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Series/Staff Member: Patsy Fleming

Subseries: National AIDS Strategy

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Carol Rasco 5/17/96 Meeting

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Jeremy's Comments

Summary of Strategy

Areas that have the potential to be challenging are noted with ** in the left-hand margin.

A. Letter from the Director of the Office of National AIDS Policy

- The epidemic is a national and international public health crisis.
- This strategy to address the epidemic is the first-ever of its kind for the United States.

B. Scope of the HIV/AIDS Pandemic

- HIV is an expanding public health threat with 40,000 and 60,000 Americans becoming newly infected each year. Internationally, 2.4 million cases of AIDS have occurred worldwide.

- Communities of color are more severely and disproportionately affected.

- Prejudice and discrimination are still encountered by people living with HIV, their families, and loved ones.

C. Goal of the National Strategy

Given where we are in the course of the epidemic, set common goals and identify areas that warrant attention.

Common Goals: (1) a cure and a vaccine;
(2) reduce new infections every year until there are none; and
(3) appropriate and ethical care of persons living with HIV.

Opportunity Areas: (1) strengthening HIV prevention activities;
(2) supporting diversified research approaches;
(3) strengthening approaches to substance abuse treatment and prevention;
(4) strengthening the health care and services safety net;
(5) improving translation of research results into medical practice; and
(6) improving evaluation and priority setting.

D. Overview of Federal Efforts

1. Prevention

a. Background

We know that prevention can work. Developing effective programs and implementing them will require a dedicated alliance among the Federal government, states, local governments, communities, businesses, non-governmental

organizations, families, and individuals.

b. Opportunities for Progress

Modes of Transmission. Developing effective prevention programs begins with knowing who is getting infected. Current CDC surveillance systems do not consistently capture who is at risk; refinement is needed.

Gaps in Scientific Knowledge. We cannot **assume** we know what prevention approaches will work. Need further research in:

(1) Basic Behavioral Research (determinants of HIV-associated sexual and drug-using behaviors);

(2) Intervention research (approaches for modifying behavior), and

(3) social marketing research (what makes prevention initiatives work).

Gaps in Program Areas. To prevent new infections, effective prevention programs need to reach persons at risk. There is a need for attention in the following areas;

(1) Community Involvement. To develop programs that more effectively reach target populations, there is a need for increased community involvement, Federal-local partnerships, and community planning based on local epidemiology.

** (2) Substance Abuse Treatment. Injection drug use accounts for approximately half of all new cases. Increasing the availability of treatment and integrating HIV prevention into substance abuse treatment can help slow the spread of the epidemic.

(3) Treatment for Sexually Transmitted Diseases and TB. The epidemics of HIV, STDs, and TB are linked. Integrating an HIV component into STD and TB prevention and treatment has the potential to curb all three epidemics.

** (4) Harm Reduction. **(Full text from Strategy follows.)** ~~In addition to efforts directed towards enrolling drug users in treatment programs for their addiction(s), harm reduction should be considered by communities when treatment fails or is unavailable. Although harm reduction programs for drug users have not been well accepted in our country,~~

~~There is scientific evidence that controversial harm reduction approaches, such as needle exchange programs, can be effective. Among the conclusions presented in a recent report by the Institute of Medicine (IOM) was that there is no credible evidence that drug use is increased among~~

~~participants as a result of needle exchange programs that provide legal access to sterile equipment. The IOM also concluded that the lower the fraction of needles in circulation that are contaminated, the lower the risk of new infections. They went on to recommend that needle exchange programs be regarded as an effective component of a comprehensive strategy to prevent infectious disease. There is also evidence that needle exchange programs provide an opportunity to get people into treatment, thereby further reducing their risk and the risk for their sexual partners.~~

~~While the data strongly support the effectiveness of needle exchange programs in preventing the spread of infection, we continue to believe that decisions regarding these approaches should be a community decision based on local epidemiology. We also believe that certain existing statutes restrict potential prevention efforts. The Federal government will work with state and local officials to provide the information they need to take advantage of this intervention.~~

NEW TEXT --

Experts feel that it is in this area that we may be able to make a significant impact in stemming the tide of the epidemic.

The use of federal funds to support needle exchange programs has been specifically ~~prohibited or~~ restricted by the language contained in a series of statutes enacted by Congress since 1988. P.L. 102-394, section 514 (1993) bans federal support for needle exchange programs unless the Surgeon General of the United States determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs. The S.

A recent Institute of Medicine (IOM) panel conducted a comprehensive examination and assessment of the data currently available on needle exchange programs, bleach distribution programs, and paraphernalia and prescription laws. The IOM report concluded that well-implemented needle exchange programs can be effective in preventing the spread of HIV and do not increase the use of illegal drugs. There is also evidence that needle exchange programs provide an opportunity to get people into treatment, thereby further reducing their risk and the risk for their sexual partners. ~~The PHS has not yet made a ruling regarding P.L. 102-394, however in light of this report, it is appropriate for the PHS to carefully reexamine this issue.~~

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The Surgeon General has not determined that the conditions of the statute have been met, and there continues to be no federal funding for needle exchange programs. It should be noted that

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and possession of needles without a prescription) ~~restrict potential prevention efforts~~. The IOM reported on a CDC study regarding the impact of laws enacted to permit small purchases of needles without a prescription; the result was an increase in the use of sterile equipment. The CDC has begun to work with state and local officials to provide the information regarding this intervention option.

(5) Integration into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. This includes incorporating a patient's sexual history when a medical history is taken, offering HIV-related counseling and voluntary testing, and working with HIV positive individuals so they do not infect others, and offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission.

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a. Background

The Nation has reaped benefits of supporting research, and there is reason for hope.

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Coordinated Biomedical Plan and Budget. Improved collaboration on biomedical research across departments and agencies can enhance progress.

Vaccines. Reaching the goal of developing a vaccine will require the joint commitment of government and the private sector. Support diversified research approaches through the NIH and DOD.

Microbicides. Many scientists believe that prevention of STDs, including HIV, will depend on the development of a safe, effective, barrier methods. Support for all aspects of development, from basic research to clinical trials.

Clinical Effectiveness Research. There are new drugs available but there is no information on their long-term effectiveness, ability to extend life, or improve quality of life. Need to conduct studies that will answer these unknowns.

Public-Private Partnerships. No one sector can develop a cure, a vaccine, or a microbicide alone.

Continued Investment in Research. Research must continue to be supported at adequate levels if we hope to find a cure and a vaccine.

3. Care and Services

a. Background

Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, states, the private sector, local communities, community-based organizations, clinics, families, and individuals.

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** *The Health Care Safety Net.* ~~(Full text follows.) We must continue to adequately fund the program that is the cornerstone of care -- Medicaid. Medicaid is the lifeline of support to millions of Americans. It provides access to doctors, hospitals, treatments, and home care -- the services that allow people to live longer more productive lives. Present Congressional plans to cut the Medicaid program overall by $169 billion and turn it into a block grant in effect reverses this Nation's 30 year National commitment to the poor and those in need. Cutting Medicaid to this level would cut the lifeline for millions of Americans, including those living with HIV and AIDS. Maintaining this program in a viable format must be a National priority.~~

~~With the potential cuts in Medicaid and welfare, the importance of the public health safety net increases for all vulnerable populations -- disproportionately so for people with AIDS. This will require several responses. First, no one Federal program will be able to absorb the unmet need that may be created by proposed changes to the Medicaid, Medicare and welfare programs. All Federal programs, along with state and local organizations, must share the responsibility for serving and caring for people with AIDS. This must include the full integration of HIV related care into programs that serve the needy, such as community health centers. Second, it is important that programs such as those funded under the CARE Act receive sufficient funding so as to maintain the safety net. In addition, AIDS programs must do a better job of prioritizing what services they can provide -- and Federal agencies must assist grantees in this regard. Treatment and primary care must come before ancillary services. And finally, the shift to managed care will have implications for programs such as the Ryan White Care Act programs. As this approach becomes more common, HRSA will need to provide more technical assistance to prepare grantees to work within a managed care structure.~~

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Maintenance of the Federal guarantee of Medicaid coverage for eligible individuals is essential to the continued ability of the Nation to respond to the health care needs of people living with HIV/AIDS. Of particular importance is the maintenance of a Federal definition of disability. The 30-year State partnership in Medicaid also must be maintained while the program is made more flexible for state innovations.

With a strong Medicaid program in place, it continues to be vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage. Many people with HIV and AIDS are too poor or too disabled to work yet they are not poor enough or disabled enough to qualify for Medicaid. For them, and for their families, the CARE Act provides essential protection.

Integrated Continuum of Care. Providing people access to an integrated continuum of health care services (i.e., counseling and testing, comprehensive health care, home health care, substance abuse treatment, and prevention services) affords better care and can reduce the spread of infection.

Housing Services. Housing is the foundation upon which any program of care or services are built. People living with HIV experience discrimination and it is estimated that 50 percent of person living with HIV are at risk for becoming homeless during the course of their illness.

** *Prisoners.* Improving access to appropriate HIV-related care in prisons must be a priority. At the federal level significant advances are being made in the quality of care, improved coordination, and developing models of care.

Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons, strengthening linkages between prisons and outside public health departments and agencies, improving discharge planning.

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The Federal government needs to simplify its funding structures so integrated service programs are more easily achievable.

Evaluation. Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority setting.

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a. Background

AIDS is a global pandemic. If we do not stop the pandemic globally, we will not be able to halt its spread in the United States. It threatens economic advances in Africa and Asia.

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** *International Leadership.* The United States has established a global leadership role in combatting the epidemic. This leadership must continue through supporting UNAIDS, making more effective use of available resources, and encouraging non-traditional donor countries to provide much needed contributions.

Supporting UNAIDS and its innovative programmatic efforts, and its goal of working to assure that therapeutics (and vaccines when developed) are made available to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

Sharing Technology and Bringing Lessons Home. Based on the Vice President's initiative to bring the lessons back home through the "Lesson without Borders Project" to inner city and rural areas with problems similar to those experienced overseas, the goal is to create linkages between U.S. community organizations and international projects in order to share solutions to problems that know no borders. The U.S., through its various agencies will continue to build

and strengthen international networks.

Program Coordination. One of the most challenging aspects of the U.S. effort is effective coordination among a host of agencies with varied missions and activities. The State Department and agencies such as USAID and USIA are primarily focused on country-specific activities, that include many HIV-related objectives. Agencies which conduct research, such as NIH and CDC, plan their activities not around where they take place, but around scientific gaps and interests. Agencies supporting international activities must develop a mechanism for coordinating the U.S. effort.

5. *Translation of Science into Practice*

a. Background

An important element in our fight against AIDS is ensuring that new knowledge is incorporated into standard medical practice of clinicians caring for persons living with HIV. Dramatic changes in the way HIV is treated have taken place over the last 15 years.

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Coordination of Federal Activities. The most pressing need in the area of information dissemination is to improve coordination among Public Health Service agencies. Ensuring that information about research breakthroughs and prevention models is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, will require a high level of cooperation and coordination among Public Health Service agencies.

6. *Civil Rights*

a. Background

One of the Nation's common goals is to ensure the ethical treatment of persons with AIDS. Discrimination based on HIV status is illegal and morally wrong.

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Leadership. As a Nation we need to be vigilant and vocal in our efforts to fight discrimination. This is a responsibility that must be shared among Federal agencies, states, communities, and the citizens of this country.

Continued Enforcement of Existing Laws. The Federal government has aggressively and successfully prosecuted

private sector violations of the ADA. These efforts will continue.

** *Federal Policies.* The Federal government must also actively work to remedy any of its own existing discriminatory policies. ~~In order to identify areas of possible concern, the Director of the Office of National AIDS Policy will as soon as possible conduct a systematic review of agency and department testing programs.~~ The Director of the Office of National AIDS Policy is working with Federal agencies to ensure that HIV testing programs follow the recommendations of public health professionals. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

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** *The Health Care Safety Net.* The cornerstone of care for people living with AIDS in the U.S. is Medicaid. Nearly 50 percent of all Americans living with AIDS -- including 92 percent of children with AIDS -- rely on Medicaid for their sole source of health coverage. Medicaid provides coverage for hospitalizations, physician visits, x-rays and laboratory tests, home health care, nursing home care, and outpatient prescription drugs. These services extend the length and the quality of life for people living with HIV and AIDS. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is estimated at $1.8 billion, nearly six times the amount expended on the Ryan White CARE Act.

Maintenance of the Federal guarantee of Medicaid coverage for eligible individuals is essential to the continued ability of the Nation to respond to the health care needs of people living with HIV/AIDS. Of particular importance is the maintenance of a Federal definition of disability. The 30-year State partnership in Medicaid also must be maintained while the program is made more flexible for state innovations.

With a strong Medicaid program in place, it continues to be vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage. Many people with HIV and AIDS are too poor or too disabled to work yet they are not poor enough or disabled enough to qualify for Medicaid. For them, and for their families, the CARE Act provides essential protection.

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NEW TEXT -- * define Harm Reduction out of IOM Report.

HHS/ONAP/ ONDCP

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OK JENNIFER 5/17/96 please review? b Medicaid

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(3) strengthening approaches to substance abuse treatment and prevention;
(4) strengthening the health care and services safety net;
(5) improving translation of research results into medical practice; and
(6) improving evaluation and priority setting.

D. Overview of Federal Efforts

1. Prevention

a. Background

We know that prevention can work. Developing effective programs and implementing them will require a dedicated alliance among the Federal government, states, local governments, communities, businesses, non-governmental

organizations, families, and individuals.

b. Opportunities for Progress

Modes of Transmission. Developing effective prevention programs begins with knowing who is getting infected. Current CDC surveillance systems do not consistently capture who is at risk; refinement is needed.

Gaps in Scientific Knowledge. We cannot **assume** we know what prevention approaches will work. Need further research in:

(1) Basic Behavioral Research (determinants of HIV-associated sexual and drug-using behaviors);

(2) Intervention research (approaches for modifying behavior), and

(3) social marketing research (what makes prevention initiatives work).

Gaps in Program Areas. To prevent new infections, effective prevention programs need to reach persons at risk. There is a need for attention in the following areas;

(1) Community Involvement. To develop programs that more effectively reach target populations, there is a need for increased community involvement, Federal-local partnerships, and community planning based on local epidemiology.

** (2) Substance Abuse Treatment. Injection drug use accounts for approximately half of all new cases. Increasing the availability of treatment and integrating HIV prevention into substance abuse treatment can help slow the spread of the epidemic.

(3) Treatment for Sexually Transmitted Diseases and TB. The epidemics of HIV, STDs, and TB are linked. Integrating an HIV component into STD and TB prevention and treatment has the potential to curb all three epidemics.

** (4) Harm Reduction. **(Full text from Strategy follows.)** ~~In addition to efforts directed towards enrolling drug users in treatment programs for their addiction(s), harm reduction should be considered by communities when treatment fails or is unavailable. Although harm reduction programs for drug users have not been well accepted in our country,~~

~~There is scientific evidence that controversial harm reduction approaches, such as needle exchange programs, can be effective. Among the conclusions presented in a recent report by the Institute of Medicine (IOM) was that there is no credible evidence that drug use is increased among~~

~~participants as a result of needle exchange programs that provide legal access to sterile equipment. The IOM also concluded that the lower the fraction of needles in circulation that are contaminated, the lower the risk of new infections. They went on to recommend that needle exchange programs be regarded as an effective component of a comprehensive strategy to prevent infectious disease. There is also evidence that needle exchange programs provide an opportunity to get people into treatment, thereby further reducing their risk and the risk for their sexual partners.~~

~~While the data strongly support the effectiveness of needle exchange programs in preventing the spread of infection, we continue to believe that decisions regarding these approaches should be a community decision based on local epidemiology. We also believe that certain existing statutes restrict potential prevention efforts. The Federal government will work with state and local officials to provide the information they need to take advantage of this intervention.~~

NEW TEXT --

Experts feel that it is in this area that we may be able to make a significant impact in stemming the tide of the epidemic.

The use of federal funds to support needle exchange programs has been specifically prohibited or restricted by the language contained in a series of statutes enacted by Congress since 1988. P.L. 102-394, section 514 (1993) bans federal support for needle exchange programs unless the Surgeon General of the United States determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.

A recent Institute of Medicine (IOM) panel conducted a comprehensive examination and assessment of the data currently available on needle exchange programs, bleach distribution programs, and paraphernalia and prescription laws. The IOM report concluded that well-implemented needle exchange programs can be effective in preventing the spread of HIV and do not increase the use of illegal drugs. There is also evidence that needle exchange programs provide an opportunity to get people into treatment, thereby further reducing their risk and the risk for their sexual partners. The PHS has not yet made a ruling regarding P.L. 102-394, however in light of this report, it is appropriate for the PHS to carefully reexamine this issue.

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and possession of needles without a prescription) restrict potential prevention efforts. The IOM reported on a CDC study regarding the impact of laws enacted to permit small purchases of needles without a prescription; the result was an increase in the use of sterile equipment. The CDC has begun to work with state and local officials to provide the information regarding this intervention option.

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a. Background

The Nation has reaped benefits of supporting research, and there is reason for hope.

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Vaccines. Reaching the goal of developing a vaccine will require the joint commitment of government and the private sector. Support diversified research approaches through the NIH and DOD.

Microbicides. Many scientists believe that prevention of STDs, including HIV, will depend on the development of a safe, effective, barrier methods. Support for all aspects of development, from basic research to clinical trials.

Clinical Effectiveness Research. There are new drugs available but there is no information on their long-term effectiveness, ability to extend life, or improve quality of life. Need to conduct studies that will answer these unknowns.

Public-Private Partnerships. No one sector can develop a cure, a vaccine, or a microbicide alone.

Continued Investment in Research. Research must continue to be supported at adequate levels if we hope to find a cure and a vaccine.

3. Care and Services

a. Background

Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, states, the private sector, local communities, community-based organizations, clinics, families, and individuals.

b. Opportunities for Progress

** *The Health Care Safety Net.* ~~(Full text follows.) We must continue to adequately fund the program that is the cornerstone of care -- Medicaid. Medicaid is the lifeline of support to millions of Americans. It provides access to doctors, hospitals, treatments, and home care -- the services that allow people to live longer more productive lives. Present Congressional plans to cut the Medicaid program overall by $169 billion and turn it into a block grant in effect reverses this Nation's 30 year National commitment to the poor and those in need. Cutting Medicaid to this level would cut the lifeline for millions of Americans, including those living with HIV and AIDS. Maintaining this program in a viable format must be a National priority.~~

~~With the potential cuts in Medicaid and welfare, the importance of the public health safety net increases for all vulnerable populations -- disproportionately so for people with AIDS. This will require several responses. First, no one Federal program will be able to absorb the unmet need that may be created by proposed changes to the Medicaid, Medicare and welfare programs. All Federal programs, along with state and local organizations, must share the responsibility for serving and caring for people with AIDS. This must include the full integration of HIV-related care into programs that serve the needy, such as community health centers. Second, it is important that programs such as those funded under the CARE Act receive sufficient funding so as to maintain the safety net. In addition, AIDS programs must do a better job of prioritizing what services they can provide -- and Federal agencies must assist grantees in this regard. Treatment and primary care must come before ancillary services. And finally, the shift to managed care will have implications for programs such as the Ryan White Care Act programs. As this approach becomes more common, HRSA will need to provide more technical assistance to prepare grantees to work within a managed care structure.~~

The cornerstone of care for people living with AIDS in the U.S. is Medicaid. Nearly 50 percent of all Americans living with AIDS -- including 92 percent of children with AIDS -- rely on Medicaid for their sole source of health coverage. Medicaid provides coverage for hospitalizations, physician visits, x-rays and laboratory tests, home health care, nursing home care, and outpatient prescription drugs. These services extend the length and the quality of life for people living with HIV and AIDS. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is estimated at $1.8 billion, nearly six times the amount expended on the Ryan White CARE Act.

Maintenance of the Federal guarantee of Medicaid coverage for eligible individuals is essential to the continued ability of the Nation to respond to the health care needs of people living with HIV/AIDS. Of particular importance is the maintenance of a Federal definition of disability. The 30-year State partnership in Medicaid also must be maintained while the program is made more flexible for state innovations.

With a strong Medicaid program in place, it continues to be vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage. Many people with HIV and AIDS are too poor or too disabled to work yet they are not poor enough or disabled enough to qualify for Medicaid. For them, and for their families, the CARE Act provides essential protection.

Integrated Continuum of Care. Providing people access to an integrated continuum of health care services (i.e., counseling and testing, comprehensive health care, home health care, substance abuse treatment, and prevention services) affords better care and can reduce the spread of infection.

Housing Services. Housing is the foundation upon which any program of care or services are built. People living with HIV experience discrimination and it is estimated that 50 percent of person living with HIV are at risk for becoming homeless during the course of their illness.

** *Prisoners.* Improving access to appropriate HIV-related care in prisons must be a priority. At the federal level significant advances are being made in the quality of care, improved coordination, and developing models of care.

Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons, strengthening linkages between prisons and outside public health departments and agencies, improving discharge planning.

** *Program Coordination.* Creating a community program that integrates primary care with substance abuse treatment and prevention, and sexually transmitted disease screening, prevention, access to clinical trials, and housing assistance would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD. Efforts to simplify federal funding applications to facilitate improved integration of service programs have already begun. For example, HRSA and SAMSHA have issued joint announcements and the HUD and HRSA have issued a joint announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration should be continued and expanded.

The Federal government needs to simplify its funding structures so integrated service programs are more easily achievable.

Evaluation. Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority setting.

4. *International Activities*

a. Background

AIDS is a global pandemic. If we do not stop the pandemic globally, we will not be able to halt its spread in the United States. It threatens economic advances in Africa and Asia.

b. Opportunities for Progress

** *International Leadership.* The United States has established a global leadership role in combatting the epidemic. This leadership must continue through supporting UNAIDS, making more effective use of available resources, and encouraging non-traditional donor countries to provide much needed contributions.

Supporting UNAIDS and its innovative programmatic efforts, and its goal of working to assure that therapeutics (and vaccines when developed) are made available to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

Sharing Technology and Bringing Lessons Home. Based on the Vice President's initiative to bring the lessons back home through the "Lesson without Borders Project" to inner city and rural areas with problems similar to those experienced overseas, the goal is to create linkages between U.S. community organizations and international projects in order to share solutions to problems that know no borders. The U.S., through its various agencies will continue to build

and strengthen international networks.

Program Coordination. One of the most challenging aspects of the U.S. effort is effective coordination among a host of agencies with varied missions and activities. The State Department and agencies such as USAID and USIA are primarily focused on country-specific activities, that include many HIV-related objectives. Agencies which conduct research, such as NIH and CDC, plan their activities not around where they take place, but around scientific gaps and interests. Agencies supporting international activities must develop a mechanism for coordinating the U.S. effort.

5. Translation of Science into Practice

a. Background

An important element in our fight against AIDS is ensuring that new knowledge is incorporated into standard medical practice of clinicians caring for persons living with HIV. Dramatic changes in the way HIV is treated have taken place over the last 15 years.

b. Opportunities for Progress

Coordination of Federal Activities. The most pressing need in the area of information dissemination is to improve coordination among Public Health Service agencies. Ensuring that information about research breakthroughs and prevention models is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, will require a high level of cooperation and coordination among Public Health Service agencies.

6. Civil Rights

a. Background

One of the Nation's common goals is to ensure the ethical treatment of persons with AIDS. Discrimination based on HIV status is illegal and morally wrong.

b. Opportunities for Progress

Leadership. As a Nation we need to be vigilant and vocal in our efforts to fight discrimination. This is a responsibility that must be shared among Federal agencies, states, communities, and the citizens of this country.

Continued Enforcement of Existing Laws. The Federal government has aggressively and successfully prosecuted

private sector violations of the ADA. These efforts will continue.

** *Federal Policies.* The Federal government must also actively work to remedy any of its own existing discriminatory policies. ~~In order to identify areas of possible concern, the Director of the Office of National AIDS Policy will as soon as possible conduct a systematic review of agency and department testing programs.~~ The Director of the Office of National AIDS Policy is working with Federal agencies to ensure that HIV testing programs follow the recommendations of public health professionals. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

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Summary of Strategy

Areas that have the potential to be challenging are noted with ** in the left-hand margin.

A. Letter from the Director of the Office of National AIDS Policy

- The epidemic is a national and international public health crisis.
- This strategy to address the epidemic is the first-ever of its kind for the United States.

B. Scope of the HIV/AIDS Pandemic

- HIV is an expanding public health threat with 40,000 and 60,000 Americans becoming newly infected each year. Internationally, 2.4 million cases of AIDS have occurred worldwide.

- Communities of color are more severely and disproportionately affected.

- Prejudice and discrimination are still encountered by people living with HIV, their families, and loved ones.

C. Goal of the National Strategy

Given where we are in the course of the epidemic, set common goals and identify areas that warrant attention.

Common Goals: (1) a cure and a vaccine;
(2) reduce new infections every year until there are none; and
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Opportunity Areas: (1) strengthening HIV prevention activities;
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We know that prevention can work. Developing effective programs and implementing them will require a dedicated alliance among the Federal government, states, local governments, communities, businesses, non-governmental

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This doesn't work. Either PHS has not made the findings Recent Report (IOM), it should be noted — that a recent Report

Describe what IOM did — based on data and other studies.

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State statutes → Restrictive small bulk purchases,

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CDC doing training to expand on this.

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The Nation has reaped benefits of supporting research, and there is reason for hope.

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Clinical Effectiveness Research. There are new drugs available but there is no information on their long-term effectiveness, ability to extend life, or improve quality of life. Need to conduct studies that will answer these unknowns.

Public-Private Partnerships. No one sector can develop a cure, a vaccine, or a

microbicide alone.

Continued Investment in Research. Research must continue to be supported at adequate levels if we hope to find a cure and a vaccine.

3. Care and Services

a. Background

Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, states, the private sector, local communities, community-based organizations, clinics, families, and individuals.

b. Opportunities for Progress

Jen Klein should work

** *The Health Care Safety Net.* (Full text follows.) We must continue to adequately fund the program that is the cornerstone of care -- Medicaid. Medicaid is the lifeline of support to millions of Americans. It provides access to doctors, hospitals, treatments, and home care -- the services that allow people to live longer more productive lives. Present Congressional plans to cut the Medicaid program overall by $169 billion and turn it into a block grant in effect reverses this Nation's 30 year National commitment to the poor and those in need. Cutting Medicaid to this level would cut the lifeline for millions of Americans, including those living with HIV and AIDS. Maintaining this program in a viable format must be a National priority.

With the potential cuts in Medicaid and welfare, the importance of the public health safety net increases for all vulnerable populations -- disproportionately so for people with AIDS. This will require several responses. First, no one Federal program will be able to absorb the unmet need that may be created by proposed changes to the Medicaid, Medicare and welfare programs. All Federal programs, along with state and local organizations, must share the responsibility for serving and caring for people with AIDS. This must include the full integration of HIV-related care into programs that serve the needy, such as community health centers. Second, it is important that programs such as those funded under the CARE Act receive sufficient funding so as to maintain the safety net. In addition, AIDS programs must do a better job of prioritizing what services they can provide -- and Federal agencies must assist grantees in this regard. Treatment and primary care must come before ancillary services. And finally, the shift to managed care will have implications for programs such as the Ryan White Care Act programs. As this approach becomes more common, HRSA will need to provide more technical assistance to prepare grantees to work within a managed care structure.

Integrated Continuum of Care. Providing people access to an integrated continuum of health care services (i.e., counseling and testing, comprehensive health care, home

health care, substance abuse treatment, and prevention services) affords better care and can reduce the spread of infection.

Housing Services. Housing is the foundation upon which any program of care or services are built. People living with HIV experience discrimination and it is estimated that 50 percent of person living with HIV are at risk for becoming homeless during the course of their illness.

** *Prisoners.* Improving access to appropriate HIV-related care in prisons must be a priority. This will require improving the knowledge and skill of the health care teams in the prisons, strengthening linkages between prisons and outside public health departments and agencies, improving discharge planning.

** *Program Coordination.* Creating a community program that integrates primary care with substance abuse treatment and prevention, and sexually transmitted disease screening, prevention, access to clinical trials, and housing assistance would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD. The Federal government needs to simplify its funding structures so integrated service programs are more easily achievable.

Evaluation. Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority setting.

4. International Activities

a. Background

AIDS is a global pandemic. If we do not stop the pandemic globally, we will not be able to halt its spread in the United States. It threatens economic advances in Africa and Asia.

b. Opportunities for Progress

** *International Leadership.* The United States has established a global leadership role in combatting the epidemic. This leadership must continue through supporting UNAIDS, making more effective use of available resources, and encouraging non-traditional donor countries to provide much needed contributions.

Supporting UNAIDS and its innovative programmatic efforts, and its goal of working to assure that therapeutics (and vaccines when developed) are made available to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

Sharing Technology and Bringing Lessons Home. Based on the Vice President's initiative to bring the lessons back home through the "Lesson without Borders

Project" to inner city and rural areas with problems similar to those experienced overseas, the goal is to create linkages between U.S. community organizations and international projects in order to share solutions to problems that know no borders. The U.S., through its various agencies will continue to build and strengthen international networks.

Program Coordination. One of the most challenging aspects of the U.S. effort is effective coordination among a host of agencies with varied missions and activities. The State Department and agencies such as USAID and USIA are primarily focused on country-specific activities, that include many HIV-related objectives. Agencies which conduct research, such as NIH and CDC, plan their activities not around where they take place, but around scientific gaps and interests. Agencies supporting international activities must develop a mechanism for coordinating the U.S. effort.

5. Translation of Science into Practice

a. Background

An important element in our fight against AIDS is ensuring that new knowledge is incorporated into standard medical practice of clinicians caring for persons living with HIV. Dramatic changes in the way HIV is treated have taken place over the last 15 years.

b. Opportunities for Progress

Coordination of Federal Activities. The most pressing need in the area of information dissemination is to improve coordination among Public Health Service agencies. Ensuring that information about research breakthroughs and prevention models is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, will require a high level of cooperation and coordination among Public Health Service agencies.

6. Civil Rights

a. Background

One of the Nation's common goals is to ensure the ethical treatment of persons with AIDS. Discrimination based on HIV status is illegal and morally wrong.

b. Opportunities for Progress

Leadership. As a Nation we need to be vigilant and vocal in our efforts to fight discrimination. This is a responsibility that must be shared among Federal agencies, states, communities, and the citizens of this country.

Continued Enforcement of Existing Laws. The Federal government has aggressively and successfully prosecuted private sector violations of the ADA. These efforts will continue.

** *Federal Policies.* The Federal government must also actively work to remedy any of its own existing discriminatory policies. ~~In order to identify areas of possible concern~~, the Director of the Office of National AIDS Policy will as soon as possible conduct a systematic review of agency and department testing programs. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

GHR - Concern about
Director of ONAP
is working c fed agencies to ensure
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Bring Revised language to Friday mtg.

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Patsy - Draft of 'political hops' memo. Jane

DRAFT -- National Strategy for HIV and AIDS

I. Background themes

Major Tenets: Need for improved government-wide coordination in partnership with industry, communities, and individuals. It is the first time goals have been linked to budget objectives for HIV-related efforts.

It sets three broad goals for government activities:

(1) a cure and a vaccine;
(2) reduce new infections every year until there are none; and
(3) appropriate and ethical care of persons living with HIV.

The report is organized around substantive areas (i.e., prevention, research, care and services, international activities, civil rights, and translation of science into practice) and identifies six areas where the opportunity for progress is greatest:

(1) strengthening HIV prevention activities;
(2) supporting diversified research approaches;
(3) strengthening approaches to substance abuse treatment and prevention;
(4) strengthening the health care and services safety net;
(5) improving translation of research results into medical practice; and
(6) improving evaluation and priority setting.

one of the President's (calls it "Plan")

Campaign Promise: The Strategy was a campaign promise. ~~It is expected by~~ the Presidential Advisory Council on HIV and AIDS (PAC) and ~~also~~ addresses one of the recommendations set forth by the National Commission on AIDS.

anticipates its release

~~**How It Got Made:**~~ The Strategy was developed ~~from the bottom up~~. Last year the Office of National AIDS Policy (ONAP) formed the Interdepartmental Task Force on HIV and AIDS (IDTF) which consists of representatives from ~~Executive Branch~~ Departments and Agencies. Each IDTF ~~member~~ submitted an individual plan that articulated goals, objectives, unmet needs, ~~and~~ linked ~~their~~ goals to budget objectives. Based on these submissions and issues raised by participants at the White House Conference on AIDS, the ~~activist~~ community, the PAC, the National Commission on AIDS, reports from the Institute of Medicine, Office of Technology Assessment and General Accounting Office, and people on the front-lines of the epidemic, the above-cited goals and opportunities for progress were established. The final draft was distributed to all IDTF members for review and comment. ~~concurrence is pending from DHHS~~. only HHS has not yet responded.

with programs and/or policies related to HIV/AIDS

agency represented in the

(need to describe)

with the participation of . . . .

as well as

II. ~~Preparation for Release~~

~~As we prepare to release this document~~, we need to address concerns that may be raised.

Within Federal Government

DHHS in particular appears to be uncomfortable with higher level coordination efforts. At NIH there is also a strong discomfort with higher level coordination and suggestions based on public health interests. The basic research supported by NIH has brought great scientific advances. However, we are making unnecessarily slow progress in some areas (i.e., research on clinical effectiveness, microbicides, and opportunistic infections) in part because these areas of investigation are not attractive to researchers seeking to publish and advance their careers. Answers in these areas could yield tremendous public health benefits.

Outside Government

Activist Community. Despite the tremendous advances in research, care, and civil rights made by the Administration, within the activist community the strategy may be viewed as not going far enough by putting forth mandates for states and agencies, promising vetoes of legislation, increasing funding, etc. The strategy links goals to real budget figures, which in some cases are not as high as the community would like. They would probably want to see even greater support for:

- Maintaining the safety net.

  Strategy maintains the importance of the public health safety net increases for all vulnerable populations, disproportionately so for persons with HIV and advocates adequately funding Medicaid, Medicare, welfare, HOPWA, and HRSA programs.

- Explicit population-based social-marketing campaigns for a variety of groups, such as young gay and bisexual men.

  Strategy advances a public-private division of responsibility and Federal support for improved surveillance in addition to more behavioral, intervention, and social marketing research but does not commit to specific programs or projects.

- Lifting the ban on federal funding for needle exchange programs.

  Strategy states that supporting harm reduction programs such as needle exchange should be a community decision based on local epidemiology. The Federal role is to provide state and local officials the information they need to make informed decisions regarding this intervention approach.

- Substance abuse treatment.

  Strategy states it must be part of the Federal response to: increase the availability of treatment of a range of addictions; improve integration of HIV prevention activities

and substance abuse treatment and prevention programs; and integrate STD and TB prevention with HIV prevention.

- Improved treatment of prisoners.

  Strategy states improving access to appropriate HIV-related care in prisons must be a priority. There is a need to improve the knowledge and skill of health care teams in the prisons, improve discharge planning, and develop linkages between prisons and outside public health departments and agencies who have experience in providing care for prisoners.

- Support for OAR and its single appropriation.

  Strategy states the single appropriation is essential for OAR to effectively plan, prioritize, and manage the $1.4 billion program HIV research program across 24 institutes, centers, and divisions.

- Medicaid waivers ensure access to a comprehensive continuum of care and mandated coverage for counseling and testing.

  In the Strategy there is general support for an integrated continuum of care, including counseling and testing but no explicit language on using Medicaid waivers.

- All FDA-approved drugs should be covered by Medicaid, even when prescribed for off-label use.

  Not addressed in the Strategy.

Non-Activist Community. There may be perception that AIDS is receiving more than its fair share of Federal funding. (However, spending for AIDS is not out of balance with other diseases. Overall HHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer, and heart disease than for AIDS. In FY 1995 HHS spent approximately: $38.0 billion for heart disease, $17.5 billion for cancer, and $ 6.0 billion for AIDS.)

There may be concern that there is statement of strong support for the safety net.

There may also be concern that there is explicit support for increasing the availability of drug treatment, harm reduction programs (including needle exchange), and improved treatment of prisoners.

THE WHITE HOUSE

WASHINGTON

Date: 9 April 1996

To: PF

From: JS

Re: Memo revisions

You requested that I make your editorial changes, draft a brief summary of the strategy including a couple of sentances on each opportunity for progress area, and highlight areas that may be controversial. The new draft is attached.

Points that should be emphasized.

- This is an historic effort. No previous administration has undertaken a task of this magnitude, i.e., convened an interdepartmental task force to facilitate planning and coordination across all agencies and departments.

- The process of improving the Federal response begins, with this effort. This document is meant to be a living document -- a starting point for bringing together all the parties that will be needed to solve these challenges.

THE WHITE HOUSE

4.8.96 DRAFT -- National Strategy for HIV and AIDS

WASHINGTON

I. Background

communities

Major Themes: Need for improved government-wide coordination in partnership with industry, communities, and individuals. It is the first time goals have been linked to budget objectives for HIV-related efforts.

It sets three broad goals for government activities:

(1) a cure and a vaccine;
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The report is organized around substantive areas (i.e., prevention, research, care and services, international activities, civil rights, and translation of science into practice) and identifies six areas where the opportunity for progress is greatest:

(1) strengthening HIV prevention activities;
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(6) improving evaluation and priority setting.

Campaign Promise: The Strategy was one of the President's campaign promises (called a "plan"); the Presidential Advisory Council on HIV and AIDS (PAC) anticipates its release and it addresses one of the recommendations set forth by the National Commission on AIDS.

The Strategy was developed with the participation of program staff at the front lines of the Federal effort. Last year the Office of National AIDS Policy (ONAP) formed the Interdepartmental Task Force on HIV and AIDS (IDTF) which consists of representatives from Departments and Agencies with programs and or policies related to HIV/AIDS. Each agency represented in the IDTF submitted an individual plan that articulated goals, objectives, unmet needs, linking goals to budget objectives. Based on these submissions as well as issues raised by participants at the White House Conference on AIDS, the "AIDS community", the PAC, the National Commission on AIDS, reports from the Institute of Medicine, Office of Technology Assessment and General Accounting Office, and people who provide services for persons living with HIV, their families and loved ones, the above-cited goals and opportunities for progress were established. The final draft was distributed to all IDTF

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members. Only HHS has not yet responded.

II. Summary of Strategy

Below is a brief summary. Areas that have the potential to be challengeing are noted.

A. Letter from the Director of the Office of National AIDS Policy

1. The epidemic is a national and international public health crisis.
2. This strategy to address the epidemic is the first-ever for the United States.

B. Scope of the HIV/AIDS Pandemic

- HIV is an expanding public health threat with 40,000 and 60,000 Americans becoming newly infected each year. Internationally, 2.4 million cases of AIDS have occured worldwide.
- Communities of color are more severly and disproportionately affected.
- Prejucide and discrimination are still encountered by people living with HIV, their families, and loved ones.

C. Goal of the National Strategy ~~To solve problems~~ set common goals and identify areas requiring attention given where we are on the problem.

The strategy is broader than any past planning efforts.

Common Goals: (1) a cure and a vaccine;
(2) reduce new infections every year until there are none; and
(3) appropriate and ethical care of persons living with HIV.

Opportunity Areas: (1) strengthening HIV prevention activities;
(2) supporting diversified research approaches;
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(4) strengthening the health care and services safety net; (5) improving translation of research results into medical practice; and (6) improving evaluation and priority setting.

D. Overview of Federal Efforts

1. Prevention Background. Developing effective prevention programs begins with knowledge of the

A. Modes of Transmission ~~Effective~~ current
Need to know who is getting infected. CDC surveillance systems do not ~~currently~~ consistently capture who is at risk; refinement is needed.

B. Gaps in Scientific Knowledge
We cannot **assume** we know what prevention approaches will work. Need further research in the areas of:

basic behavioral research (determiniants of HIV-asssociated sexual and drug-using behaviors);

intervention research (approaches for modifying behavior), and social marketing research (what makes prevention initiatives work).

3. Gaps in Program Areas Background

To prevent new infections, effective prevention programs need to reach persons at risk. ~~There is a need for:~~

Community Involvement. Increased community involvement. Federal-local partnerships. Community planning based on local epidemiology.

Substance Abuse Treatment. Integrate HIV prevention into substance abuse treatment. Increase availabilty of treatment.

Treatment for Sexually Transmitted Diseases and Tb. Integrate HIV prevention into STD and TB prevention and treatment.

Harm Reduction. (May be controversial - full text follows.) In addition to efforts directed towards enrolling drug users in treatment programs for their addiction(s), harm reduction should be considered by communities when treatment fails or is unavailable. Although harm reduction programs for drug users have not been well accepted in our country, experts feel that it is in this area that we may be able to make a significant impact in stemming the tide of the epidemic.

There is scientific evidence that controversial harm reduction approaches, such as needle exchange programs, can be effective. Among the conclusions presented in a recent report by the Institute of Medicine was that there is no credible evidence that drug use is increased among participants as a result of needle exchange programs that provide legal access to sterile equipment. The IOM also concluded that the lower the fraction of needles in circulation that are contaminated, the lower the risk of new infections. They went on to recommend that needle exchange programs be regarded as an effective component of a comprehensive strategy to prevent infectious disease.[1] There is also evidence that needle exchange programs provide an opportunity to get people into treatment, thereby further reducing their risk and the risk for their sexual partners.

While the data strongly support the effectiveness of needle exchange programs in preventing the spread of infection, we continue to believe that decisions regarding these approaches should be a community decision based on local epidemiology. We also believe that certain existing statutes restrict potential prevention efforts. The Federal

government will work with state and local officials to provide the information they need to take advantage of this intervention.

Integration into Primary Care. Include prevention messages in primary health care services.

Evaluation. Important to assess the effectiveness of prevention programs. to improve the next generation of programs.

Research

Background

Nation has reaped benefits of supporting research, and there is reason for hope.

Opportunities for Progress

Coordinated Biomedical Plan and Budget. Need to have better collaboration on biomedical research across agencies. Can ~~improve~~ enhance our progress. Build on FG ever plan for the future.

Vaccines. Support diversified research approaches through the NIH and DOD. Given that scientific

Microbicides. Support for all aspects of development, from basic research to clinical trials. → Area of hope to prevent new infections.

Clinical Effectiveness Research. There are new drugs available but there is no information on their long-term effectiveness, ability to extend life, or improve quaility of life. Research is needed to determine their effectiveness. Implications for

Public-Private Partnerships. No one sector can acheive a cure or a vaccine alone.

Continued Investment in Research. Research must continue to be supported at adequate levels if we hope to find a cure and a vaccine.

Care and Services

Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, states, the private sector, local communities, community-based organizations, clinics, families, and individuals.

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With the potential cuts in Medicaid and welfare, the importance of the public health safety net increases for all vulnerable populations -- disproportionately so for people with AIDS. This will require several responses. First, no one Federal program will be able to absorb the unmet need that may be created by proposed changes to the Medicaid, Medicare and welfare programs. All Federal programs, along with state and local organizations, must share the responsibility for serving and caring for people with AIDS. This must include the full integration of HIV-related care into programs that serve the needy, such as community health centers. Second, it is important that programs such as those funded under the CARE Act receive sufficient funding so as to maintain the safety net. In addition, AIDS programs must do a better job of prioritizing what services they can provide -- and Federal agencies must assist grantees in this regard. Treatment and primary care must come before ancillary services. And finally, the shift to managed care will have implications for programs such as the Ryan White Care Act programs. As this approach becomes more common, HRSA will need to provide more technical assistance to prepare grantees to work within a managed care structure.

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Continued Enforcement of Existing Laws. The Federal government has aggressively and successfully prosecuted private sector violations of the ADA. These efforts will continue.

Federal and State laws do exist to protect persons with HIV. Many of the more common legal issues faced by people living with HIV and AIDS, such as family law issues, estate planning, landlord/tenant problems are regulated by state law. The primary source of Federal statutory protection for people living with HIV is the Americans with Disabilities Act of 1990 (ADA). (Federal agencies are prohibited from discriminating against people with disabilities under the Rehabilitation Act of 1973.) Title I of the ADA prohibits discrimination against qualified disabled individuals in employment settings. The Equal Employment Opportunity Commission (EEOC) is responsible for enforcing Title I. Title II of the ADA prohibits discrimination on the basis of disability with regard to public services while Title III prohibits discrimination on the basis of disability in public accommodations. The Department of Justice (DOJ) is responsible for enforcing Titles II and III. The Health Care Financing Administration (HCFA) also enforces regulations regarding the treatment of HIV-infected persons.

The Federal government has aggressively and successfully prosecuted private sector violations of the ADA. These efforts will continue. Under this provision the government has been extremely successful in prosecuting a range of cases, including clinicians who have refused to care for HIV infected patients and

employers who have dismissed persons based on their actual or perceived HIV status. In addition to ongoing efforts, a joint Department of Justice and Health and Human Services program will seek to combat nursing home discrimination against persons living with AIDS.

The Federal government must also actively work to remedy any of its own existing discriminatory policies. In order to identify areas of possible concern, the Director of the Office of National AIDS Policy will as soon as possible conduct a systematic review of agency and department testing programs. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

Civil Rights

Resolution of these issues would take different forms, but ingeneral it would be through the IDTF with participation of relevant outside groups, consumers, etc.

We need to address concerns that may be raised.

Within Federal Government
DHHS in particular appears to be uncomfortable with higher level coordination efforts. At NIH there is also a strong discomfort with higher level coordination and suggestions based on public health interests. The basic research supported by NIH has brought great scientific advances. However, we are making unnecessarily slow progress in some areas (i.e., research on clinical effectiveness, microbicides, and opportunistic infections) in part because these areas of investigation are not attractive to researchers seeking to publish and advance their careers. Answers in these areas could yield tremendous public health benefits.

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1. Preventing HIV Transmission: The Role of Sterile Needles and Bleach. Jacques Normand, David Vlahov, and Lincoln E. Moses, Editors. National Academy Press, Washington, DC. 1995