disability support through Medicaid, Medicare, Disability Insurance and Supplemental Security Income programs to people infected with AIDS. In addition, the HHS request includes a $25 million emergency fund, as sought by the President, for unanticipated problems and opportunities.

HUMAN IMMUNODEFICIENCY VIRUS (HIV) FUNDING
Government-wide Crosscut
(Obligations in $ millions)

	FY82	FY83	FY84	FY85	FY86	FY87	FY88	FY89*	FY90*
Public Health Service ..... (Research & Prevention)	6	29	61	109	234	502	956	1287	1600
Medicaid (Federal share) ...	0	10	30	70	130	200	330	490	670
Medicare	0	0	0	5	5	10	20	30	40
Social Security									
DI	0	0	5	10	25	40	70	110	170
SSI	0	0	1	3	8	15	18	28	39
Human Development Services .	0	0	0	0	0	0	1	3	3
Office of Civil Rights	0	0	0	0	0	0	0	3	3
Veterans Admin ..... (Res, Prev, & Treatment)	2	5	6	10	23	54	69	98	106
Defense Department ..... (Res, Prev, & Treatment)	0	0	0	0	79	74	52	52	58
AID ..... (Prevention)	0	0	0	0	0	0	30	40	42
Bureau of Prisons ..... (Prev & Treatment)	0	0	0	0	1	1	1	2	3
State Department ..... (Prevention)	0	0	0	0	0	1	2	1	2
Labor Department ..... (Prevention)	0	0	0	0	0	1	1	1	1
Education Department ..... (Prevention)	0	0	0	0	0	0	1	0	1
TOTAL	8	44	104	207	504	898	1549	2145	2816

* Estimate

Detail may not add to total due to rounding.

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

Point 7 responds to 68 of the Commission's recommendations.

Evaluation of Health Care Financing HHS has begun a one-year evaluation of the health care system. The evaluation will concentrate on financing and insurance issues. In conducting the evaluation, HHS will use a Health Care Financing Administration (HCFA) team as well as an outside contract for needed expert information and research support. The study is to be completed by September 1989. (See Tab B.)

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

- stimulating states to apply for the home- and community-based services waiver program;
- soliciting research and demonstration projects to study the effectiveness of out-of-hospital and case-managed care;
- evaluating patterns of utilization and costs in AIDS service demonstration grant projects (due late summer 1989);
- evaluating regional AIDS education and training centers (due late summer 1989).

Risk Pools In January, the Secretary of HHS will send an advisory letter to State Governors and legislative leaders to encourage replication of risk pools for the medically uninsurable in States which now lack such programs. The letter will suggest sources of technical information and assistance which interested States may use.

Infants, Children and Adolescents The HHS Secretary's Task Force on Pediatric HIV Infection Report recommends specific studies regarding infants, children, and adolescents. HHS will be implementing many of the report's recommendations within the next year and will be asking states to review the report for implementation of the relevant recommendations.

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

Point 8 responds to 41 of the Commission's recommendations.

In December, the Department of State submitted a three year plan to accomplish the following goals:

- The 70 countries with which the U.S. is working will have implemented HIV public information campaigns;
- All of these countries will have implemented, and most will have evaluated, educational programs aimed at the reduction of high risk behavior;
- All of these countries will have implemented blood transfusion screening programs for HIV;
- New HIV diagnostics appropriate for use in developing countries will have been field tested and will be in common use;
- Vaccine field trial sites will have been established;
- Better estimates of the number of HIV infected individuals in developing countries will have been completed.

Implementation of the plan assumes coordination between State, HHS, and the World Health Organization's Global Programme on AIDS (GPA). In FY 1989, Congress appropriated $25.5 million for the GPA.

9. Update the 1986 Public Health Service plan for combatting HIV infection.

PHS has published its Report of the Second Public Health Service AIDS Prevention and Control Conference. It is based upon a meeting convened in June 1988 to develop an updated plan for combatting HIV infection. Experts in various fields, including basic research scientists, clinicians, epidemiologist, public health policy makers, pharmaceutical manufacturers, health care providers, minorities and consumers provided advice and guidance to the Federal officials who attended the conference. The Charlottesville report is intended as a guide for the Public Health Service to manage its $1.29 billion HIV program. The issues, goals and objectives are divided among nine areas:

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

Although the Charlottesville Report is not a direct response to the Report of the Presidential Commission on the HIV Epidemic, it was developed within the same time frame and after a year of close interaction of PHS staff with the Commissioners. Consequently, many of the elements in the Charlottesville Report address specific recommendations of the Presidential Commission. PHS will begin to report quarterly on progress in carrying out the plan's goals in January. Each goal will be cross referenced to similar recommendations in the Presidential Commission Report. The FY 1990 budget request contains additional expenditures to implement recommendations of the President's Commission and the 1988 PHS report.

10. Respond equitably and compassionately to those with HIV infection and to their families. Direct all Federal agencies to adopt a policy based on OPM guidelines, and request American businesses, unions and schools examine and consider adopting education and personnel policies based on the OPM and Centers for Disease Control guidelines.

Point 10 responds to 89 of the Commission's recommendations.

Antidiscrimination In October, the Department of Justice issued a legal opinion clarifying the coverage of the Rehabilitation Act. The opinion clarifies that the act protects HIV-infected individuals in Federal employment and programs and activities receiving Federal funds (i.e. schools, hospitals). It also concludes that if the infection is a direct threat to the health or safety of others or renders an individual unable to perform the duties of his or her job, an employer is not required to retain or hire that person.

The Health Omnibus Programs Extension Act of 1988 requires the Secretary of HHS to conduct a study of State laws concerning HIV-related discrimination and confidentiality of counseling and testing records. HHS plans to meet the May deadline for completion of this study. (See Tab B.)

Federal Agencies Implement OPM Guidelines The Office of Personnel Management's (OPM) has reported the status of the largest 22 Federal agencies (representing 96 percent of the work force):

- All 22 agencies are putting AIDS policy guidelines in place. Thirteen agencies have issued AIDS policies. The nine others are presently drafting policies/guidelines to be issued no later than early 1989.

- Twenty-one agencies have initiated formal training and education programs on AIDS-related issues for employees, supervisors and managers. The one remaining agency is currently developing a program and plans to have it in place by December.

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

OPM AIDS Clearinghouse OPM has established a clearinghouse of specific policy statements, educational materials, and training manuals developed by Federal agencies for their AIDS in the workplace programs.

Conference Sponsored In September, OPM sponsored a very successful conference on "AIDS in the Workplace." Presenters discussed issues concerning implementation of an effective AIDS education program. More than 120 Federal managers and personnel specialists attended the conference.

TAB B

TAB B: Unresolved Issues

The HIV/AIDS epidemic raises significant and complex medical, legal, economic and political issues. The President's 10-point action plan directed primary attention to some specific immediate needs and gave encouragement to continuance of efforts already underway. Several key issues, however, were either deferred for further study or deemed more appropriately resolved by the Bush Administration. These unresolved issues and my recommendations are outlined below.

I. Management

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

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

Recommendation I recommend that the Bush Administration examine ways to strengthen the leadership position of HHS. Revision of the HHS structure could include bringing HCFA/PHS together under a senior health official who reports directly to the Secretary and who holds the rank of Deputy Secretary or Under Secretary.

This option would produce the least amount of perturbation in the system and would retain the day-to-day decision-making authority from the Department with most of the responsibility and expertise.

II. Privacy (Confidentiality)

Issue The HIV Commission recommended Federal law to assure privacy and confidentiality of medical information obtained during testing, counseling and treatment encounters. Such assurances are particularly important to people with illnesses such as AIDS which are surrounded with stigma.

With adequate assurances I believe that HIV-infected individuals will come forward for testing and early counseling and treatment. A balance must be reached, however, between privacy/confidentiality and a genuine public health "need to know." Any such efforts, however, will need to be balanced, as we do with other communicable diseases, by the public health "need to know."

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

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

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

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

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

III. Discrimination

Issue Many considered enactment of Federal legislation to protect those who are HIV-infected against discrimination the key recommendation of the Presidential Commission. The President's 10-point action plan, which contained a strong antidriscrimination message and directive, was much criticized in the press for not going far enough. In October, the Department of Justice issued an opinion which

clarified that HIV infected persons are covered by anti-discrimination provisions of Section 504 of the Vocational, Education and Rehabilitation Act.

To enact Federal anti-discrimination raises complex medical, legal, economic and political issues. States have been moving to shore up their protections, but still there are significant gaps. The Department of Justice is reviewing options for additional Federal action. HHS, as required by Congress, is conducting a six month study on the adequacy of existing State laws.

Recommendation I recommend that final decision on this sensitive and complex issue be deferred pending reports from HHS and DOJ.

IV. Shortage of Health Care Workers

Issue The shortage of health care workers, especially nurses, is already affecting our general medical system. This shortage will be greatly intensified if no provisions are made for the 172,000 persons with AIDS it is predicted will require care in 1992. No curative therapy is likely to be available by then. Case managed care and other new approaches will place less reliance on hospital care but not enough to relieve the overburdened system. Two commissions -- the Presidential Commission on the HIV Epidemic and the HHS Commission on the Nursing Shortage -- have made recommendations that address this major problem. HHS is studying these recommendations.

Recommendation I recommend that the next Administration request the Secretary of HHS to make recommendations to the President on measures to improve the adequacy of health care providers.

V. Health Care Financing

Issue The Public Health Service projects that annual medical care costs for AIDS in 1992 will be in the $5-13 billion range. Current trends suggest that the epidemic is spreading most rapidly in populations unable to pay for their medical care.

The 10-point action plan directed HHS to begin a one year study of the current system of health care financing.

Recommendation I recommend that the Bush Administration carefully monitor this important HHS study due for report in September 1989.

VI. AIDS Commission

Issue The Health Omnibus Programs Extension of 1988 establishes a two-year National Commission on AIDS as a successor to the Presidential Commission on the HIV Epidemic. Its purpose is to promote the development of a consensus on AIDS policy and make recommendations regarding policy. Among its functions, the new Commission is to monitor the implementation of the recommendations of the Presidential AIDS Commission, and modify those recommendations as the Commission considers appropriate. Five members are to be appointed by the President, three of whom are specified by the legislation as the Secretary of Health and Human Services, the Secretary of Defense, and the Administrator of Veterans' Affairs. Additionally, five members are to be appointed by the Speaker of the House and five others by the President pro tempore of the Senate.

Recommendation I recommend that the next Administration give high priority to appointment of its members to this very visible and important commission. I further recommend that the necessary expenses for staffing the Commission be discussed with the Congress and some arrangement for a special appropriation be arranged.

Conclusion The HIV/AIDS crisis will continue and in many ways escalate during the next four years. We must not lose momentum but build on the excellent foundation which has been laid and stop the spread of this deadly disease.

TAB C

TAB C: Major Advances Against HIV Infection

Advances since the President's 10-Point Action Plan

The President established a 10-point action plan to advance the U.S. battle against AIDS and HIV. The plan, based on recommendations of the Presidential Commission on the HIV Epidemic, calls for actions to assure compassion towards those with HIV infection, to allow for their care with dignity and kindness, and to inform and educate citizens to prevent further spread of the disease. The President further instructed the Federal government to take the lead in protecting HIV-infected persons against discrimination in the Federal workplace.

- A U.S. Health Summit on HIV infection (November 28-29) 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.

- To promote fairness and compassion, the 22 largest Federal agencies will have the OPM guidelines in place by December.

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

- On September 26, you requested Congress grant authority to the NIH to begin construction of a consolidated office building devoted exclusively to HIV research.

- Legislation you signed in November includes the largest increase for drug abuse treatment to date.

- Your 1990 budget includes a 24 percent funding increase for Public Health Service HIV/AIDS activities and additional funding for other programs (e.g., Medicaid).

- The Food and Drug Administration has implemented a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.

- The Public Health Service has set in place a plan to implement many of the specific recommendations of your Commission.

- The Department of State has begun a three-year plan to enhance international prevention activities.

Advances Prior to the President's 10-Point Action Plan Report

Over the past seven years, the Reagan Administration has committed more than $5.3 billion to biomedical research, drug

trials, prevention education, treatment, financial assistance programs, and other measures to protect public health against HIV. State and local governments and our nation's charitable institutions have also spent generously. The President has commissioned two major reports on the epidemic: the Surgeon General's Report on AIDS and the Report of the Presidential Commission on the HIV Epidemic. Among the advances:

- Discovery of HIV, the virus that causes AIDS.
- Determination of HIV incidence, prevalence and disease transmission.
- Development of a screening test which has virtually eliminated virus transmission through the blood supply.
- Establishment of a HIV prevention program in every state.
- Establishment of clearinghouses in the Department of Health and Human Services and the Department of Justice for distribution of information on HIV infection.
- Distribution of Understanding AIDS, an educational booklet, to 105 million American households.
- Development of recommendations and guidelines to protect the public against infection in the workplace, schools and the community at large.
- Clearance in record time of one significant drug therapy (AZT) and substantial progress on a number of others.
- Production of two HIV vaccines now being tested in human volunteers.
- Support of international AIDS efforts and funding for the World Health Organization's Global Programme on AIDS.

USA TODAY ®

"USA TODAY hopes to serve as a forum for better understanding and unity to help make the USA truly one nation."
—Allen H. Neuharth
Chairman and Founder
Sept. 15, 1982

John C. Quinn
Editor

John Seigenthaler
Editorial Director

OPINION

The Debate: FIGHTING AIDS

Today's debate includes our opinion that new laws on partner notification are not needed, an opposing view from California, other views on AIDS from Tennessee, Virginia and the District of Columbia, and voices from across the USA.

Help those at risk without new laws

The USA's war against the scourge of AIDS, which has claimed 40,000 casualties, depends upon a volunteer army.

It depends upon those at high risk of contracting AIDS — intravenous drug users and homosexual men — coming forward to be tested. Voluntarily.

And it depends upon those who have the AIDS virus telling their partners about their condition. Voluntarily.

Or they could have health officials do that for them. Partner notification, or contact tracing, is what that's called.

It's been part of state public health department battle strategies against other sexually transmitted diseases for decades. And it's becoming an important weapon against the spread of AIDS as well.

This week, the House will begin debate on a bill that would give $100 million to state health departments for testing, counseling and partner notification.

Already, South Carolina, Idaho, Virginia and 12 other states have programs in which health officials notify, visit and counsel the partners of people who test positive for the AIDS virus. With more federal money, most other states could institute such programs, too.

Some contact tracing makes sense.

In the first two months of its program, New Jersey contacted 18 people who might have become infected. They are being tested and counseled now.

Since 1986, Colorado has checked 418 people, 52 of whom were found to be unknowingly infected. They could be counseled and their behavior changed.

In those cases, health officials used contact tracing to help halt the AIDS contagion. They reached people who did not know they were at risk or that their sex partners were infected. They also kept names totally confidential, and AIDS testing was voluntary.

But some people want to use contact tracing to punish AIDS victims rather than fight the disease.

Supporters of an initiative in California, whose views you can read elsewhere on this page, want to trace *all* the sexual contacts of AIDS victims and put their names and addresses on a list. Without protecting confidentiality.

Such quick-fix approaches would waste millions of dollars in the war against AIDS. And they won't work.

It costs $2,000 to identify one infected individual in San Francisco by contact tracing. Thousands more could be reached by broad-based education programs.

And thousands of AIDS carriers, fearing discrimination, would avoid testing if they knew their names would be put on a list. AIDS testing leaped 125% in Oregon when the state stopped requiring names and addresses.

We need to protect AIDS victims from discrimination so they'll be tested. We need to educate more people about hazardous behavior so they'll change their ways.

And we need sensible contact tracing — run by health professionals, not forced by panic legislation.

The best weapons in the fight against AIDS are common sense and compassion for those fighting for their lives.

TOMORROW

THE U.S. GETS ITS ACT TOGETHER ON AIDS

■ HELPING HIGH-RISK GROUPS

The AIDS epidemic has so far kindled more partisan debate than reasoned public-health policy. But a coherent approach to the crisis is emerging, and it's about to get the biggest boost yet from several bills wending their way through the Congress. A legislative package could be enacted before adjournment in October. The key provisions call for speeding up research and drug development; budgeting $670 million--more than three times what has been spent to date--for AIDS education and prevention; establishing a national commission on AIDS to advise Congress and the President, and expanding access to HIV (human immunodeficiency virus) tests by earmarking $400 million a year over the next three years for clinics, hospitals and health centers to conduct tests on a voluntary, anonymous basis. The aim is simply to get more people tested and counseled. Seventy to 80 percent of the estimated 1.5 million Americans who are infected don't know it. Much of the money will be targeted at reaching intravenous drug users and the inner-city poor.

■ WHAT STATES MUST DO

The bills' real punch comes from making receipt of federal funds conditional on certain practices. Clinics will have to get a patient's consent before administering the test, and they must offer counseling. But once that is done, patients will be cautioned against intravenous drug use and other behavior that puts people at the greatest risk of contracting HIV. States, to get funds, will have to require counseling and testing of all persons convicted of prostitution, sexual assault or crimes related to i.v. drug abuse; establish criminal penalties for any HIV-infected person who knowingly infects another person, and set up contact-tracing programs to notify the sexual or intravenous-drug-sharing partners of those found infected. Clinics and states will not be required to keep lists of the names of infected persons.

The legislation also establishes clear-cut guidelines on confidentiality, with fines of up to $10,000 for intentional or negligent release of the names of persons who test positive for HIV. Notably lacking are an antidiscrimination statute--it was dropped because of conservative opposition--and a comprehensive approach to the financing of AIDS care. Costs are expected to rise to $10 billion a year by 1993, from roughly $4 billion now.

■ WHY THE FEDS ARE NEEDED

While Congress and the administration have dawdled, courts and the states have led the way on AIDS. Eight states have passed specific AIDS antidiscrimination laws, and 24 others have extended protections now enjoyed by the handicapped to those who suffer from AIDS. "Employers understand that if they fire someone with AIDS, they're probably in for a lawsuit," says Nan Hunter, director of the American Civil Liberties Union's AIDS Project. But she and others say a federal statute is still needed. "Many state laws lack teeth when it comes to private employers."

State legislatures have passed some 200 other AIDS laws--89 in this year alone. Twenty-seven states have laws protecting confidentiality of AIDS-test results; 16 mandate informed consent and counseling with testing; 10 have criminal penalties for willful transmission of the virus. But some laws have backfired. Illinois and Louisiana statutes mandating premarital testing aren't popular; couples flock to nearby states to get married. And measures enacted in four states and the District of Columbia that forbid insurance companies to use test results in screening applicants have led some firms to cease writing certain policies in those areas.

■ TROUBLE AHEAD

Despite the promise of new federal legislation, AIDS will clearly remain a major battlefront. One key harbinger is a California fight, in which a proposition on the November ballot would overturn confidentiality laws by forcing the state to record the names of all those found to be infected. The measure, if approved by voters, would also eliminate anonymous testing. A host of health, civil-rights and gay groups oppose the proposition, and they're scared. Benjamin Schatz, a lawyer with the National Gay Rights Advocates, concedes that the proposal "seems to have a lot of support." In other words, the fight against AIDS will still be uphill.

by Steven Findlay

Cong'l. Quarterly

9/17/88

Babies With AIDS

The House Sept. 13 passed legislation aimed at helping find foster homes or other residential settings for babies abandoned in hospitals because their parents are unable or unwilling to care for them. Infants with AIDS are especially in need of help.

By voice vote, members approved S 945, which the Senate passed Aug. 5, 1987. Before passing the measure, the House substituted an amended version of HR 4843 (H Rept 100-821), approved by the Energy and Commerce Committee June 29. *(Weekly Report p. 1837)*

The bill would authorize a total of $37 million over three years for demonstration projects on ways to find appropriate care for so-called "boarder babies," who are not sick enough to require hospital care, but who have no place else to go.

"The present 'non-system,' whereby infants wait an undue length of time in hospitals after they have been medically cleared for discharge, is both inhumane and absurdly wasteful," said Major R. Owens, D-N.Y., sponsor of HR 4843. Owens said that while hospital care costs up to $237,000 per year, "costs for good quality foster care, attuned to the needs of these infants, are considerably less, in the range of $80,000 to $100,000."

The bill would also require a series of studies, including one to determine how many such "boarder babies" are in hospitals and how many suffer from AIDS. Another study would address cost-effective methods to help all AIDS patients pay the costs of needed care. ▮

Health Notes:

Justice Reverses AIDS Policy; Sen. Helms Delays Legislation

Policies recommended by the president's AIDS commission received a boost from one direction and a setback from another the week of Oct. 3.

The advance came in the form of an Oct. 6 Justice Department opinion reversing an earlier stance and declaring that a federal law barring discrimination against the handicapped also applies to those carrying HIV, the virus that causes AIDS. The AIDS commission had stressed the need for such anti-bias protections.

On the other hand, Jesse Helms, R-N.C., was blocking Senate action on legislation (S 1220) to expand AIDS testing, counseling and research, and to ensure confidentiality of test results. Many of the bill's provisions reflected commission recommendations.

In 1987 the Supreme Court ruled in *School Board of Nassau County, Fla. v. Arline* that Section 504 of the Rehabilitation Act of 1973 bars discrimination by recipients of federal funds against those with contagious diseases, including AIDS. But the ruling did not address the question of whether the law also bars discrimination against those carrying the HIV virus but not manifesting symptoms of AIDS.

The Justice Department in 1986 said the law did not apply to HIV carriers. President Reagan ordered the department to review that opinion when he issued an "AIDS action plan" Aug. 2 in response to the June 24 report by his AIDS commission. *(Weekly Report p. 2189)*

Attorney General Dick Thornburgh said the department's reversal was "the necessary result of the Supreme Court's decision [in the *Arline* case], recent legislative actions and the medical views of the surgeon general."

Meanwhile, the threat of a Helms filibuster was jeopardizing enactment of S 1220, passed Sept 23 by the House. Among other things, the bill would authorize $1.2 billion in federal grants to increase the availability of voluntary AIDS blood tests, guarantee the confidentiality of test results and expedite AIDS research. *(Weekly Report p. 2652)*

The House version, originally HR 5142, sets forth policies on who should be tested for AIDS, and who should learn of the results. The Senate version, approved April 28, has no such language, but it authorizes education and research activities not covered by the House measure.

Sponsors had hoped to combine the two bills into a single package in conference. In fact, staffers from both chambers were engaged in informal talks to that end even before the House voted Sept. 23.

But Helms is blocking the appointment of Senate conferees, normally done by unanimous consent. And without officially going to conference, the only way a compromise bill could be brought to the Senate floor would be to open up every provision to amendment, considered too time-consuming in the waning days of the 100th Congress.

In an interview Oct. 5, Helms denied his refusal to allow appointment of conferees was part of a strategy to kill S 1220. But he said he had significant problems with confidentiality provisions of the House bill.

Helms indicated he wants provisions, rejected by the House, to require notification of spouses of those who test positive for HIV. He also said he wanted stronger protections for health workers who might be exposed to patients with AIDS or the HIV virus.

"If it's defective, why pass it?" asked Helms, who said he is conducting his own negotiations with S 1220 sponsors Edward M. Kennedy, D-Mass., and Orrin G. Hatch, R-Utah. ▮

—By Julie Rovner

Clinical Lab Regulation

Legislation to stiffen federal oversight of the nation's clinical laboratories moved a step closer to enactment Oct. 6.

By voice vote, the House approved a House-Senate compromise bill (HR 5471) that would require virtually all of the nation's laboratories — including those in doctors' offices — to be federally certified.

The measure, the result of informal House-Senate negotiations, replaces HR 5150, which the House passed Sept. 13, and S 2477, approved Aug. 10 by the Senate Labor and Human Resources Committee. The Senate is expected to clear the bill for the president before Congress adjourns. *(Weekly Report p. 2586)*

Gone from the legislation is a controversial provision from the Senate bill that would have required independent laboratories to bill patients directly, instead of through their doctors, as is often the practice. The aim was to prevent price markups by physicians and to eliminate the incentive for doctors to order unnecessary tests.

However, the American Medical Association, which represents physicians, vehemently opposed the provision, arguing that in many cases such direct billing could jeopardize the confidentiality of certain sensitive tests and preclude physicians from passing on savings they get by sending tests in bulk.

Sponsors also compromised on how stringently to regulate laboratories that perform only simple, relatively reliable tests. Under the compromise, all labs would have to provide information on the types of tests they perform, but those doing only simple tests could receive "certificates of waiver" that would excuse them from meeting more stringent inspection and proficiency-testing requirements that would apply to other laboratories.

As with most compromises, not everyone was fully satisfied with the final product. "The fact is too many medical labs are making too many mistakes, and too many people are being hurt as a result," said Energy and Commerce member Ron Wyden, D-Ore., sponsor of a bill (HR 4325) whose key provisions were ultimately folded into the compromise. "For patients the issue is accuracy. Even simple tests done inaccurately can do great physical harm," he said. ▮

Abandoned Babies

The Senate Oct. 4 cleared for the president legislation aimed at helping find foster homes or other residential settings for babies abandoned in hospitals because their parents are unable or unwilling to care for them.

The measure is aimed particularly at helping infants with AIDS, many of whom have no immediate medical need to be in a hospital but have nowhere else to go. Babies born to drug-abusing mothers are also often stranded in hospitals.

The Centers for Disease Control reports that nearly 1,500 children and adolescents have AIDS, and projects that the incidence of pediatric AIDS will double annually for the near future.

Final action on the bill (S 945) came when the Senate concurred in amendments adopted by the House before it passed the measure Sept. 13. *(Weekly Report p. 2586)*

The bill authorizes $37 million over three years in grants to public and non-profit private enterprises for demonstration projects aimed at helping parents to care for their afflicted infants or finding foster homes for abandoned "boarder babies."

The measure requires the secretary of health and human services to report to Congress within a year on the number of abandoned infants in hospitals and on how many of them have AIDS. The report must also include an estimate of the cost to the federal and state governments of housing and caring for such children.

A separate title of the bill requires a study to determine the most cost-effective ways of caring for all AIDS patients, regardless of age, and an estimate of how much the federal government is spending on AIDS patients through the federal-state Medicaid program of health coverage for the poor. ▮

Rights of the Mentally Ill

Congress Oct. 5 cleared for the president legislation (S 2393) aimed at protecting the rights of the institutionalized mentally ill.

The House approved the compromise bill by voice vote, a day after the Senate took the same action.

As cleared, the bill authorizes $13 million in fiscal 1989 and "such sums as may be necessary" the following two years for "protection and advocacy" systems required in each state to address complaints of abuse or neglect of mental patients. *(Weekly Report p. 2655)*

Such advocacy systems were first created in 1986 (PL 99-319) and were modeled after similar systems already in place for the mentally retarded. ▮

HMO Reauthorization

The House Oct. 5 approved a compromise version of legislation to reauthorize provisions of federal law setting standards for the nation's health maintenance organizations (HMOs) and providing incentives for their development.

By voice vote, members adopted the conference report on the bill (HR 3235 — H Rept 100-1056), which would ease considerably federal constraints on HMO operations and on employers who make such prepaid health plans available to their workers. The Senate, which passed its version of the measure Aug. 11, is expected to follow suit before Congress adjourns. *(Weekly Report p. 2347)*

The legislation would allow patients to go outside their HMO for up to 10 percent of physician services in any given year and still have their costs covered by the HMO. But the HMO could charge the patient a "reasonable deductible" for care obtained from an outside doctor.

The bill repeals the current requirement that employers contribute the same dollar amount for employees who enroll in HMOs as they do for workers who opt for other types of health coverage. The bill does, however, require that the employer's contributions not be unfair to workers who choose HMO membership.

It also gives HMOs greater freedom in their financial organization and the way they set their premiums. For the first time, the legislation would allow HMOs to vary their rates according to the characteristics of the groups they serve.

In addition, the bill would forbid states from imposing requirements that would prevent HMOs from achieving federal standards for qualification and would end, as of Oct. 1, 1993, a requirement that employers who offer health coverage of other types offer coverage by a federally qualified HMO as well.

Finally, the bill would prohibit the Department of Health and Human Services from changing current regulations, policy statements, interpretations or practices regarding abortion services offered by federally qualified HMOs. ▮

Preventive Health

Four public-health programs whose focus is on prevention of disease and injury would be reauthorized under legislation approved by the House Oct. 5.

By voice vote, members adopted the conference report on S 1579 (H Rept 100-1055), which would reauthorize for three years the Preventive Health and Health Services Block Grant program, the federal Office of Health Promotion and Disease Prevention, and federal grants to states to help prevent and treat sexually transmitted diseases.

The House passed S 1579 July 26, while the Senate passed the bill in a different form Feb. 3. The Senate is expected to clear the measure before Congress adjourns. *(Previous action, Weekly Report p. 2108)*

The compromise version would authorize $110 million in fiscal 1989 for the Preventive Health and Health Services Block Grant, which provides funds to states to operate a variety of programs, including water fluoridation and rape crisis counseling. "Such sums as necessary" would be authorized for fiscal 1990 and 1991. Only $84.7 million was appropriated for the program for fiscal 1989 as part of the appropriations measure for the Departments of Labor, Health and Human Services, and Education (PL 100-436). That was down from $85.7 million the year before. *(Appropriations funding, Weekly Report p. 2607)*

The bill also authorizes $3 million in fiscal 1989, $4 million in fiscal 1990 and $5 million in fiscal 1991 for grants to help provide emergency medical services to children.

For the federal Office of Health Promotion and Disease Prevention, the bill would authorize $10 million for each of fiscal 1989-91. The Research Centers for Health Promotion and Disease Prevention would be authorized to receive $6 million in fiscal 1989, $8 million in fiscal 1990, and $10 million in fiscal 1991.

Finally, the legislation would authorize $78 million in fiscal 1989 for grants to fight sexually transmitted diseases, with "such sums as necessary" approved for fiscal 1990 and 1991. A total of $68.1 million was appropriated for the program for fiscal 1989, up from $54.6 million the previous year. ▮