THE WHITE HOUSE

WASHINGTON

October 14, 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patricia S. Fleming

RE: Presidential Advisory Council on HIV and AIDS
Welfare Reform Letter to the President

Attached is the Welfare Reform letter from the Council.

cc: Jeremy BenAmi

PRESIDENTIAL
ADVISORY
COUNCIL ON
HIV/AIDS

October 8, 1996

The Honorable William Jefferson Clinton
The White House
Washington, D.C. 20500

As members of the Presidential Advisory Council on HIV/AIDS (the "Council"), we write to express our deep concern regarding the potential impact of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (the "welfare reform bill") on people living with HIV. We support effective reform of the nation's welfare system. However, in order to preserve the public health and protect the most vulnerable, the Council would like to work with you in the coming weeks to strengthen the new law to ensure that it will best serve the hundreds of thousands of HIV-infected individuals who depend on public assistance.

The Council applauds the administration for its attempts, often successful, to eliminate or weaken many of the meanspirited, bigoted and punitive provisions in welfare reform legislation originally proposed by Congress. We believe that your administration's efforts to improve the bill succeeded in preserving Medicaid coverage for most people with HIV. We share your concern that this grand national experiment must be monitored closely, and revised as needed, to avoid undermining the public health and causing needless harm and suffering to the most vulnerable and needy, particularly the hundreds of thousands of our bothers, sisters, mothers, fathers and children living with HIV.

Despite the administration's improvements to the welfare reform bill, we fear that the bill, as enacted, could present gave risks to many people living with HIV:

> *Provision in the Welfare Reform Bill Threaten Continued Medicaid Coverage for Many People with HIV.* Nationally, at least half of all people with HIV/AIDS look to Medicaid for their health coverage, making this program the linchpin of the nation's HIV care infrastructure. The administration successfully advocated for an amendment to the bill requiring states to provide Medicaid coverage to all families that meet their state's AFDC rules as of July 1996. Under the enacted legislation, however, states retain the discretion to terminate Medicaid for any adult whose cash

750 17th Street, N.W., Suite 600
Washington, DC 20503

assistance is ended due to his or her failure to satisfy work requirements, including women, who now constitute 19 percent of the AIDS cases reported in the United States. As noted below, the bill also authorizes states to withhold Medicaid coverage from legal immigrants.

The Welfare Reform Bill's Immigrant Provisions Threaten the Further Spread of HIV and Other Communicable Diseases. Substantial evidence demonstrates that HIV prevention efforts are often most effective when integrated with primary medical care. The welfare bill, however, effectively terminates medical care for tens of thousands of HIV-infected immigrants, denying vital health services while encouraging the unnecessary spread of the virus. Under the legislation, legal immigrants are no longer eligible for Supplemental Security Income (SSI), and states have the option to deny Medicaid coverage to current legal immigrants. In the future, incoming legal immigrants will be barred from access to Medicaid for 5 years, whereas refugees' eligibility for Medicaid will be limited to 5 years. Undocumented immigrants will become entirely ineligible for most federal public benefits and will be presumed ineligible for state and local benefits, unless states specifically enact laws declaring their eligibility for such programs. These provisions targeting foreign-born individuals will devastate our nation's ability to preserve a meaningful continuum of care for people with HIV. More than 16 percent of all Hispanic AIDS cases were born outside of the United States and its territories, and an additional 30 percent were born in Puerto Rico. Foreign-born individuals represent 12 percent, 17 percent, and 7 percent of all AIDS cases in California, Florida, and New York, respectively. By withholding vital medical services from such an enormous component of the HIV-infected population, the welfare reform bill will tear the fabric of the nation's carefully-woven response to the AIDS epidemic.

The Welfare Reform Bill's Drug Use Provisions Will Increase the Nation's Health and Social Service Costs. Injection drug use accounted for 25 percent of all AIDS cases reported in 1994 and 1995, and is indirectly responsible for the bulk of heterosexually acquired AIDS cases. With respect to new infections, epidemiologist estimate that injection drug use is responsible for 50 percent of all cases. Injection drug users frequently become involved with the criminal justice system; in New York State, for example, 30.5 percent of all individuals seeking drug treatment have a current criminal justice status. In a misguided effort to promote the war on drugs, the welfare reform bill takes aim at this population, prohibiting the provision of cash assistance and food stamps to persons convicted of felonies related to drug possession, use, or distribution, subsequent to enactment. Although states have the ability under the legislation to opt out of this provision, we fear it is unlikely that states will make this choice. Because of these provisions, countless individuals may become homeless and be unable to sustain proper nutrition, which will in turn lead to unnecessary sickness and associated health care expenditures.

Food Stamp Cuts Will Devastate Efforts to Ensure Proper Nutrition for People with HIV. Proper nutrition is an essential component of health maintenance for people living with HIV. Unfortunately, the welfare reform bill will make it far more

difficult to ensure proper nutrition for indigent people with HIV. According to the Center on Budget and Policy Priorities, the welfare reform bill's $27.7 billion cut over six years in the food stamp program will reduce average food stamp benefits by 20 percent.

In summary, the welfare reform bill potentially undermines the nation's fight against AIDS in two ways. First, by withholding medical care from important segments of the HIV-infected population, the legislation makes it impossible to craft a coherent national strategy to care for infected individuals and to ensure the provision of primary HIV prevention services. Second, even where medical coverage is retained, the bill undermines the safety net for people with HIV by potentially withholding or reducing cash assistance and food stamps, increasing the risk of homelessness and reducing the country's ability to provide proper nutrition for HIV-infected individuals.

We are heartened by your commitment to ensure that the welfare reform bill is implemented in as fair and equitable a manner as possible for individuals who need public assistance that most. To that end, we believe that a number of general strategies exist to protect indigent persons with HIV disease.

First, the legislation authorizes the administration to enact regulations to effectuate many of the bill's provisions. For example, the bill directs the administration to develop a list of non-means-tested programs that are exempted from the legislation's provisions regarding legal immigrants. Similarly, regulations to be enacted by the administration could determine the breadth of social service agencies' responsibility to participate in the welfare reform bill's mandates regarding verification of individual clients' immigration status. We believe that careful drafting of these and other regulations could ease the bill's potentially negative impact on the nation's public health.

*Second,*the bill provides broad discretion to states to structure their public assistance programs as they see fit. In some cases, states have to the option of exercising exceptions to some of the bill's most problematic provisions. We believe that the administration can have an important influence on the decisions that states make under the new legislation.

Third, as you have acknowledge publicly, the bill is so flawed in certain respects that legislative redress is required. Only new legislation, for example, can right the wrong done by the provisions withholding basic human services to legal immigrants. By making a strong case to the public, the administration can lay the groundwork for corrective legislation in the next Congress, and this Council would like to work with you in that effort.

Fourth, early monitoring of state-level policy and administrative changes under the new bill could highlight problems with proposed state changes. Tracking welfare recipients with HIV disease could spotlight problems with the legislation which require correction.

We offer the Council's assistance to the administration in exploring regulatory and legislative strategies to protect people with HIV from many of the bill's provisions. The Council would like to work with the administration through the Office of National AIDS Policy prior to the next Council meeting on December 15-17, 1996, to explore regulatory and legislative strategies to protect people with HIV/AIDS. Working together, we trust that we can prevent certain provisions of the welfare reform bill from subverting our nations' fight against the AIDS epidemic.

Sincerely,

R. Scott Hitt

Members of the Presidential
Advisory Council on HIV/AIDS

Presidential Advisory Council on HIV and AIDS

Stephen N. Abel, D.D.S.
Mr. Terje Anderson
Ms. Regina Aragon
Ms. Judith Billings
Mary Boland, R.N., M.S.N.
Mr. Nicholas Bollman
Mr. Tonio Burgos
Jerry Cade, M.D.
Mr. Robert Fogel
Ms. Debra Fraser-Howze
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Ms. Sandra Thurman
Mr. Charles Quincy Troupe
Bruce Weniger, M.D.

THE WHITE HOUSE

WASHINGTON

MAR - 4 1996

MEMORANDUM TO CAROL RASCO

FROM: PATSY FLEMING

SUBJECT: Needle Exchange Programs

The largest proportion of new AIDS cases is now related to injection drug use. HIV is transmitted through the sharing of used needles and syringes that contain HIV infected blood. Health guidelines have long recommended against the sharing of injection equipment, but such equipment is not readily available because of legal restrictions on over-the-counter sale of needles and syringes.

To address this problem, many community organizations around the country have developed needle exchange programs as a form of AIDS prevention. They have -- sometimes in violation of local ordinances -- offered clean needles in exchange for used needles from addicts. There are about 70 needle exchange programs across the United States operating in 46 cities in 21 states. Some are operated by local health departments.

Legislation enacted in 1987 disallows the use of Federal funds for needle exchange programs (unless for research purposes) until the Surgeon General determines that needle exchange programs decrease HIV transmission and do not increase injection drug use.

A series of research studies have concluded that the criteria outlined in this legislation can in fact be met. The most recent and most thorough of these studies was one issued recently by the National Academy of Sciences. It concluded:

- Needle exchange programs increase the availability of sterile injection equipment, resulting in a lower number of contaminated needles in circulation. (Therefore, the logical assumption is that needle exchange programs reduce transmission of HIV.)

- There is no credible evidence that drug use is increased among participants as a result of programs that provide legal access to sterile equipment. In fact, exchange programs can be seen as outreach programs to substance users who ultimately are brought into treatment for their addiction.

Despite this scientific evidence, there is considerable controversy about the morality of needle exchange programs. A growing number of communities have embraced this approach, others have rejected it. One key policy question is *whether localities can choose to use Federal funds for needle exchange programs. The other question is whether government officials can say that needle exchange programs funded with state, local or private funds are effective strategies in blocking HIV transmission.* (N.B. In my public speaking, this is what I say.)

Many in the public health community argue that needle exchange programs are our most effective weapon in reducing HIV transmission among substance users. They are not asking that the Federal government adopt this approach nationwide. They are asking only that the restriction on *local* decisions on use of federal funds for this purpose be lifted (for example, in the use of substance abuse block grant money). They recognize that if the Public Health Service lifts the funding restrictions, Congress may reimpose or even tighten them. But they also believe it is important for you to show leadership by publicly acknowledging the effectiveness of needle exchange programs. This would strengthen those in the public health community who want to use local funds for such programs.

There are three possible approaches to this issue:

(1) Oppose needle exchange programs as too controversial and as sending the wrong message regarding drug use. This would run counter to leading public health opinion.

(2) Lift the restrictions by having the Surgeon General or, since we don't have one, the Secretary, make a determination that the criteria set forth in existing statute have been met. This may well result in a determination in favor of lifting the restrictions and could lead to even more restrictive legislation. However, such a determination would make clear to the country that this is an option that should be considered. Even if the restrictions are lifted, *the decision to adopt needle exchange programs would remain a local one.*

(3) Applaud the National Academy of Sciences report as a major contribution to the public debate on this issue. Acknowledge that needle exchange programs seem to work in preventing HIV transmission and encourage states and localities as well as community based organizations to consider them in the context of broad-scaled harm reduction and substance abuse treatment efforts. But whatever the science may say, this remains a divisive issue socially and politically. It should be a community decision, not a Federal decision. We are supporting research that will give communities the information they need to make this decision. This approach, while not discouraging local initiatives, would not free up Federal funds for these efforts.

Project/Issue	Description	Status
Report to President on state of epidemic among adolescents	Brief report outlining specific actions government can take to increase visibility and action on this issue.	At the printer; scheduled release date is March 5th.
National Strategy on HIV/AIDS	Product of Interdepartmental Task Force on AIDS; identifies key goals and opportunities for progress; summarizes HIV-related activities of all government agencies.	Agency review almost complete; projected release of mid-March. (Do we want to do photo op with POTUS on this?)
Funding	Ongoing discussions with agencies and OMB re FY 1997	Final numbers are at FY 1996 request or higher; ADAP amendment for FY 1996.
Medicaid	Reflecting concerns of AIDS community re entitlement status, disability definition, scope of benefits, and right of private action during Medicaid debate.	Ongoing. Comparability now required on in-kind benefits.
Office of AIDS Research Lerner Report - commissioned an external review - Top Scientists. - report coming out in March -	Protection of the single appropriation for OAR and its authority to drive spending and programs is vital to the research effort. The FY 96 CR for NIH does not protect this line item; this authority is up for reauthorization this year.	We are working with OMB and HHS to increase the visibility of our support for the single line; we have worked out a mechanism with OMB to assure that OAR still determines spending on AIDS at NIH even without the single appropriation. The FY 97 passback retains the single appropriation. We are meeting with constituency groups this week to reassure them of our support.

Release ~~Issue~~ in March

roll out

Project/Issue	Description	Status
Interdepartmental research plan and budget	Consolidated plan and budget for AIDS research in HHS, VA, Energy, and VA; led by NIH Office of AIDS Research.	Organizational meeting held; departments have named representatives to working groups; first working group meets next week; delivery date is April 15.
VP meeting with drug industry	Private discussion led by VP between industry and government scientists to better define relative roles, assess what can be done to inspire greater investment in AIDS treatments, vaccines, and microbicides.	Meeting with industry CEOs was held on February 20th; follow up -- including innovative approach to funding post-marketing clinical trials -- is under discussion with OVP.
Substance abuse and HIV prevention	President announced CDC would host a meeting of substance abuse program and HIV prevention officials to develop a coordinated strategy for integration of HIV and substance abuse prevention.	ONAP hosted a preliminary meeting February 23rd to outline a comprehensive range of options re substance abuse and HIV prevention; this will help set the agenda for the CDC meeting to be held in late spring.
Town Meetings/Site Visits	In partnership with Funders Concerned About AIDS, the National AIDS Fund and members of the Advisory Council, we will do site visits, press events, and community forums in five regions (Dallas, San Diego/LA/SF, NYC, Greensboro NC, Miami/Key West/Tampa.	First trip to Dallas was a success; March meetings in Florida; April is California.
Advisory Council Recommendations	Working with relevant agencies to determine ability to implement recommendations. Goal is to have as comprehensive (and positive) a response as possible before April 24th meeting of Council.	Recommendations from December meeting have been transmitted; initial discussions with several agencies regarding response.

Project/Issue	Description	Status
DoD discharge	Assuring legislative, legal, and administrative steps are taken to repeal and/or mitigate impact of Dornan amendment.	Ongoing.
Plan to prevent perinatal transmission plan First Lady interest	Release of government-wide plan to assure access to voluntary counseling and testing and AZT treatment to prevent perinatal transmission. CDC guidelines — voluntary counseling; testing. Pres. signature	The pieces of the plan are in place from the relevant agencies (HCFA and PHS). We are waiting for resolution of the mandatory testing debate on the Ryan White CARE Act to do an event.
Mandatory testing review	An examination of the mandatory testing programs of civilians by federal agencies based on public health rationale. Job Corps, Peace Corps, Foreign Service, Bureau of Prisons	Attempting to schedule CDC/Job Corps meeting in late February. Initial discussions with Justice and community re Bureau of Prisons policy.
Increasing knowledge of HIV status	We are seeking to develop model programs that could increase the number of people who voluntarily learn their HIV status -- as a pro-active alternative to mandatory testing.	Meeting was held February 23rd of PHS, CDC, HRSA, and selected community leaders to discuss alternative models and potential demonstration programs. Follow up discussions with constituency groups, social marketing experts, and agency officials are planned.
Performance Partnership Grants	Community has strongly objected to last year's proposal to merge HIV/STD/TB prevention funding streams.	FY 1997 budget will remove HIV from the PPG. But performance measures will remain required
Harm Reduction	Review of Administration position on syringe exchange programs in light of recent Institute of Medicine study.	Initial discussions with PHS. Focus of initial meeting with McCaffrey next week.

Project/Issue	Description	Status
Managed care	Monitoring of waiver applications as they affect people with HIV; development of guidelines for Medicaid managed care per Advisory Council recommendation.	Good success so far in NYC and NYS waivers; HCFA has informally agreed to a series of guidelines, this needs to be formalized.
International	Patsy Fleming is the US representative on the governing board of UNAIDS; ongoing dialogue with agencies working through the international working group of the Interdepartmental Task Force on AIDS, we are working to raise the visibility of international issues, assure coordination among the agencies working on international issues, and protect the funding of US contributions to international efforts. Outreach to non-governmental organizations working on international issues.	Ongoing. UNAIDS - joint effort UNICEF, UNESCO, WHO etc. build capacity
Prisons	We are working with community, HRSA, CDC, and BOP to identify key issues regarding AIDS in prisons, including linkage of federally funded services and prevention programs to the incarcerated (and assuring linkage services upon release) and developing a standard of care for HIV-positive prisoners that could be applied at the state and federal levels.	Initial meetings with community representatives have been held. We are now developing a six-month plan for addressing these issues through this office.

FEB 16 1996

ROUTING SLIP

DATE: 2/14/96

FROM: Stephanie Streett and Anne Walley
Deputy Assistants to the President and Directors of Scheduling

SUBJECT: Video for HIV Prevention Community Planning

Don Baer	✓	Mack McLarty	
Erskine Bowles		Leon Panetta	
Peg Cusack		Jack Quinn	
Rahm Emanuel		Carol Rasco	✓
Jack Gibbons		Paige Reffe	
Laura Graham		Patti Solis	
Pat Griffin		Doug Sosnik	
Marcia Hale		Speechwriting	✓
Alexis Herman		G. Stephanopoulos	
Nancy Hernreich		Todd Stern	
Kitty Higgins		Ann Stock	
Harold Ickes		Kim Tilley	
Jennifer Jose	✓	Jodie Torkelson	
Ron Klain		Laura Tyson	
Anthony Lake		Melanne Verveer	
Bruce Lindsey		Maggie Williams	
Mike McCurry	✓		

FILE: Pending

COMMENTS: Per SS and AW on 2/14/96

Per Jonny 1/18 Card - ok'd as general piece 2/24/95. -ESD

VIDEO REQUEST PROPOSAL **Date: 01/18/96**

___ ACCEPT **___ REJECT** **___ PENDING**

TO:	Stephanie Streett Deputy Assistant to the President & Director of Scheduling Anne Walley Deputy Assistant to the President & Director of Scheduling
FROM:	Carol H. Rasco, Assistant to the President for Domestic Policy
REQUEST:	Video message for the Centers for Disease Control and Prevention "HIV Prevention Community Planning Co-Chairs Meeting"
PURPOSE:	This annual CDC meeting of 800+ participants from all 50 states is a prime opportunity to indicate the Administration's strong support for AIDS prevention and for partnership with states and communities.
DATE AND TIME:	Conference opens March 7, 1996.
SOURCE OF PAYMENT:	Centers for Disease Control and Prevention
BACKGROUND:	Approximately 800 AIDS prevention leaders from all 50 states, DC, and Puerto Rico will attend this meeting in Atlanta GA. This is a one-time usage.
DURATION:	Three to five minutes
REMARKS ATTACHED:	Script is attached to the request.
STAFF CONTACT:	Richard Sorian, Office of National AIDS Policy, 632-1090
ORIGIN OF PROPOSAL:	Office of National AIDS Policy

Centers for Disease Control and Prevention Video

- This video is for the opening of the Centers for Disease Control and Prevention "HIV Prevention Community Planning Co-Chairs Meeting"
- The video allows the President to demonstrate the Administration's strong commitment to AIDS prevention and to partnership with states and communities.
- Approximately 800 community leaders in HIV/AIDS prevention will be meeting for two days in Atlanta GA to discuss a series of issues related to prevention of AIDS. The Community Planning Process was launched by the Clinton Administration in 1993 to improve local input to prevention programs.

DRAFT SCRIPT

Centers for Disease Control and Prevention Video

The PRESIDENT: It's a pleasure to join you today for the annual HIV Prevention Community Planning meeting. I'm sorry I can't be there with you in person.

I'd like to thank Dr. Satcher and Dr. Gayle and their team of committed public health professionals for their remarkable leadership in our national fight against HIV and AIDS.

And let me thank each and every one of you for your work on the front lines of this epidemic. In community after community across this great nation, you provide the thoughtful leadership and passionate commitment that is needed to turn the tide in this epidemic.

I am proud of the work we have done together to create the community planning process. In its short history, this effort has already transformed HIV prevention from a top-down bureaucratic approach to a bottom-up community effort. Working in partnership we have provided millions of Americans with the kind of honest, targeted information they need to protect themselves and their loved ones from HIV.

But you and I know that the job is not yet done. Not when forty to sixty thousand Americans are still becoming infected with HIV each year. Not when seventy to eighty thousand of our brothers and sisters are being diagnosed with AIDS every year. And not when more than one hundred Americans are dying of AIDS every day.

We have a lot more to do and I am confident that with you leading the way we will reverse these truly troubling trends.

In December, at the historic White House Conference on HIV and AIDS, I called on our public health professionals to work toward a very important goal -- to reduce the number of HIV infections each and every year until there are none.

THE PRESIDENT: It will take a national effort, beginning in communities like yours, to achieve that important goal. And we will need the help of businesses, schools, churches, and other community organizations to get there.

We all recognize that changing behavior is very difficult. And this is especially true among young people. I am troubled by the continued rise in new infections among teenagers. Too many young people seem to believe they are either bulletproof or doomed to a life of misery. In either case, they take risks with their health and increasingly those gambles are resulting in deadly consequences. We've got to break that death spiral and we've got to do it now.

We also must do more to break the grip that illegal drugs have on too many Americans. And we must strengthen the link between AIDS prevention and drug abuse prevention efforts.

My Administration remains committed to leading the fight against AIDS. Our recently released national plan makes clear that that fight includes three important elements: a search for a cure and a vaccine; comprehensive care for all those who are living with HIV and AIDS; and a continued effort to reduce new infections through prevention.

Together we can reach those goals and change the future of our country.

Thank you and God bless you.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

16-Feb-1996 02:01pm

TO: (See Below)

FROM: Carol H. Rasco
Domestic Policy Council

SUBJECT: URGENT

I know messages like this go in and out of ears and minds, but I am pleading with each person that regardless of whether you have sent a scheduling request to me via email for approval you MUST send the hard copy to me for initialing. The bottom line is that if I have not initialed the hard copy, the request will upon arrival in scheduling be pitched in the round file, label that the TRASH CAN.

Many thanks!

Distribution:

TO: Carol H. Rasco
TO: Jeremy D. Benami
TO: Jennifer L. Klein
TO: Cathy R. Mays
TO: Rosalyn A. Miller
TO: Bruce N. Reed
TO: Michael T. Schmidt
TO: Stephen C. Warnath
TO: Paul J. Weinstein, Jr
TO: Patsy Fleming
TO: Janet B. Abrams
TO: Julie E. Demeo
TO: Diana M. Fortuna
TO: Christopher C. Jennings
TO: Jeffrey Levi
TO: Gaynor R. McCown
TO: Molly Brostrom
TO: Dorothy L. Karayannis
TO: Deborah L. Fine
TO: Janet B. Abrams
TO: Dennis Burke
TO: Patricia E. Romani
TO: Denise Ricketson
TO: Pamela Cicetti
TO: Elizabeth E. Drye

- Call Michael Fitzpatrick – meet w/him and Paul Weinstein re. Judicial related language

- Set up mtg w/Pates / Jeff re ethics (1)
  (2) – details?
  – needle exchange
  (3) potus. request for video tape / CDC

DRAFT

April 2, 1996

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy

SUBJECT: Amendment regarding mandatory HIV testing of newborns

cc: Jennifer Klein

House-Senate conferees met last week to try to resolve differences regarding an amendment on HIV testing of newborns that was added to the Ryan White CARE Act reauthorization bill during House consideration. The Coburn-Waxman amendment would trigger mandatory HIV testing of newborns if certain conditions are not met. Leading medical groups (such as the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the Pediatric AIDS Foundation) oppose this amendment and support voluntary HIV testing of pregnant women. In addition, AIDS advocacy organizations are nearly universally opposed to this amendment.

The Coburn-Waxman amendment would require the Secretary of Health and Human Services to determine, within two years, if HIV testing of newborns is the standard of care when the HIV status of the mother is unknown. If it is the standard of care, the Secretary must then determine, within 18 months, that newborn testing is occurring voluntarily in 95 percent of the infants born to mothers who have not been tested. If the Secretary determines that 95 percent of such newborns have not been voluntarily tested, then mandatory HIV testing of newborns would be required in those states not in compliance. The states would have three-and-a-half years to reach the 95 percent level through voluntary testing.

During Senate consideration of the Ryan White CARE Act, an amendment offered by Senator Kassebaum was approved that would require states to adopt the Public Health Service's guidelines making routine counseling and voluntary testing of all *pregnant women* the standard of care. The emphasis on the prenatal period, of course, has the greatest potential for preventing transmission to newborns. Newborn testing will have virtually no impact on HIV transmission to newborns. Prenatal HIV testing would permit HIV infected mothers to take AZT during pregnancy and childbirth, which has been demonstrated to reduce the likelihood of transmission by as much as two-thirds.

It is worth noting that there are already encouraging results confirming that the combination of routine HIV counseling, voluntary testing, and AZT by choice is highly effective at reducing perinatal transmission. A study from North Carolina indicates that, after being counseled about HIV, most women choose to be tested and that, if positive, most choose to

DRAFT

take AZT. The rate of perinatal transmission fell from 21 percent of all infants born to HIV-positive mothers in 1993 to just 8.5 percent in 1994, on a par with the original NIH study. Results from hospitals in major urban centers -- such as Miami, Atlanta, and Harlem, show similar high rates of testing and AZT use.

Discussions in conference have focused on possible changes to the Coburn-Waxman amendment, such as changing the trigger for mandatory HIV testing of newborns to a failure to achieve a 50 percent reduction in perinatal transmission. But the underlying mandatory nature of the amendment remains.

The Administration has deliberately not taken a position on Coburn-Waxman. Instead, we have consistently emphasized the importance of implementing the PHS recommendations for voluntary prenatal testing as the most effective intervention and the various HHS agencies have taken major steps to assure that testing and treatment are readily available to those women who need it. At the White House Conference on HIV/AIDS on December 6th, you stated that this is an issue that should be left to the public health officials to resolve, not politicians.

It is not clear how the conferees will resolve this issue, but it is quite possible that the final bill will contain something along the lines of the Coburn-Waxman amendment. While all the AIDS groups oppose the amendment, it is quite likely that they will be very divided over the issue of whether the CARE Act should be vetoed if it comes with a mandatory testing amendment. Some will consider reauthorization of Ryan White to be a higher priority; others will be more concerned about the precedent of signing mandatory testing legislation. At this time, we are giving no indication of future action until it is clear what the conference will do.

Office of HIV/AIDS Policy

Office of the Assistant Secretary for Health
U.S. Public Health Service/DHHS
200 Independence Avenue, S.W.
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Tel. (202) 690-5560

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☐ Room 730-E
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Deliver to: Elizabeth Dorn

Fax: 456-7028

Tel: 456-5573

From: Deborah von Zinkernagel

Date: _____ : _____

This fax contains 10 pages + cover

If transmission problems occur, please call _____

Comments: Re: 3p meeting

TO: Ellen Cooper, M.D., OAR

FROM: Lynne Mofenson, M.D., PAMA, NICHD

DATE: November 27, 1996

RE: Clinical trials in the PACTG

I've taken an attachment I developed for the RFP for the NICHD central clinical trials coordinating center and updated it and added some newer trials/comments. The below studies are currently underway or in development within the collaborative NICHD/NIAID PACTG. I've listed the larger, phase III studies (generally several hundred patients) first, followed by the small phase I studies (generally under 50 patients, usually under 20). New concept sheets/capsules are reviewed and prioritized monthly by the appropriate scientific committee.

I've also included the most recent chart I developed on global perinatal studies. The information here comes from the WHO Working Group on Perinatal Transimssion that I am an NICHD/NIH representative to, as we discussed on the telephone.

PACTG Clinical Trials

- **PRIMARY THERAPY**

  Initial therapy:

  ACTG 239 (ongoing, Phase I/II): comparing ddI alone to AZT/ddI in very young (<120 days old) infected infants

  ACTG 300 (ongoing, Phase III): comparing combination therapy with 3TC/AZT to ddI and ddI/AZT.

  ACTG 311 (on hold, Phase I): indinavir/AZT in infected infants under 2 years of age. *(NOTE: currently on hold due to lack of liquid preparation with decent bioavailability)*

  ACTG 321 (to open soon, Phase I): 1592U89 in infected infants under 2 years of age.

  ACTG 339 (in development, Phase I): delavirdine in infected children, dose escalating pharmacokinetic and safety study.

  ACTG 345 (in development, Phase I): ritonavir/ZDV/3TC safety and dose-escalating pharmacokinetics study in infected infants under 2 years.

  ACTG 356 (in development, Phase I/II): nevirapine/ZDV/3TC in infected children under 2 years of age who have RNA copy number >1,000 at entry; assess safety/tolerance and antiretroviral activity, including intensive viral and CD4 kinetic studies.

Alternative therapy for children who have received prior therapy:

ACTG 245 (ongoing, completed enrollment, Phase II/III): comparing nevirapine/AZT/ddI to nevirapine/ddI vs AZT/ddI in children with advanced disease.

ACTG 274 (ongoing, Phase I): ddI/ribavirin in combination in infected children.

ACTG 310 (ongoing, Phase I): bis-POM PMEA in infected children.

ACTG 327 (ongoing, Phase II): d4T/ddI in infected children on long-term d4T monotherapy and d4T vs d4T/ddI in children with long-term AZT therapy.

ACTG 330 (in development, Phase I): 1592U89 alone and in combination with other antiretroviral agents in infected children.

ACTG 338 (in final development, Phase II): a rolling protocol virologic comparison of novel therapies in infected children on stable antiretroviral therapy who are clinically stable; first protocol will compare AZT/3TC vs d4T/ritonavir vs AZT/3TC/ritonavir.

ACTG 339 (in development, Phase I): delavirdine in combination with AZT in infected children.

ACTG 345 (in development, Phase I): ritonavir/AZT/3TC in infected infants under 2 years of age.

- **PERINATAL TRANSMISSION**

ACTG 185 (ongoing, Phase III): evaluating combination therapy of HIVIG/AZT to IVIG/AZT for reduction of transmission in infected pregnant women with advanced disease *(NICHD coordinating this study: NICHD Contractor is the ACTG data and analysis center for this trial; NHLBI purchased the HIVIG being used in the study and is a collaborating Institute).*

ACTG 250 (ongoing, Phase I): nevirapine in pregnancy (starting at 38 weeks gestation)/labor/to newborn.

ACTG 249 (ongoing, Phase I): ddI in pregnancy and the newborn.

ACTG 296 (ongoing, completed enrollment, Phase I): intracellular pharmacokinetics of AZT in pregnant women/newborns.

ACTG 315 (in development, Phase III): comparison of the 076 AZT regimen to AZT plus nevirapine given during labor and once to the newborn for reduction of transmission.

ACTG 324 (to open soon, Phase I): pharmacokinetics of oral AZT given during labor.

ACTG 331 (to open soon, Phase I): pharmacokinetics of AZT in premature infants.

ACTG 332 (in development, Phase I): d4T in pregnancy and the newborn.

ACTG 353 (in development, Phase I): nelfinavir/AZT/3TC in pregnant infected women.

ACTG 354 (in development, Phase I): ritonavir/AZT/3TC in pregnant infected women.

ACTG 358 (in development, Phase I): indinavir/AZT/3TC in pregnant infected women.

ACTG 357 (in development, Phase I): 1592U89/AZT in pregnant infected women. *(NOTE: not clear this will proceed, due to lack of drug company interest in evaluating the drug in pregnancy)*

- **OPPORTUNISTIC INFECTION**

ACTG 179 (ongoing, completed enrollment, Phase I/II): daily vs weekly dapsone for PCP prevention.

ACTG 254 (ongoing, Phase III): evaluating TMP/SMX to azithromycin/ atovoqone for prevention of PCP and bacterial infections.

ACTG 225 (ongoing, Phase III): comparison of immunogenicity of single vs two doses of measles vaccine in infected children.

A number of Phase I studies in infected children all proceeding:

- **ACTG 226** oral gancilovir (completed enrollment, under analysis)
- **ACTG 227** atovaqone (completed enrollment, under analysis)
- **ACTG 253** valacyclovir (ongoing)
- **ACTG 265** varicella vaccine (ongoing)
- **ACTG 292** pneumococcal conjugate vaccine (ongoing)

ACTG 352 (in development, Phase I): cidofovir safety and pharmacokinetics for CMV infection in infected children.

- **HIV IMMUNOTHERAPY (VACCINES, ETC)**

ACTG 230 (ongoing, completed enrollment, Phase I): evaluating 2 different envelope recombinant vaccines in newborns of infected mothers.

ACTG 273 (ongoing, completed enrollment Phase I): evaluating 3 doses of HIVIG for therapy of infected children. *(Note: NHLBI purchased the HIVIG for this study and is a collaborating Institute)*

ACTG 299 (to start, Phase I): interleukin-2 in infected children.

ACTG 318 (in development, Phase I): monoclonal antibodies 2F5 and 2G12 in infants born to infected women.

ACTG 319 (in development, Phase I): monoclonal antibodies 2F5 and 2G12 in infected children.

ACTG 326 (in development, Phase I): evaluating live recombinant canarypox ALVAC HIV vaccine in infants born to infected women.

ACTG 361 (in development, Phase I): CD4-IgG pharmacokinetics and antiretroviral activity in infected children.

- **SUPPORTIVE CARE/OTHER**

ACTG 247 (to start, Phase III): evaluating regular vs supplemented formula on early growth (enrollment in neonatal period infants born to infected women; infection status will be defined by 2 months of age and infected infants and small number uninfected infants continue on study) *(the NICHD Contractor has contracted with Ross Laboratories for purchase of special formula supply for all PACTG sites for this study; formula now in repository, awaiting opening of study).*

- **OBSERVATIONAL**

ACTG 219 (ongoing): long-term outcomes for children born to mothers who participated in perinatal trials and infected children who participated in clinical trials.

ACTG 220 (ongoing): "pre-enrollment" adolescent protocol.

ACTG 288 (ongoing): 3-year postpartum follow-up of mothers who participated in ACTG 076.

- **GYNECOLOGIC (WOMEN-SPECIFIC STUDIES)** *(Note: selected NICHD sites with an established ob/gyn infrastructure are supported for enrollment of infected women into gyn-specific trials)*

ACTG 200 (ongoing, Phase II/III): evaluating topical vaginal 5-fluorouracil maintenance therapy vs no further therapy after standard treatment for high grade cervical dysplasia in HIV-infected women.

ACTG 293 (ongoing, Phase II/III): evaluating oral isotretinoin compared to observation for low grade cervical dysplasia in HIV-infected women.

STATUS OF NIH AIDS RESEARCH RELATED TO WOMEN AND CHILDREN

The HIV/AIDS Pandemic

In the United States today, AIDS is the number one cause of death among young adults. The HIV/AIDS epidemic in the United States is shifting into new populations, disproportionately affecting persons from racial and ethnic minorities. More than 29 million men, women, and children around the world have been infected with HIV; more than 3 million of those infections occurred in just the past year. Nearly 95% of these infections occur in the poorest parts of the world, without resources or the health care systems to benefit from the dramatic successes in the development of therapeutic agents against HIV. Absent a vaccine, it can be anticipated that AIDS will soon overtake tuberculosis as the leading infectious cause of death in the world.

NATURAL HISTORY AND EPIDEMIOLOGY

The NIH conducts studies to examine the transmission of HIV and the progression of HIV-related disease, including opportunistic infections (OIs); malignancies; neurological, neurobehavioral, and oral manifestations; and other sequelae.

NIAID has established the HIV Efficacy Trials Network (HIVNET) in preparation for vaccine and other prevention trials of biomedical interventions. These trials have already begun to evaluate mass STD treatment, microbicides, and perinatal interventions with antiretrovirals and immunotherapy, as well as behavioral approaches linked to biomedical interventions.

Another area of primary prevention research is focusing on reduction of perinatal transmission in the United States and worldwide, with particular emphasis on methods appropriate to the developing world.

HIV Infection in Women

While many of the clinical manifestations of HIV infection in women are identical to those that occur in men, women also experience some that are unique and more prevalent than in men, such as vaginal and esophageal candidiasis, and chronic herpes simplex infections. The Women's Interagency HIV Study (WIHS), a major study conducted in collaboration with other PHS agencies, is identifying the nature and rate of HIV disease progression in women, characterizing clinical manifestations of HIV important to women, assessing the effects of

therapeutic regimens, and identifying sociocultural and health care access factors that affect disease outcomes in women.

An important concern is the impact of HIV on cervical cancer. Case reports suggest that HIV-associated cases progress more rapidly and are refractory to therapy. The NCI Surveillance, Epidemiology, and End Result (SEER) program has established a Special Surveillance Study to define more closely the incidence and spectrum of the histopathology of cervical cancer in HIV-infected women. The Multistate AIDS Cancer Match Registry is a project aimed at enhancing knowledge about HIV-associated cancer. Coinfection with human papillomavirus (HPV) is common in HIV-infected women. HPV and HIV have been shown to act synergistically to increase expression of individual viral genes. The enhanced expression of viral proteins results in increased viral replication, abrogates host tumor suppressor functions, and further exacerbates cellular immunodeficiency.

Mother-to-Child Transmission

The NIH continues to study the progression of HIV-related disease in infants and pregnant women, including the timing, mechanisms, and risk factors of maternal-fetal transmission. The development of improved diagnostic assays for the early detection of HIV infection among infants, as well as markers predicting rapid versus slower disease progression, form an important part of this effort. In addition, quantitative assessment of viral concentration in body fluids and tissues, and its role as a determinant of vertical transmission and disease outcome, is ongoing.

In the United States, the NIH is funding a large epidemiologic study evaluating factors associated with risk of perinatal transmission, as well as factors associated with maternal and infant disease progression. This study, the Women and Infants Transmission Study (WITS), collectively funded by NIAID, NICHD, and NIDA, includes extensive laboratory studies as well as a specimen repository. Another pediatric epidemiologic study assessing cardiac and pulmonary complications among HIV-infected children (P2C2) is funded by NHLBI. Perinatal prevention trials in the United States are done within the Pediatric AIDS Clinical Trial Group with funding from NIAID and NICHD.

Internationally, a wide variety of perinatal HIV prevention transmission studies are under way. These include antiretroviral and immunotherapy trials in Africa, the Caribbean, and Thailand that are being funded by NIAID and NICHD. In addition, NICHD, NIAID, and FIC are collaborating on several studies in Africa to determine whether micronutrient supplementation can reduce mother-to-child transmission or ameliorate disease progression in HIV-infected children. Likewise, NCI, NIAID, and FIC are collaborating on studies in Africa to assess whether vaginal and neonatal cleansing with microbicides can reduce the risk of perinatal HIV transmission and to clarify the role of breastfeeding in HIV transmission.

Recent evidence suggests that co-infection with other viruses may result in increased morbidity. For example, data from P2C2 suggest that HIV-infected pregnant women may be at greater risk for delivering infants with congenital cytomegalovirus (CMV) infection, and that these infected children are more vulnerable to CMV morbidity in the first years of life. Data from WITS indicate that, among drug-using women, women who are co-infected with hepatitis C and have the highest RNA plasma hepatitis C levels are at the highest risk of transmitting HIV to their infants.

ETIOLOGY AND PATHOGENESIS

HIV Pathogenesis Affecting Women and Maternal-Fetal Transmission

In response to the changing demographics of the disease, studies have been designed to elucidate the pathogenic mechanisms more commonly observed in women, children, and adolescents with HIV infection. As part of this effort, the NIH supports a number of epidemiologic cohort studies specifically focused on women and adolescents. The study of patient samples and data generated by these cohorts is providing critical information about the course of the disease in these populations. These NIH-sponsored cohort studies represent an important scientific link between epidemiology and basic research into the pathogenic mechanisms of HIV disease.

In the area of maternal-fetal transmission, studies have demonstrated that the transmission rate of HIV from mother to infant is between 20 and 35 percent. A recently completed large clinical trial has determined that administration of zidovudine during gestation and labor and to the infant after birth significantly reduces the rate of HIV transmission. An ongoing clinical trial is evaluating hyperimmune anti-HIV immunoglobulin (HIVIG) for blocking or reducing maternal-fetal transmission. However, crucial issues associated with maternal-fetal transmission remain, including the specific mechanisms involved and the time distribution at the point at which HIV transmission occurs between mother and infant; whether specific strains (monocytotropic or lymphocytotropic) of the virus are more likely to be transmitted; delineation of the role of maternal immunity in prevention of transmission to the fetus; and the role of cofactors such as substance abuse and other infections.

HIV-associated heart disease (HIVHD) also represents a cause of morbidity and mortality in seropositive children and adults. Additional ongoing studies are examining the pulmonary effects of HIV infection, elucidating the basis of HIV-associated nephropathy, and delineating the early cutaneous manifestations of HIV infection.

THERAPEUTICS

Clinical Trials

The NIH has the primary responsibility for the federally supported clinical trial efforts in the evaluation of potential therapies for the treatment of HIV infection and its sequelae. These efforts consist of 35 adult AIDS Clinical Trials Units (ACTUs) and 22 Pediatric ACTUs supported by the NIAID-funded AIDS Clinical Trials Group (ACTG), 16 NIAID-funded Terry Beirn Community Programs for Clinical Research on AIDS (CPCRAs), 50 sites of the NIAID-sponsored Division of AIDS Treatment Research Initiative (DATRI), 27 NICHD-funded sites that are full partners in the Pediatric ACTG, 12 NEI-funded sites, and 3 NIH intramural sites. More than 45,000 patients have been enrolled to date in NIH-sponsored clinical studies, which have involved the evaluation of nearly 80 agents.

A NIAID- and NICHD-sponsored clinical trial demonstrated that AZT administered during gestation and labor and to the infant after birth reduces the rate of HIV transmission by approximately 67 percent. Accomplishments of NIH-sponsored clinical trials in the past year include the completion of two combination nucleoside trials in the adult and one in the pediatric HIV-infected populations which demonstrated clinical superiority of ddI monotherapy and ddi/ZDV combination therapy over ZDV monotherapy; other NIH-sponsored trials have shown clinical benefit of treatment of oral aphthous ulcers with Thalidomide, recombinant human growth hormone for treatment of AIDS-associated Wasting Syndrome (AWS), and megestrol acetate for AWS. Additional NIH trials have contributed to the further understanding of the use of protease inhibitors, such as Saquinavir, Indinavir, and Ritonavir, nucleoside analogs, such as d4T and 3TC, and nonnucleoside reverse transcriptase inhibitors, such as nevirapine and delavirdine, and the impact of these agents on viral load and on clinical outcomes.

As administration of therapeutic agents occurs only during periods of organ system development in the growing child, evaluating potential late toxic effects is an important component of therapeutic research in infected children. Such effects may not be observed with therapy in adults who have fully developed organ systems.

Pediatrics

The unique mode of HIV transmission from mother to infant constitutes a major difference between adult and pediatric HIV infection. Interventions to prevent transmission are of high priority, and intervention trials should elucidate important pathogenic factors associated with vertical transmission that apply to other transmission modes. It is especially important to identify the reasons for treatment failures. These intervention trials include evaluating long-term followup of infants (both uninfected and infected) exposed to antiretroviral agents *in utero* for late toxicity. The trials also include evaluating infected women who received prophylactic treatment during pregnancy following treatment discontinuation.

There are significant differences between the manifestations of HIV infection in children and those in adults. Also, the pharmacokinetics, toxicity, and beneficial response profiles of therapeutic agents are often a function of age due to tissue/organ immaturity, requiring specific evaluation of potential agents in children of different ages.

Specific preclinical and clinical projects involving HIV-infected pediatric patients will seek to:

- Study existing animal models as well as develop improved animal models for perinatal transmission of HIV to better understand mechanisms and timing of transmission, protection, and efficacy of interventions;

- Further understand the mechanisms and timing of perinatal transmission of HIV;

- Identify reasons for failures of ACTG 076 AZT regimens and the importance of AZT resistance in such failures, and evaluate other interventions for preventing perinatal transmission (such as use of passive immunoprophylaxis, combination antiretroviral drugs, etc.);

- Evaluate potential long-term effects of exposure to antiretroviral agents *in utero* in uninfected as well as infected infants born to HIV-infected women enrolled in studies of antiretroviral agents during pregnancy. Such studies should include evaluating passive/active immunotherapeutics and the potential short-term (3 years post partum) effects of therapies given to infected women solely during pregnancy for the prevention of perinatal transmission;

- Evaluate the safety, risks, and benefits of early initiation of therapy during the period of primary infection (perinatal period);

- Improve therapeutic regimens for managing HIV infection and its associated conditions in children, and evaluate potential late toxicities of antiretroviral agents given to the developing child;

- Identify and define markers of disease progression in clinical trials that are unique to HIV-infected children, such as physical and neurological growth and development; and

- Continue development of active and/or passive immunotherapy and use of new immunomodulatory agents for the treatment of HIV disease in children.

Participation of Underrepresented Populations

It is critical that the participation of specific populations in NIH-funded clinical trials reflect the changing demographics of HIV infection and AIDS, including women, children, adolescents, drug abusers, IDUs, minorities, the urban poor, and individuals residing in rural areas. Recruitment and enrollment of these underrepresented populations is a high priority in NIH-sponsored studies and should be a consideration within each objective of this section. Whenever possible, interagency collaboration should be fostered to enhance participation of these populations, including provision of ancillary services.

The NIH has published and implemented new and strengthened guidelines for the inclusion of women and minorities in clinical trials.

The NIAID-supported clinical trials programs (ACTG, CPCRA, DATRI) strive to ensure that a sufficient proportion of minority participants are enrolled into the clinical trials so that the results of the research may be generalizable to the affected HIV population at large. NIAID works with these networks to identify the need for and/or assist in the development of culturally sensitive education materials, identify real or potential barriers to recruitment and retention in clinical research for these groups, and identify mechanisms to overcome these barriers.

Pediatric clinical trials enroll principally minority populations. The NIAID/NICHD funded collaborative PACTG enables the flexibility to adjust the location of trials sites to accommodate the changing epidemiology of HIV in women and children along with the establishment of advanced technology sites for investigators of pathogenesis in the context of clinical trials.

"The ACTG has also sought to increase the number of underrepresented participants in a proportion reflective of the spectrum of the infected population, including prioritizing gender-specific clinical trials in the overall scientific agenda."

In addition, the ACTG supports the AIDS Clinical Trials Infrastructures in Minority Institutions to enhance HIV clinical research performed at minority institutions. Four institutions, located at Howard University (Washington, DC), Meharry Medical College (Nashville, TN), the University of Puerto Rico (San Juan), and the University of Hawaii (Honolulu), received 4-year awards as adult ACTUs. This program increases the number of minority staff involved in ACTG research and the number of minority participants in the studies.

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