

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	From: Donald Abrams, To: Jeffrey Levi, Re: (Fwd) Our Friend Al (1 page)	07/23/1996	Personal Misfile
002. email	From: Donald Abrams, To: Jeffrey Levi, Re: (Fwd) Our Friend Al (2 pages)	07/23/1996	Personal Misfile
003. email	From: Jeffrey Levi, To: Donald Abrams, Re: (Fwd) Our Friend Al (1 page)	07/23/1996	Personal Misfile
004. email	From: Jeffrey Levi, To: Patsy Fleming, Re: Debra [personal] [partial] (1 page)	07/25/1996	b(6)
005. email	From: Donald Abrams, To: Jeffrey Levi, Re: Clint's Theory (1 page)	07/25/1996	Personal Misfile

COLLECTION:

Clinton Presidential Records
Automated Records Management System [Email]
WHO ([Jeffrey Levi...])
OA/Box Number: 500000

FOLDER TITLE:

[07/23/1996 - 07/26/1996]

2018-0759-F

in424

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: aidsnews@cdcnac.aspensys.com@INET@EOPMRX

CREATION DATE/TIME:23-JUL-1996 15:52:00.00

SUBJECT: New Information from ACTIS 07/23/96

TO: levi_j (levi_j@A1@CD) (WHO)

READ:23-JUL-1996 17:59:35.32

TEXT:

July 23, 1996

NEW INFORMATION FROM ACTIS

The AIDS Clinical Trials Information Service (ACTIS) is a central resource providing current information on federally and privately sponsored clinical trials for AIDS patients and others infected with HIV. This service is a Public Health Service project produced collaboratively by the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institute of Allergy and Infectious Diseases, and the National Library of Medicine. NAC ONLINE, the computerized information service of the CDC National AIDS Clearinghouse, will alert you to any new information collected by ACTIS.

Descriptions of two recent clinical trials and a new drug record added to the ACTIS database are provided below.

For more information, call the ACTIS toll-free number to talk with a health specialist. On request, you can also obtain a printout of a customized search of the clinical trials databases. The information can also be accessed directly by subscribers through two online databases, AIDSTRIALS and AIDSDRUGS, available through the National Library of Medicine.

AIDS CLINICAL TRIALS INFORMATION SERVICE

1-800-TRIALS-A

(1-800-874-2572)

FAX: 1-301-738-6616

TTY/TDD: 1-800-243-7012

International Line: 1-301-217-0023

PROTOCOL NUMBER: NIAID ACTG 291.

TITLE: A Phase II, Double-Blind Trial of Recombinant Human Nerve Growth Factor for Treatment of HIV-Associated Sensory Neuropathy.

PHASE: Phase II.

DISEASE STATUS:

Patients have the following symptoms and conditions: 1. HIV infection with associated sensory neuropathy. 2. No acute, active opportunistic infection within 2 weeks prior to study entry OTHER THAN oral thrush; oral, genital, or rectal herpes; or MAI bacteremia. 3. Either antiretroviral naive or on a stable dose for at least the past 8 weeks.

PATIENT INCLUSION CRITERIA

SPECIFICATION CRITERIA:

Patients must have:

1. HIV infection.
2. HIV-associated sensory neuropathy.
3. No acute, active opportunistic infection within 2 weeks prior to study entry OTHER THAN oral thrush; oral, genital, or rectal herpes; or MAI bacteremia.
4. Either antiretroviral naive or on a stable dose for the past 8 weeks.
5. Ability to assess pain level throughout the study.

AGE: 18 Years - 70 Years.

SEX: M. F.

REPRODUCTIVE SPECIFICATION:

Not pregnant. Negative pregnancy test within 14 days of study entry.
Not breast-feeding. Abstinence or agree to use barrier methods of birth control / contraception during the study.

PRIOR MEDICATION:

Allowed: Prior antiretrovirals.

LABORATORY VALUES AT ENTRY

HEMOGLOBIN: ≥ 8.0 g/dl. (men); ≥ 7.5 g/dl (women).

PLATELET COUNT: ≥ 75000 platelets/mm³.

CD4 (T4 CELL) COUNT: Unspecified cells/mm³.

BILIRUBIN: ≤ 2.5 mg/dl.

SGOT (AST): $\leq 5 \times$ ULN. (ULN = upper limit of normal).

SGPT (ALT): $\leq 5 \times$ ULN.

CREATININE: < 2.5 mg/dl.

KARNOFSKY: ≥ 60 .

OTHER LABORATORY VALUES: Serum vitamin B12 ≥ 150 pg/ml. Alkaline phosphatase $\leq 5 \times$ ULN. Absolute neutrophils ≥ 750 cells/mm³.

PATIENT EXCLUSION CRITERIA

AGE: 01 Days - 17 Years. 71 Years - 99 Years.

REPRODUCTIVE SPECIFICATION:

Pregnant. Positive pregnancy test within 14 days of study entry.

Breast-feeding. No abstinence or no agreement to use barrier methods of birth control / contraception during the study.

RISK BEHAVIOR:

Active drug or alcohol abuse that would affect study compliance.

PRIOR MEDICATION:

Excluded:

1. Neurotoxic systemic chemotherapy within the past 90 days.
2. Systemic corticosteroids or immunomodulators within the past 30 days.
3. Initiation of non-opioid prescription medication for pain within the past 2 weeks (including tricyclic antidepressants, mexiletine, phenytoin, and carbamazepine).
4. Treatment for acute opportunistic infections within the past 14 days (maintenance therapy for CMV retinitis, MAI bacteremia, or cryptococcal meningitis is permitted).

CONCURRENT MEDICATION:

Excluded:

1. Chemotherapeutic agents.
2. Systemic corticosteroids or immunomodulators.
3. Initiation of new antiretroviral to a stable regimen.

CO-EXISTING CONDITIONS OR DISEASES:

Patients with the following symptoms or conditions are excluded:

1. Evidence of another contributing cause for peripheral neuropathy, such as diabetes mellitus, hereditary neuropathy, current vitamin B12 deficiency, or treatment with any drug that might contribute to sensory neuropathy.
2. Major active psychiatric disorder (depression is allowed provided patient has received a stable antidepressant regimen for the past month).
3. Current active malignancy.
4. Any conditions, including dementia and myelopathy, that would interfere with patient evaluation.

GENERIC DRUG NAME

Drug 1: Recombinant human nerve growth factor. Growth factor.

DRUG COMPANIES

Drug 1: Genentech Incorporated
460 Point San Bruno Boulevard
South San Francisco, CA 94080

Contact: Professional Services (800) 821-8590.

END POINT

Efficacy, toxicity.

DISCONTINUE TREATMENT

Patients discontinue treatment for the following reasons:

1. Unacceptable toxicity.
2. Treatment with disallowed medications.
3. Pregnancy.
4. Development of any new malignancy including KS.
5. Any confounding illness that precludes participation.
6. Patient noncompliance or desire to withdraw from study.

PARTICIPATING UNITS

0000001388:

Stanford University Medical Center

300 Pasteur Drive / S156

Stanford, CA 94305-5107

Contact: Virginia Tallman (415) 723-2804

Contact: (415) 723-6231

OPEN 960711 ACTU: 0501.

0000001365:

Northwestern University Medical School

303 East Superior Street / Passavant Pavilion / Room 823

Chicago, IL 60611

Contact: Baiba L Berzins (312) 908-4655

Contact: (312) 908-9636

OPEN 960711 ACTU: 2701.

0000001316:

Mount Sinai Medical Center

One Gustave Levy Place / PO Box 1042

New York, NY 10029

Contact: Dr Eileen Chusid (212) 241-0433

OPEN 960711 ACTU: 1801.

0000001307:

Ohio State University Hospital Clinic

456 West 10th Avenue / Room 4725

Columbus, OH 43210-1228

Contact: Judy Neidig (614) 293-8112

Contact: (614) 293-5282

OPEN 960711 ACTU: 2301.

0000001466:
Univ TX Galveston Medical Branch
Route H-82 / Clay Hall
Galveston, TX 77555-0882
Contact: Karen Waterman (409) 772-0361
OPEN 960711 ACTU: 6301.

PROTOCOL NUMBER: NIAID ACTG 310.

TITLE: A Phase IA Single Dose Pharmacokinetics and Safety Study of the
Oral Antiviral Compound,
9-[2-(Bisphivaloyloxymethyl)phosphonylmethoxyethyl]adenine (
bis-POM PME A) (Adefovir Dipivoxil) in Children With HIV-1
Infection.

PHASE: Phase I A.

DISEASE STATUS:

Patients have the following symptoms and conditions:
Asymptomatic or mildly symptomatic HIV infection (CDC Class
categories N and A, respectively), with no worse than grade 1
toxicity for any symptoms.

PATIENT INCLUSION CRITERIA

SPECIFICATION CRITERIA:

Patients must have:

1. Asymptomatic or mildly symptomatic HIV infection, with no worse than grade 1 toxicity for any symptoms.
2. Consent of parent or guardian.

AGE: 01 Days - 17 Years.

SEX: M. F.

REPRODUCTIVE SPECIFICATION:

Not pregnant. Negative pregnancy test. Abstinence or agree to use
barrier methods of birth control / contraception during the study.

WEIGHT:

> 2500 g

PRIOR MEDICATION:

Allowed:

1. IV gammaglobulin and aerosolized pentamidine for PCP prophylaxis.
2. Antiretrovirals if discontinued by 72 hr prior to study entry.

LABORATORY VALUES AT ENTRY

CD4 (T4 CELL) COUNT: Unspecified cells/mm3.

PATIENT EXCLUSION CRITERIA

REPRODUCTIVE SPECIFICATION:

Pregnant. Positive pregnancy test. No abstinence or no agreement to use barrier methods of birth control / contraception during the study.

WEIGHT:

<= 2500 g

PRIOR MEDICATION:

Excluded within 72 hr prior to study entry:

1. Antiretrovirals other than study drug.
2. Other investigational agents.
3. Immunomodulators.
4. HIV-1 vaccines.
5. Glucocorticoids.
6. Drugs with potential for adverse interaction with study drug or that would interfere with quantitation of study drug in serum or plasma.
7. TMP / SMX and dapsone.

CONCURRENT MEDICATION:

Excluded:

1. Antiretrovirals other than study drug.
2. Other investigational agents.
3. Immunomodulators.
4. HIV-1 vaccines.
5. Glucocorticoids.
6. Drugs with potential for adverse interaction with study drug or that would interfere with quantitation of study drug in serum or plasma.
7. TMP / SMX and dapsone.

CO-EXISTING CONDITIONS OR DISEASES:

Patients with the following symptoms or conditions are excluded:
Acute or chronic infections that require treatment during study.

AVAILABILITY:

Unable to be followed at an ACTG center for study duration.

GENERIC DRUG NAME

Drug 1: Adefovir dipivoxil. Antiretroviral.

DRUG TRADE NAME

Drug 1: bis-POM PMEA.

DRUG COMPANIES

Drug 1: Gilead Sciences Incorporated
353 Lakeside Drive
Foster City, CA 94404
Contact: Dr Jay Toole (415) 573-4751.

END POINT

Toxicity, pharmacokinetic profile.

PARTICIPATING UNITS

0000003235:
University of Florida Health Science Center / Pediatrics
653-1 West 8th Street
Jacksonville, FL 32209
Contact: Michelle Eagle (904) 549-3051
OPEN 960522 ACTU: 5051.

0000001363:
Chicago Children's Memorial Hospital
2300 Children's Plaza / PO Box 20
Chicago, IL 60614-3394
Contact: Debbie Fonken (312) 880-3669
OPEN 960507 ACTU: 4001.

0000001358:
Johns Hopkins University Hospital
600 North Wolfe Street / Blalock 1140
Baltimore, MD 21287
Contact: Laura J Flautt (410) 955-9749
OPEN 960613 ACTU: 3701.

0000001270:
Saint Jude Children's Research Hospital of Memphis
332 North Lauderdale
Memphis, TN 38105-2794
Contact: Micki Roy (901) 495-3485
OPEN 960408 ACTU: 6501.

DRUG RECORD

Accession Number:

DRG-0249.

Generic Name:

Recombinant human nerve growth factor (NIAID ACTG 291).

Protocol Number(s):

Open NIAID ACTG 291

Alias/Trade Name:

rhNGF (NIAID ACTG 291).

Drug Company(ies):

Genentech Incorporated

460 Point San Bruno Boulevard

South San Francisco, CA 94080

Contact: Professional Services (800) 821-8590.

Therapeutic Classification:

Growth factor (NIAID ACTG 291).

Drug Description:

Homodimer consisting of predominately a 118-amino acid residue monomer.

(NIAID ACTG 291)

Physical Description:

Clear, colorless liquid. (NIAID ACTG 291)

Adverse Effects/Toxicity:

Adverse effects with intravenous administration have included mild to moderate pain with swallowing, pain in the masseter muscles, pain in the throat, and painful muscles in other areas. Adverse effects with subcutaneous administration have included moderate diffuse muscle pain and injection site hyperalgesia, described as increased sensitivity to touch or heat around the injection site.

(NIAID ACTG 291)

Contraindications:

Contraindicated in pregnant and nursing women.

(NIAID ACTG 291)

Dosage Form:

2 mg/ml in 0.5 ml vials.

(NIAID ACTG 291)

Mode of Delivery:

Subcutaneous, intravenous. (NIAID ACTG 291)

Storage Instructions:

Store at 2-8 C (35-46 F). Do not freeze.

(NIAID ACTG 291)

AIDS-Related Uses:

HIV-related peripheral neuropathy. (NIAID ACTG 291)

Other Uses:

Diabetic peripheral neuropathy.

(NIAID ACTG 291)

Bibliographic References:

94330699. Petty BG, Cornblath DR, Adornato BT, Chaudhry V, Flexner C, Wachsmann M, Sinicropi D, Burton LE, Peroutka SJ. The effect of systemically administered recombinant human nerve growth factor in healthy human subjects. Ann Neurol 1994 Aug;36(2):244-6.

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:23-JUL-1996 15:53:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)

by PMDF.EOP.GOV (PMDf V5.0-4 #6879) id <0117F1TXN5N4001E28@PMDf.EOP.GOV> for

levi_j@a1.eop.gov; Tue, 23 Jul 1996 15:52:34 -0400 (EDT)

Received: from aspen3.aspensys.com (aspensys3.aspensys.com)

by STORM.EOP.GOV (PMDf V5.0-7 #6879) id <0117F1TKX0L000007K@STORM.EOP.GOV> for

levi_j@a1.eop.gov; Tue, 23 Jul 1996 15:52:20 -0700 (MST)

Received: by aspen3.aspensys.com (SMI-8.6/SMI-SVR4) id PAA05263; Tue,

23 Jul 1996 15:52:31 -0400

Errors-to: shelly_olim_at_aspenpo@smtpinet.aspensys.com

Precedence: bulk

Originator: aidsnews@cdcnac.aspensys.com

X-Comment: CDC National AIDS Clearinghouse

X-Listprocessor-version: 6.0c -- ListProcessor by Anastasios Kotsikonas

===== END ATTACHMENT 1 =====

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	From: Donald Abrams, To: Jeffrey Levi, Re: (Fwd) Our Friend Al (1 page)	07/23/1996	Personal Misfile

COLLECTION:

Clinton Presidential Records
Automated Records Management System [Email]
WHO ([Jeffrey Levi...])
OA/Box Number: 500000

FOLDER TITLE:

[07/23/1996 - 07/26/1996]

2018-0759-F
jn424

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
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C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Nancy-Ann E. Min (MIN_N) (OMB)

CREATION DATE/TIME:23-JUL-1996 20:38:11.37

SUBJECT: RE: finding me

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:23-JUL-1996 21:57:15.61

TEXT:

I've just tried to call you 8 times--and the line is busy every time--to tell you that we leaked the budget amendment announcement to the times today and the potus is going to talk about it in his speech in ca tonight. i will keep trying to call you but i am wondering if the phone is off the hook--if so, you are getting some well-deserved rest.

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: aidsnews@cdcnac.aspensys.com@INET@EOPMRX

CREATION DATE/TIME:23-JUL-1996 11:29:00.00

SUBJECT: CDC AIDS Daily Summary 7/23/96

TO: levi_j (levi_j@A1@CD) (WHO)

READ:23-JUL-1996 12:00:18.23

TEXT:

AIDS Daily Summary
July 23, 1996

The Centers for Disease Control and Prevention (CDC) National AIDS Clearinghouse makes available the following information as a public service only. Providing this information does not constitute endorsement by the CDC, the CDC National AIDS Clearinghouse, or any other organization. Reproduction of this text is encouraged; however, copies may not be sold, and the CDC National AIDS Clearinghouse should be cited as the source of this information.
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"Liz Taylor on AIDS: Battle Far From Won"
"Zimbabwe Lifts Ban on Gay Group at Fair"
"Across the USA: Rhode Island"
"Number of AIDS Cases Doubles in Russia"
"Thai Government Unveils New Anti-AIDS Plan"
"Anti-HIV Agent Delavirdine Promising in Phase I/II Study"
"Namibia Urged to Widen AIDS Control Program"
"President Clinton and the First Lady to Serve as Honorary
Co-Chairs for the Display of the Entire AIDS Memorial Quilt This
Fall"
"HIV as the Cause of AIDS"
"Pataki's AIDS Drug Ruse"

"Liz Taylor on AIDS: Battle Far From Won"
Washington Post--Health (07/23/96) P. 6; Trafford, Abigail
In her speech to the National Press Club Monday, Elizabeth Taylor, a long-time AIDS activist who helped found the American Foundation for AIDS Research (AmFAR), warned against complacency in the fight against AIDS. Like many AIDS researchers, she said that the recent advances in treatment should not be perceived as a cure. The cost of the new drugs is a critical issue for access, Taylor pointed out, saying that "the most promising treatments will be least available to those who need them." Prevention strategies should not be overlooked because therapies are improving. "People don't think it could happen to them," Taylor said, especially teenagers who think of abstinence as a "remote

idea." Taylor also criticized President William Clinton and Republican presidential candidate Bob Dole for their views and actions on AIDS. Specifically, she pointed to the ban against needle exchanges, saying that "misunderstanding, social squeamishness and lack of compassion have prevailed over sensible public health practice."

"Zimbabwe Lifts Ban on Gay Group at Fair"
New York Times (07/23/96) P. A8

A homosexual group will be allowed to participate in an international book fair, the Zimbabwe government said Monday, reversing a ban it made last year. The organizers of the state-supported Zimbabwe International Book Fair have given the Gays and Lesbians Society of Zimbabwe permission to display literature, mostly on AIDS, at the week-long fair which starts on July 29.

"Across the USA: Rhode Island"
USA Today (07/23/96) P. 8A

The first clinical trials of SPC-3, a drug designed to block HIV infection, will be conducted at Roger Williams Medical Center in Providence, R.I.

"Number of AIDS Cases Doubles in Russia"
United Press International (07/22/96)

The number of new HIV infections in Russia during the first half of 1996 was twice the number for the same period of 1995, the head of the Russian AIDS Center said Monday. Vadim Pokrovski said the number of AIDS cases in Russia for 1996 would at least double last year's total, and that it could reach 100,000 by 2000. By the end of 1995, 1,269 people were infected with HIV, mostly as a result of intravenous drug use. In the former Soviet Republics, the number of infections is much higher, Pokrovski said.

"Thai Government Unveils New Anti-AIDS Plan"
Xinhua News Agency (07/23/96)

On Monday, the Thai government announced a new five-year plan to combat the spread of AIDS by promoting family values and awareness of self-protection. Prime Minister Banharn Silpa-Archa unveiled the 1997-2001 National AIDS Prevention and Control Plan, which calls for higher social status for women and efforts to educate people about preventing HIV infection. The plan stresses community and family roles to help HIV-positive and AIDS patients.

"Anti-HIV Agent Delavirdine Promising in Phase I/II Study"
Reuters (07/22/96)

Delavirdine mesylate (DLV), a nonnucleoside reverse transcriptase inhibitor, is apparently safe and well-tolerated even at high doses, government and industry researchers report in the July issue of Antimicrobial Agents and Chemotherapy. R.T. Davey, Jr., of the National Institute of Allergy and Infectious Diseases, and colleagues at Chiron and Upjohn, reported that DLV was safe and well-tolerated in the phase I/II study. Among the 85

HIV-positive patients participating in the study, those taking DLV, zidovudine, and didanosine benefited most.

"Namibia Urged to Widen AIDS Control Program"

Xinhua News Agency (07/22/96)

The Namibian government needs to expand its national HIV/AIDS control program (NACP) to deal with the growing number of HIV cases in the country, an independent review advised. The review panel included members from national and international organizations and other specialists. They said the Ministry of Health and Social Services and the NACP are no longer able to cope with the growing epidemic, and that individuals and organizations in the government, and non-governmental and private groups must be called on to help. An estimated 21,737 HIV infections have been reported in Namibia since 1986.

"HIV as the Cause of AIDS"

Lancet (07/06/96) Vol. 348, No. 9019; P. 31; Barre-Sinoussi, Françoise

In an essay on the structure and mechanism of HIV compared to other primate lentiviruses, Françoise Barre-Sinoussi of the Pasteur Institute in Paris suggests that the simian immunodeficiency virus (SIV) may be a valuable model for studying HIV and AIDS. HIV shows extensive genetic diversity, even within patients, and the evolution of virus isolates increases with their ability to infect cells as the clinical disease progresses. This ability allows HIV-1 to quickly develop resistance to antiviral drugs. Genetic analysis has found two distinct groups of HIV-1 isolates--the M group and the O group. The M group, which contains most HIV-1 isolates, is subdivided into at least 10 strains. The discovery of HIV-1 in West Africa and its similarity to SIV has raised the possibility of a link between human and non-human primate lentiviruses. The divergence between HIV-1 group M subtypes and SIV suggests that chimpanzee viruses may have been introduced into the human population 30 to 50 years ago. The origin of HIV-1 group O remains to be explained, however. SIVs, while genetically similar to HIVs, do not cause disease in their natural hosts, though cross-species transmission may result in pathogenic infections. Barre-Sinoussi concludes that non-human lentiviruses from Old World primates can provide useful models for studying the interaction between the human host and viral factors that cause AIDS.

"Pataki's AIDS Drug Ruse"

Village Voice (07/09/96) Vol. XLI, No. 28; P. 11; Schoofs, Mark

Although New York Gov. George Pataki promised that the state's AIDS Drug Assistance Program would cover the costly new protease inhibitors, his plan would exclude 129--or 70 percent--of the drugs currently available. Pataki's proposal would remove drugs for diarrhea, parasites, bacterial infections, life-threatening blood disorders, and AIDS-related wasting from the program. Advocates for AIDS patients are lobbying the state to restore coverage for the drugs. The state Assembly has pledged to allocate \$15 million, which would cover the drugs, and

the Senate has promised \$4 million, while the governor has not promised any additional funds.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:23-JUL-1996 21:59:26.53

SUBJECT: RE: finding me

TO: Nancy-Ann E. Min (MIN_N) (OMB)

READ:24-JUL-1996 09:02:19.96

TEXT:

Alas, I was busy with business...but thank you for all the heavy lifting you have been doing. It's good that this is out there ...I still find it hard to believe, sometimes, that everyone is on the same team.

I am faxing to you a chart that addresses the four states that are closing off new enrollments -- the bottom line is that they are not tapping all the existing resources the feds are already providing -- i.e., they are using a very small percentage of their Title II funds for ADAP (as compared to other states) and they have not asked their Title I cities to contribute.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:23-JUL-1996 12:01:43.76

SUBJECT: daily news

TO: Patsy Fleming (FLEMING_P) (WHO)
READ:24-JUL-1996 16:03:55.76

TO: Ursula Sanville (SANVILLE_U) (OPD)
READ:NOT READ

TO: Lahoma Romocki (ROMOCKI_L) (OPD)
READ:13-AUG-1996 15:39:28.97

TEXT:

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE:23-JUL-1996 11:28:00.00

ATT BODYPART TYPE:E

ATT CREATOR: aidsnews

ATT SUBJECT: CDC AIDS Daily Summary 7/23/96

ATT TO: levi_j (levi_j@A1@CD)

TEXT:

AIDS Daily Summary
July 23, 1996

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Co-Chairs for the Display of the Entire AIDS Memorial Quilt This Fall"

"HIV as the Cause of AIDS"

"Pataki's AIDS Drug Ruse"

"Liz Taylor on AIDS: Battle Far From Won"

Washington Post--Health (07/23/96) P. 6; Trafford, Abigail

In her speech to the National Press Club Monday, Elizabeth Taylor, a long-time AIDS activist who helped found the American Foundation for AIDS Research (AmFAR), warned against complacency in the fight against AIDS. Like many AIDS researchers, she said that the recent advances in treatment should not be perceived as a cure. The cost of the new drugs is a critical issue for access, Taylor pointed out, saying that "the most promising treatments will be least available to those who need them." Prevention strategies should not be overlooked because therapies are improving. "People don't think it could happen to them," Taylor said, especially teenagers who think of abstinence as a "remote idea." Taylor also criticized President William Clinton and Republican presidential candidate Bob Dole for their views and actions on AIDS. Specifically, she pointed to the ban against needle exchanges, saying that "misunderstanding, social squeamishness and lack of compassion have prevailed over sensible public health practice."

"Zimbabwe Lifts Ban on Gay Group at Fair"

New York Times (07/23/96) P. A8

A homosexual group will be allowed to participate in an international book fair, the Zimbabwe government said Monday, reversing a ban it made last year. The organizers of the state-supported Zimbabwe International Book Fair have given the Gays and Lesbians Society of Zimbabwe permission to display literature, mostly on AIDS, at the week-long fair which starts on July 29.

"Across the USA: Rhode Island"

USA Today (07/23/96) P. 8A

The first clinical trials of SPC-3, a drug designed to block HIV infection, will be conducted at Roger Williams Medical Center in Providence, R.I.

"Number of AIDS Cases Doubles in Russia"

United Press International (07/22/96)

The number of new HIV infections in Russia during the first half of 1996 was twice the number for the same period of 1995, the head of the Russian AIDS Center said Monday. Vadim Pokrovski said the number of AIDS cases in Russia for 1996 would at least double last year's total, and that it could reach 100,000 by 2000. By the end of 1995, 1,269 people were infected with HIV, mostly as a result of intravenous drug use. In the former Soviet Republics, the number of infections is much higher, Pokrovski said.

"Thai Government Unveils New Anti-AIDS Plan"

Xinhua News Agency (07/23/96)

On Monday, the Thai government announced a new five-year plan to combat the spread of AIDS by promoting family values and awareness of self-protection. Prime Minister Banharn Silpa-Archa unveiled the 1997-2001 National AIDS Prevention and Control Plan, which calls for higher social status for women and efforts to educate people about preventing HIV infection. The plan stresses community and family roles to help HIV-positive and AIDS patients.

"Anti-HIV Agent Delavirdine Promising in Phase I/II Study"

Reuters (07/22/96)

Delavirdine mesylate (DLV), a nonnucleoside reverse transcriptase inhibitor, is apparently safe and well-tolerated even at high doses, government and industry researchers report in the July issue of *Antimicrobial Agents and Chemotherapy*. R.T. Davey, Jr., of the National Institute of Allergy and Infectious Diseases, and colleagues at Chiron and Upjohn, reported that DLV was safe and well-tolerated in the phase I/II study. Among the 85 HIV-positive patients participating in the study, those taking DLV, zidovudine, and didanosine benefited most.

"Namibia Urged to Widen AIDS Control Program"

Xinhua News Agency (07/22/96)

The Namibian government needs to expand its national HIV/AIDS control program (NACP) to deal with the growing number of HIV cases in the country, an independent review advised. The review panel included members from national and international organizations and other specialists. They said the Ministry of Health and Social Services and the NACP are no longer able to cope with the growing epidemic, and that individuals and organizations in the government, and non-governmental and private groups must be called on to help. An estimated 21,737 HIV infections have been reported in Namibia since 1986.

"HIV as the Cause of AIDS"

Lancet (07/06/96) Vol. 348, No. 9019; P. 31; Barre-Sinoussi, Francoise

In an essay on the structure and mechanism of HIV compared to other primate lentiviruses, Francoise Barre-Sinoussi of the Pasteur Institute in Paris suggests that the simian immunodeficiency virus (SIV) may be a valuable model for studying HIV and AIDS. HIV shows extensive genetic diversity, even within patients, and the evolution of virus isolates increases with their ability to infect cells as the clinical disease progresses. This ability allows HIV-1 to quickly develop resistance to antiviral drugs. Genetic analysis has found two distinct groups of HIV-1 isolates--the M group and the O group. The M group, which contains most HIV-1 isolates, is subdivided into at least 10 strains. The discovery of HIV-1 in West Africa and its similarity to SIV has raised the possibility of a link between human and non-human primate lentiviruses. The divergence between HIV-1 group M subtypes and SIV suggests that chimpanzee viruses may have been introduced into the human population 30 to 50 years

ago. The origin of HIV-1 group O remains to be explained, however. SIVs, while genetically similar to HIVs, do not cause disease in their natural hosts, though cross-species transmission may result in pathogenic infections. Barre-Sinoussi concludes that non-human lentiviruses from Old World primates can provide useful models for studying the interaction between the human host and viral factors that cause AIDS.

"Pataki's AIDS Drug Ruse"

Village Voice (07/09/96) Vol. XLI, No. 28; P. 11; Schoofs, Mark

Although New York Gov. George Pataki promised that the state's AIDS Drug Assistance Program would cover the costly new protease inhibitors, his plan would exclude 129--or 70 percent--of the drugs currently available. Pataki's proposal would remove drugs for diarrhea, parasites, bacterial infections, life-threatening blood disorders, and AIDS-related wasting from the program. Advocates for AIDS patients are lobbying the state to restore coverage for the drugs. The state Assembly has pledged to allocate \$15 million, which would cover the drugs, and the Senate has promised \$4 million, while the governor has not promised any additional funds.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:23-JUL-1996 17:58:01.47

SUBJECT: fyi, share with MC

TO: Ursula Sanville (SANVILLE_U) (OPD)

READ:23-JUL-1996 19:37:20.49

TEXT:

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:23-JUL-1996 15:32:00.00

ATT BODYPART TYPE:B

ATT CREATOR: Diana M. Fortuna

ATT SUBJECT: grandmothers

ATT TO: Jeffrey Levi (LEVI_J)

TEXT:

Saw your weekly report item on grandmothers. There are some interesting demos HHS is now evaluating whether to give waivers for that involve subsidized guardianship that may apply in such settings. Lyn Hogan is taking over child welfare, so you might want to check in with her if you haven't already.

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:23-JUL-1996 22:02:25.29

SUBJECT: RE: fyi

TO: Jeremy D. Benami (BENAMI_J) (WHO)

READ:24-JUL-1996 11:17:51.52

TEXT:

Thanks for passing this on. I have found a chart that reveals interesting info about these states: they are using very small percentages of their Title II funds for ADAP -- and they are not asking any of their Title I cities to contribute either. In other words, there are additional federal resources available to them, if they chose to use them for this (rather than some other activities) -- as other states have done. This is a TA problem that HRSA could resolve by working with these states to look at alternative distributions of existing federal dollars.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:23-JUL-1996 17:59:59.26

SUBJECT: actis

TO: Ursula Sanville (SANVILLE_U) (OPD)

READ:24-JUL-1996 19:26:39.23

TEXT:

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:23-JUL-1996 15:52:00.00

ATT BODYPART TYPE:E

ATT CREATOR: aidsnews

ATT SUBJECT: New Information from ACTIS 07/23/96

ATT TO: levi_j (levi_j@Al@CD)

TEXT:

July 23, 1996

NEW INFORMATION FROM ACTIS

The AIDS Clinical Trials Information Service (ACTIS) is a central resource providing current information on federally and privately sponsored clinical trials for AIDS patients and others infected with HIV. This service is a Public Health Service project produced collaboratively by the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institute of Allergy and Infectious Diseases, and the National Library of Medicine. NAC ONLINE, the computerized information service of the CDC National AIDS Clearinghouse, will alert you to any new information collected by ACTIS.

Descriptions of two recent clinical trials and a new drug record added to the ACTIS database are provided below.

For more information, call the ACTIS toll-free number to talk with a health specialist. On request, you can also obtain a printout of a customized search of the clinical trials databases. The information can also be accessed directly by subscribers through two online databases, AIDSTRIALS and AIDSDRUGS, available through the National Library of Medicine.

AIDS CLINICAL TRIALS INFORMATION SERVICE
1-800-TRIALS-A
(1-800-874-2572)

FAX: 1-301-738-6616
TTY/TDD: 1-800-243-7012
International Line: 1-301-217-0023

PROTOCOL NUMBER: NIAID ACTG 291.

TITLE: A Phase II, Double-Blind Trial of Recombinant Human Nerve
Growth Factor for Treatment of HIV-Associated Sensory
Neuropathy.

PHASE: Phase II.

DISEASE STATUS:

Patients have the following symptoms and conditions: 1. HIV infection with associated sensory neuropathy. 2. No acute, active opportunistic infection within 2 weeks prior to study entry OTHER THAN oral thrush; oral, genital, or rectal herpes; or MAI bacteremia. 3. Either antiretroviral naive or on a stable dose for at least the past 8 weeks.

PATIENT INCLUSION CRITERIA

SPECIFICATION CRITERIA:

Patients must have:

1. HIV infection.
2. HIV-associated sensory neuropathy.
3. No acute, active opportunistic infection within 2 weeks prior to study entry OTHER THAN oral thrush; oral, genital, or rectal herpes; or MAI bacteremia.
4. Either antiretroviral naive or on a stable dose for the past 8 weeks.
5. Ability to assess pain level throughout the study.

AGE: 18 Years - 70 Years.

SEX: M. F.

REPRODUCTIVE SPECIFICATION:

Not pregnant. Negative pregnancy test within 14 days of study entry.
Not breast-feeding. Abstinence or agree to use barrier methods of birth control / contraception during the study.

PRIOR MEDICATION:

Allowed: Prior antiretrovirals.

LABORATORY VALUES AT ENTRY

HEMOGLOBIN: ≥ 8.0 g/dl. (men); ≥ 7.5 g/dl (women).
PLATELET COUNT: ≥ 75000 platelets/mm³.
CD4 (T4 CELL) COUNT: Unspecified cells/mm³.

BILIRUBIN: <= 2.5 mg/dl.
SGOT (AST): <= 5 x ULN. (ULN = upper limit of normal).
SGPT (ALT): <= 5 x ULN.
CREATININE: < 2.5 mg/dl.
KARNOFSKY: >= 60.
OTHER LABORATORY VALUES: Serum vitamin B12 >= 150 pg/ml. Alkaline phosphatase <= 5 x ULN. Absolute neutrophils >= 750 cells/mm³.

PATIENT EXCLUSION CRITERIA

AGE: 01 Days - 17 Years. 71 Years - 99 Years.

REPRODUCTIVE SPECIFICATION:

Pregnant. Positive pregnancy test within 14 days of study entry.

Breast-feeding. No abstinence or no agreement to use barrier methods of birth control / contraception during the study.

RISK BEHAVIOR:

Active drug or alcohol abuse that would affect study compliance.

PRIOR MEDICATION:

Excluded:

1. Neurotoxic systemic chemotherapy within the past 90 days.
2. Systemic corticosteroids or immunomodulators within the past 30 days.
3. Initiation of non-opioid prescription medication for pain within the past 2 weeks (including tricyclic antidepressants, mexiletine, phenytoin, and carbamazepine).
4. Treatment for acute opportunistic infections within the past 14 days (maintenance therapy for CMV retinitis, MAI bacteremia, or cryptococcal meningitis is permitted).

CONCURRENT MEDICATION:

Excluded:

1. Chemotherapeutic agents.
2. Systemic corticosteroids or immunomodulators.
3. Initiation of new antiretroviral to a stable regimen.

CO-EXISTING CONDITIONS OR DISEASES:

Patients with the following symptoms or conditions are excluded:

1. Evidence of another contributing cause for peripheral neuropathy, such as diabetes mellitus, hereditary neuropathy, current vitamin B12 deficiency, or treatment with any drug that might contribute to sensory neuropathy.
2. Major active psychiatric disorder (depression is allowed provided patient has received a stable antidepressant regimen for the past month).
3. Current active malignancy.
4. Any conditions, including dementia and myelopathy, that would interfere with patient evaluation.

GENERIC DRUG NAME

Drug 1: Recombinant human nerve growth factor. Growth factor.

DRUG COMPANIES

Drug 1: Genentech Incorporated
460 Point San Bruno Boulevard
South San Francisco, CA 94080
Contact: Professional Services (800) 821-8590.

END POINT

Efficacy, toxicity.

DISCONTINUE TREATMENT

Patients discontinue treatment for the following reasons:

1. Unacceptable toxicity.
2. Treatment with disallowed medications.
3. Pregnancy.
4. Development of any new malignancy including KS.
5. Any confounding illness that precludes participation.
6. Patient noncompliance or desire to withdraw from study.

PARTICIPATING UNITS

0000001388:
Stanford University Medical Center
300 Pasteur Drive / S156
Stanford, CA 94305-5107
Contact: Virginia Tallman (415) 723-2804
Contact: (415) 723-6231
OPEN 960711 ACTU: 0501.

0000001365:
Northwestern University Medical School
303 East Superior Street / Passavant Pavilion / Room 823
Chicago, IL 60611
Contact: Baiba L Berzins (312) 908-4655
Contact: (312) 908-9636
OPEN 960711 ACTU: 2701.

0000001316:

Mount Sinai Medical Center
One Gustave Levy Place / PO Box 1042
New York, NY 10029
Contact: Dr Eileen Chusid (212) 241-0433
OPEN 960711 ACTU: 1801.

0000001307:
Ohio State University Hospital Clinic
456 West 10th Avenue / Room 4725
Columbus, OH 43210-1228
Contact: Judy Neidig (614) 293-8112
Contact: (614) 293-5282
OPEN 960711 ACTU: 2301.

0000001466:
Univ TX Galveston Medical Branch
Route H-82 / Clay Hall
Galveston, TX 77555-0882
Contact: Karen Waterman (409) 772-0361
OPEN 960711 ACTU: 6301.

PROTOCOL NUMBER: NIAID ACTG 310.

TITLE: A Phase IA Single Dose Pharmacokinetics and Safety Study of the
Oral Antiviral Compound,
9-[2-(Bisphivaloyloxymethyl)phosphonylmethoxyethyl]adenine (
bis-POM PME A) (Adefovir Dipivoxil) in Children With HIV-1
Infection.

PHASE: Phase I A.

DISEASE STATUS:

Patients have the following symptoms and conditions:
Asymptomatic or mildly symptomatic HIV infection (CDC Class
categories N and A, respectively), with no worse than grade 1
toxicity for any symptoms.

PATIENT INCLUSION CRITERIA

SPECIFICATION CRITERIA:

Patients must have:

1. Asymptomatic or mildly symptomatic HIV infection, with no worse than grade 1 toxicity for any symptoms.
2. Consent of parent or guardian.

AGE: 01 Days - 17 Years.

SEX: M. F.

REPRODUCTIVE SPECIFICATION:

Not pregnant. Negative pregnancy test. Abstinence or agree to use
barrier methods of birth control / contraception during the study.

WEIGHT:

> 2500 g

PRIOR MEDICATION:

Allowed:

1. IV gammaglobulin and aerosolized pentamidine for PCP prophylaxis.
2. Antiretrovirals if discontinued by 72 hr prior to study entry.

LABORATORY VALUES AT ENTRY

CD4 (T4 CELL) COUNT: Unspecified cells/mm³.

PATIENT EXCLUSION CRITERIA

REPRODUCTIVE SPECIFICATION:

Pregnant. Positive pregnancy test. No abstinence or no agreement to use barrier methods of birth control / contraception during the study.

WEIGHT:

<= 2500 g

PRIOR MEDICATION:

Excluded within 72 hr prior to study entry:

1. Antiretrovirals other than study drug.
2. Other investigational agents.
3. Immunomodulators.
4. HIV-1 vaccines.
5. Glucocorticoids.
6. Drugs with potential for adverse interaction with study drug or that would interfere with quantitation of study drug in serum or plasma.
7. TMP / SMX and dapsone.

CONCURRENT MEDICATION:

Excluded:

1. Antiretrovirals other than study drug.
2. Other investigational agents.
3. Immunomodulators.
4. HIV-1 vaccines.
5. Glucocorticoids.
6. Drugs with potential for adverse interaction with study drug or that would interfere with quantitation of study drug in serum or plasma.
7. TMP / SMX and dapsone.

CO-EXISTING CONDITIONS OR DISEASES:

Patients with the following symptoms or conditions are excluded:
Acute or chronic infections that require treatment during study.

AVAILABILITY:

Unable to be followed at an ACTG center for study duration.

GENERIC DRUG NAME

Drug 1: Adefovir dipivoxil. Antiretroviral.

DRUG TRADE NAME

Drug 1: bis-POM PMEA.

DRUG COMPANIES

Drug 1: Gilead Sciences Incorporated
353 Lakeside Drive
Foster City, CA 94404
Contact: Dr Jay Toole (415) 573-4751.

END POINT

Toxicity, pharmacokinetic profile.

PARTICIPATING UNITS

0000003235:
University of Florida Health Science Center / Pediatrics
653-1 West 8th Street
Jacksonville, FL 32209
Contact: Michelle Eagle (904) 549-3051
OPEN 960522 ACTU: 5051.

0000001363:
Chicago Children's Memorial Hospital
2300 Children's Plaza / PO Box 20
Chicago, IL 60614-3394
Contact: Debbie Fonken (312) 880-3669
OPEN 960507 ACTU: 4001.

0000001358:
Johns Hopkins University Hospital
600 North Wolfe Street / Blalock 1140
Baltimore, MD 21287
Contact: Laura J Flautt (410) 955-9749

OPEN 960613 ACTU: 3701.

0000001270:

Saint Jude Children's Research Hospital of Memphis

332 North Lauderdale

Memphis, TN 38105-2794

Contact: Micki Roy (901) 495-3485

OPEN 960408 ACTU: 6501.

DRUG RECORD

Accession Number:

DRG-0249.

Generic Name:

Recombinant human nerve growth factor (NIAID ACTG 291).

Protocol Number(s):

Open NIAID ACTG 291

Alias/Trade Name:

rhNGF (NIAID ACTG 291).

Drug Company(ies):

Genentech Incorporated

460 Point San Bruno Boulevard

South San Francisco, CA 94080

Contact: Professional Services (800) 821-8590.

Therapeutic Classification:

Growth factor (NIAID ACTG 291).

Drug Description:

Homodimer consisting of predominately a 118-amino acid residue monomer.

(NIAID ACTG 291)

Physical Description:

Clear, colorless liquid. (NIAID ACTG 291)

Adverse Effects/Toxicity:

Adverse effects with intravenous administration have included mild to moderate pain with swallowing, pain in the masseter muscles, pain in the throat, and painful muscles in other areas. Adverse effects with subcutaneous administration have included moderate diffuse muscle pain and injection site hyperalgesia, described as increased sensitivity to touch or heat around the injection site.

(NIAID ACTG 291)

Contraindications:

Contraindicated in pregnant and nursing women.

(NIAID ACTG 291)

Dosage Form:

2 mg/ml in 0.5 ml vials.

(NIAID ACTG 291)

Mode of Delivery:

Subcutaneous, intravenous. (NIAID ACTG 291)

Storage Instructions:

Store at 2-8 C (35-46 F). Do not freeze.

(NIAID ACTG 291)

AIDS-Related Uses:

HIV-related peripheral neuropathy. (NIAID ACTG 291)

Other Uses:

Diabetic peripheral neuropathy.
(NIAID ACTG 291)

Bibliographic References:

94330699. Petty BG, Cornblath DR, Adornato BT, Chaudhry V,
Flexner C, Wachsman M, Sinicropi D, Burton LE, Peroutka SJ. The
effect of systemically administered recombinant human nerve growth
factor in healthy human subjects. Ann Neurol 1994 Aug;36(2):244-6.

===== END ATTACHMENT 1 =====

===== ATTACHMENT 2 =====

ATT CREATION TIME/DATE:23-JUL-1996 15:53:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDf V5.0-4 #6879) id <0117F1TXN5N4001E28@PMDf.EOP.GOV> for
levi_j@a1.eop.gov; Tue, 23 Jul 1996 15:52:34 -0400 (EDT)
Received: from aspen3.aspensys.com (aspensys3.aspensys.com)
by STORM.EOP.GOV (PMDf V5.0-7 #6879) id <0117F1TKX0L000007K@STORM.EOP.GOV> for
levi_j@a1.eop.gov; Tue, 23 Jul 1996 15:52:20 -0700 (MST)
Received: by aspen3.aspensys.com (SMI-8.6/SMI-SVR4) id PAA05263; Tue,
23 Jul 1996 15:52:31 -0400
Errors-to: shelly_olim_at_aspenpo@smtpinet.aspensys.com
Precedence: bulk
Originator: aidsnews@cdcnac.aspensys.com
X-Comment: CDC National AIDS Clearinghouse
X-Listprocessor-version: 6.0c -- ListProcessor by Anastasios Kotsikonas
===== END ATTACHMENT 2 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Diana M. Fortuna (FORTUNA_D) (OPD)

CREATION DATE/TIME:23-JUL-1996 15:37:34.33

SUBJECT: grandmothers

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:23-JUL-1996 17:57:24.15

TEXT:

Saw your weekly report item on grandmothers. There are some interesting demos HHS is now evaluating whether to give waivers for that involve subsidized guardianship that may apply in such settings. Lyn Hogan is taking over child welfare, so you might want to check in with her if you haven't already.

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. email	From: Donald Abrams, To: Jeffrey Levi, Re: (Fwd) Our Friend Al (2 pages)	07/23/1996	Personal Misfile

COLLECTION:

Clinton Presidential Records
Automated Records Management System [Email]
WHO ([Jeffrey Levi...])
OA/Box Number: 500000

FOLDER TITLE:

[07/23/1996 - 07/26/1996]

2018-0759-F
jn424

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeremy D. Benami (BENAMI_J) (WHO)

CREATION DATE/TIME:23-JUL-1996 18:49:08.79

SUBJECT: fyi

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:23-JUL-1996 21:59:39.43

TEXT:

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:23-JUL-1996 18:38:00.00

ATT BODYPART TYPE:B

ATT CREATOR: Jeremy D. Benami

ATT SUBJECT: ADAP supplemental

ATT TO: George Stephanopoulos (STEPHANOPO_G)

ATT TO: Nancy-Ann E. Min (MIN_N)

ATT TO: Martha Foley (FOLEY_M)

ATT CC: Jacob J. Lew (LEW_J)

ATT CC: Carol H. Rasco (RASCO_C)

TEXT:

From my conversations with Kevin, Jack etc. today, I understand there has been "agreement to disagree" between HHS and OMB on the ADAP issue- specifically over offsets.

Kevin tells me that "on Jack's plate" is the suggestion that we simply announce that we will send up the amendment, but leave the issue of how to pay for it to be dealt with later.

If that is the case, do we want to get this out there somehow?

George -- any guidance?

On a related matter - the rumor that four states are shutting down their ADAP programs is apparently untrue. There are four states that are not enrolling any new clients. HHS is trying to find out more about the finances of those particular programs, i.e., have they put in any state money.

===== END ATTACHMENT 1 =====

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. email	From: Jeffrey Levi, To: Donald Abrams, Re: (Fwd) Our Friend Al (1 page)	07/23/1996	Personal Misfile

COLLECTION:

Clinton Presidential Records
Automated Records Management System [Email]
WHO ([Jeffrey Levi...])
OA/Box Number: 500000

FOLDER TITLE:

[07/23/1996 - 07/26/1996]

2018-0759-F
jn424

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

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- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Ursula Sanville (SANVILLE_U) (OPD)

CREATION DATE/TIME:24-JUL-1996 12:15:52.49

SUBJECT: VP meeting preparation

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:24-JUL-1996 14:29:34.33

TO: Patsy Fleming (FLEMING_P) (WHO)

READ:24-JUL-1996 16:03:16.99

TEXT:

I got a call from Toby in the VP's office. She asked me to tell everyone that a staff level meeting to prepare for the Friday meeting with the VP has been scheduled for Tuesday, July 30th at 1:00 in the Ceremonial Office.

The invitees are: Greg Simon, Toby Donenfeld, Bill Paul, Bruce Vladek, Ken Kaiser, Tony Fauci, Harold Varmus, David Kessler, PF, JL, and JS.

I would imagine we would want to meet with Greg and Toby before this meeting -- is this something I should set up with Toby, or ... ??? Let me know.

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: KSF@s-3.com@INET@EOPMRX

CREATION DATE/TIME:24-JUL-1996 14:00:00.00

SUBJECT: Sept. Pres. Council meeting -- Update

TO: 'SMTP:LEVI_J@a1.eop.gov' (LEVI_J@A1@CD) (WHO)
READ:24-JUL-1996 14:34:14.19

TEXT:

I just spoke with Scott and told him about the switch from the Washington Marriott to the Bethesda Marriott and he seemed OK with this change. I also told him that we had prepared the logistical fact sheets and were just waiting for final approvals/clarification on a few things before sending them out to the council. (I faxed these to you on Monday, but I just found out that you are on vacation....lucky you!!)

But, he did ask me if I would check the hotel space to see if they could hold the full council meeting on Sunday. The hotel sales person is checking and will get back to me later today...I'll let you know.

Thanks.

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:24-JUL-1996 14:01:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <0117GC8NTDV4003A5E@PMDF.EOP.GOV> for
LEVI_J@a1.eop.gov; Wed, 24 Jul 1996 14:00:47 -0400 (EDT)

Received: from SSSHQ5 (206.65.240.10) by STORM.EOP.GOV (PMDF V5.0-7 #6879)
id <0117GC8BZXIM00007K@STORM.EOP.GOV> for LEVI_J@a1.eop.gov; Wed,
24 Jul 1996 14:00:31 -0700 (MST)

X-Mailer: Worldtalk (NetConnex V4.00a)/MIME

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Patsy Fleming (FLEMING_P) (WHO)

CREATION DATE/TIME:24-JUL-1996 15:58:32.72

SUBJECT: RE: lest I forget

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:24-JUL-1996 17:19:34.95

TEXT:
Excellent!

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: aidsnews@cdcnac.aspensys.com@INET@EOPMRX

CREATION DATE/TIME: 24-JUL-1996 11:52:00.00

SUBJECT: New Conference Information 07/24/96

TO: levi_j (levi_j@A1@CD) (WHO)

READ: 24-JUL-1996 14:29:17.68

TEXT:

CDC National AIDS Clearinghouse
Conference Calendar Database

NEW CONFERENCE LISTINGS
July 24, 1996

The Clearinghouse's Conference Calendar Database contains information about upcoming conferences related to HIV and AIDS.

NAC ONLINE users can search this database by selecting "Clearinghouse Databases" from the NAC ONLINE main menu. When asked to enter a database name, specify "CONF" to search the Calendar.

To access the NAC ONLINE BBS, set your communications software to dial (800) 851-7245, and set the options for 8 data bits, N parity, 1 stop bit, full duplex, and complete a new user questionnaire. Only non-profit organizations, government agencies, educational institutions, and health departments are given full access to NAC ONLINE and the NAC databases.

Overnight, 6 new listings were loaded to the Conference Calendar Database. Their records follow:

TITLE: Genetic Vaccines and Immunotherapeutic Strategies
DATE: October 23-24, 1996
LOCATION: Washington, DC
SPONSOR(S): International Business Communications (IBC)
CONTACT: International Business Communications (IBC) USA Conferences,
Inc., 225 Turnpike Rd., Southborough, MA 01772-1749, (508)
481-6400, FAX: (508) 481-7911
EVENT TYPE: Conference
TOPICS: Research programs. Vaccines. Clinical trials. Tuberculosis
(TB). Hepatitis.
NOTES: Fee: \$895; Government, university employees, and
university-affiliated hospital employees, \$495.

TITLE: Musocal Immunization: Genetic Approaches and Adjuvants
DATE: October 21-22, 1996

LOCATION: Washington, DC
SPONSOR(S): International Business Communications (IBC)
CONTACT: International Business Communications (IBC) USA Conferences,
Inc., 225 Turnpike Rd., Southborough, MA 01772-1749, (508)
481-6400, FAX: (508) 481-7911
EVENT TYPE: Conference
TOPICS: Research programs. Vaccines. Clinical trials. Simian
immunodeficiency virus (SIV).
NOTES: Fee: \$895; Government, university employees, and
university-affiliated hospital employees, \$495.

TITLE: Rare Diseases and Orphan Drugs
DATE: September 20, 1996
LOCATION: Paris, FR - France
SPONSOR(S): French Muscular Dystrophy Association; Cystic Fibrosis
Association; Ligue Contre Le Cancer and AIDS
CONTACT: Dr. Marc Bouillet, Association Francaise Contre Les Myopathies
(AFM), 33-1-42-76-58-58, FAX: 33-1-42-76-58-87
EVENT TYPE: Conference
TOPICS: Legislation or regulation. Pharmaceutical research.

TITLE: Conference on Emerging Diseases
DATE: July 27-28, 1996
LOCATION: Kyoto, JP - Japan
SPONSOR(S): National Institutes of Health (NIH); Centers for Disease Control
and Prevention (CDC); United States Department of State;
American Society of Microbiology
CONTACT: Secretariat, Conference on Emerging Diseases, c/o Research
Institute, International Medical Center of Japan, 1-21-1 Toyama,
Shinjuku-ku, Tokyo 162, Japan, 03-5273-6844, FAX: 03-3202-7364
EVENT TYPE: Conference
TOPICS: Developing nations. Federal government. Research programs.
Research needs.

TITLE: National Leadership Forum VII
DATE: November 13-16, 1996
LOCATION: Washington, DC
SPONSOR(S): Community Anti-Drug Coalitions of America
CONTACT: Community Anti-Drug Coalitions of America, 901 N. Pitt St., Ste.
300, Alexandria, VA 22314, (703) 706-0560, (800) 542-2322, FAX:
(703) 706-0565
EVENT TYPE: Conference
TOPICS: Substance abuse. Community organizations. Alcohol abuse.
NOTES: Exhibitor spaces available.

TITLE: AIDS Medicine: An Intensive Course
DATE: September 30-October 1, 1996
LOCATION: Cambridge, MA
SPONSOR(S): Department of Medicine, Massachusetts General Hospital;
Department of Medicine, Brigham and Women's Hospital

CONTACT: Harvard MED-CME, P.O. Box 825, Boston, MA 02117-0825

EVENT TYPE: Workshop

TOPICS: Treatment. Physician education. Therapeutic drugs. Women.
Vaccines. Opportunistic infections. Pneumocystis carinii
pneumonia (PCP). Cytomegalovirus (CMV). Fungal infections.
Wasting syndrome. Neurological diseases or disorders.
Parasitic infections. Immunizations.

NOTES: Fee: \$395; Residents and Fellows in training, \$150. Credit cards
not accepted.

Information about additional conferences is welcome. Please send
E-Mail to Flynn McLean (through NAC ONLINE, or
fmclean@cdcnac.aspensys.com via the Internet) at the CDC National
AIDS Clearinghouse; include the title, dates, site, sponsoring
agency, contact information, registration fee, and topics to be
discussed at the conference.

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:24-JUL-1996 11:52:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)

by PMDF.EOP.GOV (PMDf V5.0-4 #6879) id <0117G7Q49WJK003FPU@PMDf.EOP.GOV> for
levi_j@a1.eop.gov; Wed, 24 Jul 1996 11:52:04 -0400 (EDT)

Received: from aspen3.aspensys.com (aspensys3.aspensys.com)

by STORM.EOP.GOV (PMDf V5.0-7 #6879) id <0117G7PRUHAC00007K@STORM.EOP.GOV> for
levi_j@a1.eop.gov; Wed, 24 Jul 1996 11:51:48 -0700 (MST)

Received: by aspen3.aspensys.com (SMI-8.6/SMI-SVR4) id LAA19655; Wed,
24 Jul 1996 11:51:54 -0400

Errors-to: shelly_olim_at_aspenpo@smtpinet.aspensys.com

Precedence: bulk

Originator: aidsnews@cdcnac.aspensys.com

X-Comment: CDC National AIDS Clearinghouse

X-Listprocessor-version: 6.0c -- ListProcessor by Anastasios Kotsikonas

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Ursula Sanville (SANVILLE_U) (OPD)

CREATION DATE/TIME:24-JUL-1996 18:10:49.47

SUBJECT: NIH goals

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:25-JUL-1996 10:31:33.78

TEXT:

Jeff -- Wendy responded re the NIH goals (attached) -- would you take a look at them? Thanks.

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:24-JUL-1996 15:46:00.00

ATT BODYPART TYPE:E

ATT CREATOR: Wertheimer, Wendy

ATT SUBJECT: FW: NIH Goals for National Strategy

ATT TO: Ursula Sanville (SANVILLE_U@A1@CD)

ATT CC: Whitescarver, Jack (WHITESCJ@od31em1.od.nih.gov@INET@EOPMRX)

ATT CC: Jeffrey Levi (LEVI_J@A1@CD)

ATT CC: wepaul (wepaul@nih.gov@INET@EOPMRX)

TEXT:

Jane -- We have redrafted the goals.

Goal: To conduct and support natural history and epidemiological research to improve the understanding of the risk factors and mechanisms of HIV transmission and disease progression and to develop prevention strategies to reduce or prevent HIV transmission.

Goal: To conduct and support research to improve the understanding of HIV and the pathogenic mechanisms of HIV disease.

Goal: To conduct and support preclinical and clinical research to develop, test, and optimize treatments for HIV infection, HIV-associated conditions, and for the prevention of HIV transmission.

Goal: To conduct and support basic, preclinical, and clinical research to develop a safe and effective preventive HIV vaccine.

Goal: To conduct and support behavioral and social science research to further understanding of the determinants and processes that influence behaviors associated with HIV transmission and to develop and improve HIV prevention interventions strategies.

Goal: To provide appropriate training and infrastructure for the conduct of HIV-related biomedical and behavioral research domestically and internationally.

Goal: To support effective dissemination, communication and utilization of HIV-related research information to researchers, health care providers, HIV-related service providers, HIV-infected individuals and their advocates, and all constituencies of the NIH.

===== END ATTACHMENT 1 =====

===== ATTACHMENT 2 =====

ATT CREATION TIME/DATE:24-JUL-1996 16:00:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)

by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01I7GGE8GIYO003N84@PMDF.EOP.GOV>; Wed, 24 Jul 1996 15:59:48 -0400 (EDT)

Received: from web.nih.gov by STORM.EOP.GOV (PMDF V5.0-7 #6879)

id <01I7GGDUVUDO00007K@STORM.EOP.GOV>; Wed, 24 Jul 1996 15:59:31 -0700 (MST)

Received: from SMTP2.mm.hub.nih.gov by web.nih.gov (8.6.10/1.35(nsb-1.0))

id PAA24113; Wed, 24 Jul 1996 15:59:48 -0400

Received: by SMTP2.mm.hub.nih.gov with Microsoft Mail id

<31F680B0@SMTP2.mm.hub.nih.gov>; Wed, 24 Jul 1996 15:59:44 -0400 (edt)

===== END ATTACHMENT 2 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:24-JUL-1996 14:36:11.25

SUBJECT: Query....

TO: Remote Addressee (Margaret_Chesney@quickmail.ucsf.edu@INET@EOPMRX)

READ:NOT READ

TEXT:

given how things have been going lately, I probably don't want to know the answer to this...but did Helene and Joe speak with you or Tom about our counseling and testing project while they were in Vancouver?

Thanks....hope you're well. (This is written from an alleged vacation.)

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Patsy Fleming (FLEMING_P) (WHO)

CREATION DATE/TIME:24-JUL-1996 18:12:57.02

SUBJECT: RE: the attached

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:25-JUL-1996 10:32:42.88

TEXT:

Yes, of course I am.

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: aidsnews@cdcnac.aspensys.com@INET@EOPMRX

CREATION DATE/TIME:24-JUL-1996 10:48:00.00

SUBJECT: CDC AIDS Daily Summary 07/24/96

TO: levi_j (levi_j@A1@CD) (WHO)

READ:24-JUL-1996 14:28:13.29

TEXT:

AIDS Daily Summary
July 24, 1996

The Centers for Disease Control and Prevention (CDC) National AIDS Clearinghouse makes available the following information as a public service only. Providing this information does not constitute endorsement by the CDC, the CDC National AIDS Clearinghouse, or any other organization. Reproduction of this text is encouraged; however, copies may not be sold, and the CDC National AIDS Clearinghouse should be cited as the source of this information. Copyright 1996, Information, Inc., Bethesda, MD

"Clinton Seeks \$65 Million for State AIDS Programs"

"Emory Gets Patent for AIDS Drug 3TC, but Glaxo, BioChem Question Validity"

"AIDS Drug Trial Result Boosts Glaxo"

"Hospice Care Often Starts Too Late"

"AIDS Cases Increase Rapidly in India"

"Econews: AIDS-Development: AIDS Pandemic Retards [Human Development]"

"Prevalence of HIV Infection in the United States, 1984 to 1992"

"Drug Resistance: The Next AIDS Crisis"

"Clinton Seeks \$65 Million for State AIDS Programs"

New York Times (07/24/96) P. A16; Dunlap, David W.

Under a budget request announced Tuesday, President Clinton is seeking a \$65 million increase in spending on the AIDS Drug Assistance Programs. The programs allow states to provide AIDS drugs for people who cannot afford them and who are not covered by either Medicaid or private insurance. The programs, which receive about two-thirds of their money from the federal government, provided aid to 69,000 people last year. Under the budget request, which must be approved by Congress, federal spending on the programs would increase to \$195 million in the next fiscal year, from \$115 for the current fiscal year. The proposed increase comes partly in reaction to reports released at the XIth International Conference on AIDS which suggested that a combination of three costly drugs could improve a patient's

health and survival.

"Emory Gets Patent for AIDS Drug 3TC, but Glaxo, BioChem Question Validity"

Wall Street Journal (07/24/96) P. B6; Chipello, Christopher J.

Glaxo Wellcome and BioChem Pharma say they will challenge a U.S. patent for 3TC, or Epivir, an AIDS drug made by the two companies, that has been granted to Emory University. Emory said it plans to seek licensing arrangements with Glaxo and BioChem, who said earlier this year that they had all necessary patents on the drug and claim that the new patent is invalid. According to Emory, 3TC is one of two elements in BCH-189, which was discovered by BioChem Pharma, but while the latter company's patent details how to obtain BCH-189, Emory's patent specifically covers 3TC. BioChem receives a royalty of about 14 percent of Glaxo's sales of 3TC, and under their deal, a third party would receive royalties out of BioChem's share. Analysts say first-year sales of 3TC, which was approved for sale in the United States in November, could reach \$250 million.

"AIDS Drug Trial Result Boosts Glaxo"

Financial Times (07/24/96) P. 18; Green, Daniel

Due to the high success rate, a clinical trial of Glaxo Wellcome's AIDS drug Epivir has been halted so that all trial participants can be given the drug. Interim results of the trial, which was scheduled to end in March 1997, found that 54 percent fewer patients who received the drug progressed to AIDS or died compared to those who received a placebo. The trial, started in March 1995, involved 1,892 HIV-positive patients in Canada, Australia, Europe, and South Africa.

"Hospice Care Often Starts Too Late"

New York Times (07/24/96) P. C8

People dying of terminal illnesses who enter hospices die a more comfortable and less expensive death, but patients often enroll too late to receive much benefit, a new study suggests. Nicholas Christakis of the University of Chicago Medical Center, and colleagues studied the cases of 6,451 hospice patients. They report in the current issue of the New England Journal of Medicine that only 14.9 percent of the patients lived longer than 180 days after entering hospices. The results suggest that doctors and patients are reluctant to seek hospice care.

"AIDS Cases Increase Rapidly in India"

Xinhua News Agency (07/23/96)

The number of AIDS cases in India is increasing rapidly, the Indian government said Tuesday. The Minister of State for Health and Family Welfare said that as many as 1,458 AIDS patients are being treated in hospitals. So far 60 cases of AIDS in children have been reported to the National AIDS Control Organization. The minister added that the government was implementing a comprehensive awareness and prevention program for high risk groups and the general public.

"Econews: AIDS-Development: AIDS Pandemic Retards [Human Development]"

PANA Wire Service (07/23/96)

HIV and AIDS took an average toll of 1.3 years of human development progress in 56 countries between 1980 and 1992, the United Nations Development Program reported. The impact was especially severe in developing countries, where 90 percent of the world's estimated daily 6,000 HIV infections occur. Researchers at Columbia University and the Harvard Institute for International Development found that the AIDS epidemic adversely affected the human development index, a measure of basic human capabilities ranked by country. The study compared the 1980 and 1992 index for the 56 countries, and found that, without the impact of HIV, the countries would have had an additional average of 1.3 years of human development.

"Prevalence of HIV Infection in the United States, 1984 to 1992"
Journal of the American Medical Association (07/10/96) Vol. 276, No. 2, P. 126; Karon, John M.; Rosenberg, Philip S.; McQuillan, Geraldine; et al.

Researchers at the Centers for Disease Control and Prevention have developed new estimates of HIV prevalence in the United States, including estimates by gender, race, geographic region, and behavioral risk. The report, by John M. Karon and colleagues, is the first to combine numerical estimates of HIV prevalence from multiple sources. The authors estimated past HIV infection rates based on national AIDS case surveillance data and estimates of the time from HIV infection to AIDS diagnosis. They also incorporated HIV prevalence data from two national surveys, a survey of childbearing women, and a household survey of current health status. They report that an estimated 0.3 percent of U.S. residents were infected with HIV in 1992. Approximately 0.6 percent of the male population was infected, including about 2 percent of non-Hispanic black men and 1 percent of Hispanic men. About 0.1 percent of women were infected, including an estimated 0.6 percent of non-Hispanic black women. About half of all those individuals infected with HIV in 1992 were men who had sex with men, and one-fourth were injection drug users. The overall prevalence of HIV increased from 1984 to 1992, with a greater relative increase in women than in men.

"Drug Resistance: The Next AIDS Crisis"

Village Voice (07/09/96) Vol. 41, No. 28, P. 15; Schoofs, Mark

While new HIV therapies have the potential to suppress viral replication in patients, they also carry the threat of allowing drug-resistant viral strains to develop. If a strict regimen is not followed, an individual could develop resistance to their current medication as well as to other drugs. About 10 percent of people becoming infected with HIV now contract a strain resistant to AZT. As resistance spreads, people could become infected with strains that are resistant to several drugs. Treating the infection effectively depends on the ability of patients to follow a strict dosing schedule, says Julio Montaner, co-chair of the 11th International Conference on AIDS. New HIV

regimens are especially difficult to take and must be continued for longer periods of time, maybe for life. Other conditions also make the dosing difficult. For example, one protease inhibitor must be refrigerated, another must be taken on an empty stomach, and the side effects can include diarrhea and nausea. Moreover, researchers do not know how long patients may have to stay on the drugs, or if they will cause harm in the future. Making the drugs widely available, which could happen under expanded government funding efforts, would enhance the potential for misuse and resistance.

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:24-JUL-1996 10:50:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)

by PMDF.EOP.GOV (PMDf V5.0-4 #6879) id <01I7G51FFZ8G003MO3@PMDf.EOP.GOV> for levi_j@al.eop.gov; Wed, 24 Jul 1996 10:48:37 -0400 (EDT)

Received: from aspen3.aspensys.com (aspensys3.aspensys.com)

by STORM.EOP.GOV (PMDf V5.0-7 #6879) id <01I7G51IY8QS00007K@STORM.EOP.GOV> for levi_j@al.eop.gov; Wed, 24 Jul 1996 10:48:19 -0700 (MST)

Received: by aspen3.aspensys.com (SMI-8.6/SMI-SVR4) id KAA12562; Wed, 24 Jul 1996 10:48:36 -0400

Errors-to: shelly_olim_at_aspenpo@smtpinet.aspensys.com

Precedence: bulk

Originator: aidsnews@cdcnac.aspensys.com

X-Comment: CDC National AIDS Clearinghouse

X-Listprocessor-version: 6.0c -- ListProcessor by Anastasios Kotsikonas

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Carol H. Rasco (RASCO_C) (WHO)

CREATION DATE/TIME:24-JUL-1996 07:46:46.09

SUBJECT: Hurray! Hurray!

TO: Jeremy D. Benami (BENAMI_J) (WHO)
READ:24-JUL-1996 12:21:25.62

TO: Patsy Fleming (FLEMING_P) (WHO)
READ:24-JUL-1996 11:50:44.89

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:24-JUL-1996 14:26:32.16

CC: Elizabeth E. Drye (DRYE_E) (OPD)
READ:24-JUL-1996 09:08:25.39

TEXT:

Congrats and thanks to you all for pushing and working so diligently on the ADAP dollars...I am really pleased it has moved ahead. I remember very well the days in Arkansas I would be on the phone for hours with patients, parents, grandparents, partners, etc. who were begging for medications and / or the dollars for the known effective medications - sometimes both were existent, sometimes neither was existent - and I am really pleased we're trying to do more in this area.
Thanks again!

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:24-JUL-1996 14:33:31.85

SUBJECT: RE: VP meeting preparation

TO: Ursula Sanville (SANVILLE_U) (OPD)
READ:24-JUL-1996 15:44:41.61

CC: Patsy Fleming (FLEMING_P) (WHO)
READ:24-JUL-1996 15:51:40.41

TEXT:

Yes, we should probably have a little time before...PF is in LA however -- so the question is whether we could do this on Monday before she leaves. (Don't mean to talk about you in the third person, Patsy).

A word of warning -- I just had a roaring fight with Wendy about this and the strategy...but they are complaining that they are being asked to sign on to a document whose final draft they have not seen. Not true -- they are being asked if they will commit to participating in and financially supporting a process that has emerged from the report -- not the report itself. As to whether six days is enough time to grasp the concept and make a decision, you can imagine my reaction after this week of wrangling with the department over ADAP and the strategy.

If the principals invited to this meeting on the 30th don't feel they have been kept up to speed, this is not our problem -- it is an internal issue -- they had staff present at these meetings. We can't be delayed by poor staffing at their agencies.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Patsy Fleming (FLEMING_P) (WHO)

CREATION DATE/TIME:24-JUL-1996 17:14:34.70

SUBJECT: statement

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:24-JUL-1996 17:21:51.00

TEXT:

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:24-JUL-1996 11:13:00.00

ATT BODYPART TYPE:B

ATT CREATOR: Marlene A. MacDonald

ATT SUBJECT: Statement

ATT TO: Patsy Fleming (FLEMING_P)

TEXT:

===== END ATTACHMENT 1 =====

===== ATTACHMENT 2 =====

ATT CREATION TIME/DATE:24-JUL-1996 10:40:00.00

ATT CREATOR: Darby Stott

ATT SUBJECT: STATEMENT RE: AIDS DRUG ASSISTANCE PROGRAMS

ATT TO: Marlene A. MacDonald (MACDONALD_M)

ATT TO: Remote Addressee (1=US@2=TELEMAIL@3=INTERNET@*RFC-822\MWOLFE(A)MH1.JS.MIL@MRX@EOPMRX)

ATT TO: Remote Addressee (1=US@2=WESTERN UNION@3=@5=ATT.COM@*ELN\62955104@MRX@EOPMRX)

ATT TO: Remote Addressee (62955104@eln.attmail.com@INET)

ATT TO: Remote Addressee (73030.21@compuserve.com@INET)

ATT TO: Pauline M. Abernathy (ABERNATHY_P)

ATT TO: Lori E. Abrams (ABRAMS_L)

ATT TO: Brenda Anders (ANDERS_B)

ATT TO: Walker, Angelina	(Angelina Walker@EOP_OVP@CCGATE@EOPMRX)
ATT TO: Donald A. Baer	(BAER_D)
ATT TO: Karen L. Barbuschak	(BARBUSCHAK_K)
ATT TO: Rick E. Borchelt	(BORCHELT_R)
ATT TO: Gabrielle M. Bushman	(BUSHMAN_G)
ATT TO: Phillip M. Caplan	(CAPLAN_P)
ATT TO: Laura Capps	(CAPPS_L)
ATT TO: Lisa M. Caputo	(CAPUTO_L)
ATT TO: Ann M. Cattalini	(CATTALINI_A)
ATT TO: Joseph W. Cerrell	(CERREL_J)
ATT TO: C. Patricia Cogdell	(COGDELL_C)
ATT TO: Steven A. Cohen	(COHEN_SA)
ATT TO: Amanda Crumley	(CRUMLEY_A)
ATT TO: Carolyn Curiel	(CURIEL_C)
ATT TO: Chris Dorval	(DORVAL_C)
ATT TO: Anne M. Edwards	(EDWARDS_A)
ATT TO: Rahm Emanuel	(EMANUEL_R)
ATT TO: Deborah L. Fine	(FINE_D)
ATT TO: Karen E. Finney	(FINNEY_K)
ATT TO: Ben Freeland	(FREELAND_B)
ATT TO: Jeremy M. Gaines	(GAINES_J)
ATT TO: Michael A. Gill	(GILL_M)
ATT TO: Mary Ellen Glynn	(GLYNN_M)
ATT TO: Jason S. Goldberg	(GOLDBERG_JS)
ATT TO: Julia R. Green	(GREEN_J)
ATT TO: LAWRENCE J. HAAS	(HAAS_L)
ATT TO: James T. Heimbach	(HEIMBACH_J)

ATT TO: Alexis M. Herman	(HERMAN_A)
ATT TO: Russell W. Horwitz	(HORWITZ_R)
ATT TO: Helen P. Howell	(HOWELL_H)
ATT TO: Heidi Kukis	(Heidi Kukis@EOP_OVP@CCGATE@EOPMRX)
ATT TO: Manager Infomgt	(INFOMGT)
ATT TO: Annette E. Johnson	(JOHNSON_AE)
ATT TO: Brian J. Johnson	(JOHNSON_BJ)
ATT TO: Wayne C. Johnson	(JOHNSON_WC)
ATT TO: Jocelyn M. Jolley	(JOLLEY_J)
ATT TO: James Kohlenberger	(Jim Kohlenberger@EOP_OVP@CCGATE@EOPMRX)
ATT TO: Payne, Julia M.	(Julia M. Payne@EOP_OVP@CCGATE@EOPMRX)
ATT TO: David E. Kalbaugh	(KALBAUGH_D)
ATT TO: Timothy J. Keating	(KEATING_T)
ATT TO: Angus S. King	(KING_A)
ATT TO: Joshua A. King	(KING_J)
ATT TO: Nick B. Kirkhorn	(KIRKHORN_N)
ATT TO: G. N. Lattimore	(LATTIMORE_G)
ATT TO: Monica S. Lewinsky	(LEWINSKY_M)
ATT TO: Peggy A. Lewis	(LEWIS_P)
ATT TO: Evelyn S. Lieberman	(LIEBERMAN_E)
ATT TO: Cynthia J. Lizik	(LIZIK_C)
ATT TO: Gordon Li	(LI_G)
ATT TO: Julie E. Mason	(MASON_J)
ATT TO: Doris O. Matsui	(MATSUI_D)
ATT TO: Lorraine McHugh	(MCHUGH_L)
ATT TO: Kathy McKiernan	(MCKIERNAN_K)
ATT TO: APRIL K. MELLODY	(MELLODY_A)

ATT TO: Elisa M. Millsap	(MILLSAP_E)
ATT TO: Cheryl D. Mills	(MILLS_C)
ATT TO: Julia Moffett	(MOFFETT_J)
ATT TO: Elizabeth A. Montoya	(MONTOYA_E)
ATT TO: Melissa M. Murray	(MURRAY_MM)
ATT TO: Eleanor S. Parker	(PARKER_E)
ATT TO: Jonathan M. Prince	(PRINCE_J)
ATT TO: Victoria L. Radd	(RADD_V)
ATT TO: A. Victoria Rivas-Vazquez	(RIVASVAZQU_A)
ATT TO: Rica F. Rodman	(RODMAN_R)
ATT TO: Stacey L. Rubin	(RUBIN_S)
ATT TO: G. Timothy Saunders	(SAUNDERS_GT)
ATT TO: Laura D. Schwartz	(SCHWARTZ_L)
ATT TO: Jennifer Senan	(SENAN_J)
ATT TO: Douglas S. Sheorn	(SHEORN_D)
ATT TO: Susan P. Shepard	(SHEPARD_S)
ATT TO: Joshua Silverman	(SILVERMAN_J)
ATT TO: Douglas B. Sosnik	(SOSNIK_D)
ATT TO: Todd Stern	(STERN_T)
ATT TO: Michael J. Sullivan	(SULLIVAN_M)
ATT TO: Margaret M. Suntum	(SUNTUM_M)
ATT TO: Guild L. Taylor	(TAYLOR_G)
ATT TO: Virginia M. Terzano	(TERZANO_V)
ATT TO: FAX (94965034,Ann Lewis)	(TLXA1MAIL_\\F:94965034\\C:Ann Lewis\\)
ATT TO: Barry J. Toiv	(TOIV_B)
ATT TO: Jodie R. Torkelson	(TORKELSON_J)
ATT TO: Lorraine A. Voles	(VOLES_L)

ATT TO: Michael Waldman	(WALDMAN_M)
ATT TO: Christopher F. Walker	(WALKER_C)
ATT TO: Dorian V. Weaver	(WEAVER_D)
ATT TO: Michael J. Sullivan	(WEC_I)
ATT TO: Dena B. Weinstein	(WEINSTEIN_D)
ATT TO: Allison Wilkie	(WILKIE_A)
ATT TO: Natalie S. Wozniak	(WOZNIAK_N)
ATT TO: Remote Addressee	(backup@wilson.ai.mit.edu@INET)
ATT TO: Remote Addressee	(newsdesk@usnewswire.com@INET)
ATT TO: Remote Addressee	(ttate@esusda.gov@INET)
ATT TO: Remote Addressee	(usia01@access.digex.com@INET)
ATT TO: Remote Addressee	(usnwire@access.digex.com@INET)
ATT TO: Remote Addressee	(wh-outbox-distr@clinton.ai.mit.edu@INET)
ATT TO: Catherine T. Kitchen	(KITCHEN_C)
ATT TO: Wendy E. Gray	(GRAY_W)
ATT TO: Jay K. Footlik	(FOOTLIK_J)
ATT TO: Steven J. Naplan	(NAPLAN_S)
ATT TO: James T. Edmonds	(EDMONDS_J)
ATT TO: David Shipley	(SHIPLEY_D)
ATT TO: Patricia F. Lewis	(LEWIS_PF)
ATT TO: R. Lawton Jordan III	(JORDAN_RL)
ATT TO: Natalie L. Mayer	(MAYER_N)
ATT TO: Lori L. Anderson	(ANDERSON_L)
ATT TO: Mark H. Bartholomew	(BARTHOLOME_M)
ATT TO: Karin J. Abramson	(ABRAMSON_K)
ATT TO: Karin Kullman	(KULLMAN_K)
ATT TO: Mike W. Williams	(WILLIAMS_MW)

ATT TO: James S. Rubin (RUBIN_J)
ATT TO: Craig Gardenswartz (GARDENSWAR_C)
ATT TO: Annette E. Johnson (JOHNSON_AE)
ATT TO: Michael Warren (WARREN_M)
ATT TO: Melissa Marshall (MARSHALL_M)
ATT TO: Marilyn DiGiacobbe (DIGIACOBBE_M)
ATT TO: Elizabeth Berman (BERMAN_E)
ATT TO: Matthew H. Catapano (CATAPANO_M)
ATT TO: Jennifer Senan (SENAN_J)
ATT TO: Roger V. Salazar (SALAZAR_R)
ATT TO: Suzanne E. Dale (DALE_S)
ATT TO: Lisa Jordan Tamagni (TAMAGNI_L)
ATT TO: Robert S. Weiner (WEINER_R)
ATT TO: Diane A. Stumpf (STUMPF_D)
ATT TO: Samuel Seidel (SEIDEL_SA)

TEXT:
PRINTER FONT 12_POINT_ROMAN
THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release July 23, 1996

STATEMENT BY THE PRESS SECRETARY

President Clinton announced today that he will raise his 1997 budget request for State AIDS drug assistance programs (ADAP) by \$65 million to help Americans living with the human immunodeficiency virus (HIV) to get life

-saving prescription
drugs.

"New classes of drugs and new methods of treatment hold out the possibility that we can halt the progress of HIV and begin to repair the health of those who are living with this virus," the President said. "Therefore, it is important to take action to do so."

The President's announcement comes at a time of great hope and opportunity in the battle against HIV and AIDS, as

illustrated by the scientific advances discussed earlier this month at the Eleventh International Conference on AIDS in Vancouver, Canada.

State ADAP programs help about 69,000 low

-income people with
HIV buy recently

-discovered, life

-extending drug therapies; these individuals do not get Medicaid, nor do they get prescription coverage through private health insurance. The ADAP programs are partially supported by grants under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.

Earlier this year, after the Food and Drug Administration's rapid approval of the first three protease inhibitor drugs, the President asked Congress to increase the Federal commitment to ADAP by \$52 million. With strong bipartisan support, Congress agreed to the request, and the money is now being distributed to every state, the District of Columbia, and Puerto Rico.

Now, with the promising results reported in Vancouver, the President has increased his 1997 request specifically for ADAP to \$117 million, which more than doubles the amount the President is seeking specifically for these life

-saving therapies. The President also asked States to maintain their strong commitments to providing additional resources for ADAP. Similarly, the President urged pharmaceutical manufacturers, who have made an admirable investment in the development of these drugs, to continue their commitment to helping make these products available for those who need them.

"While new drug treatments offer enormous hope to people living with HIV, it is also clear that our work is far from complete," the President said.

Indeed, further research is necessary to determine the long

-term effect of protease inhibitors and other drugs, the proper dosages and combination of drugs, the optimal time to begin treatment, and the potential for drug resistance. The National Institutes of Health, working closely with scientists and clinicians from medical schools, hospitals, and the pharmaceutical industry, is committed to providing answers to these critical questions.

Without this budget amendment, thousands of Americans may lack access to the medications that hold promise for extending

the lives of people with AIDS. The House has indicated an admirable bipartisan interest in boosting 1997 funding for these drugs.

The Administration looks forward to continuing to work with Congress to see that people who need these life

-saving AIDS drugs
can have greater access to them.

-30

-30

-30-

===== END ATTACHMENT 2 =====

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
004. email	From: Jeffrey Levi, To: Patsy Fleming, Re: Debra [personal] [partial] (1 page)	07/25/1996	b(6)

COLLECTION:

Clinton Presidential Records
Automated Records Management System [Email]
WHO ([Jeffrey Levi...])
OA/Box Number: 500000

FOLDER TITLE:

[07/23/1996 - 07/26/1996]

2018-0759-F
jn424

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:25-JUL-1996 10:41:32.03

SUBJECT: Debra

TO: Patsy Fleming (FLEMING_P) (WHO)

READ:25-JUL-1996 11:56:43.37

TEXT:

(b)(6) ...you may want to touch
(b)(6) base with her -- we should also get a note from POTUS -- there are
forms in the upper left hand drawer of my desk to request such
letters from Presidential correspondence.

[004]

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Dorothy K. Craft (CRAFT_D) (OPD)

CREATION DATE/TIME:25-JUL-1996 18:49:45.28

SUBJECT: ISSUE BRIEFS

TO: Jeanine D. Smartt (SMARTT_J) (OPD)

READ:26-JUL-1996 08:46:30.66

TO: Dennis Burke (BURKE_D) (OPD)

READ:25-JUL-1996 20:20:20.22

TO: Michael Cohen (COHEN_M) (OPD)

READ:25-JUL-1996 19:34:34.06

TO: Christopher C. Jennings (JENNINGS_C) (WHO)

READ:NOT READ

TO: Christopher C. Jennings FOR SANDY (JENNINGS_C) (WHO)

READ:28-JUL-1996 17:11:06.02

TO: Lyndell Hogan (HOGAN_L) (OPD)

READ:25-JUL-1996 18:53:05.33

TO: Stephen C. Warnath (WARNATH_S) (OPD)

READ:25-JUL-1996 21:20:41.20

TO: Diana M. Fortuna (FORTUNA_D) (OPD)

READ:25-JUL-1996 18:50:01.57

TO: Molly Brostrom (BROSTROM_M) (WHO)

READ:26-JUL-1996 09:21:48.63

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:28-JUL-1996 14:43:01.76

TO: Patsy Fleming (FLEMING_P) (WHO)

READ:25-JUL-1996 19:09:35.06

TO: Paul J. Weinstein, Jr (WEINSTEIN_P) (OPD)

READ:26-JUL-1996 10:11:47.33

TEXT:

I realize I've worn out my welcome back by walking around the issue briefs, asking for background material by COB tomorrow. However, I'm emailing with good news -- kind of.

Two things:

- (1) The materials aren't needed until COB Monday (not as exciting as you'd hoped).
- (2) Our new interns would love to help you. They can search your files for background material, call contacts at agencies to

gather materials, go to the library, etc., etc.

Bridgette and Manoj are especially available to help you -- all staff should have received a list of our interns today, along with their location and extension numbers ...

Thanks!

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: Tom_Coates@quickmail.ucsf.edu@INET@EOPMRX

CREATION DATE/TIME:25-JUL-1996 16:00:00.00

SUBJECT: Re: Query....

TO: Jeffrey Levi (LEVI_J@A1@CD) (WHO)
READ:25-JUL-1996 16:50:43.63

TO: Margaret Chesney (Margaret_Chesney@quickmail.ucsf.edu@INET@EOPMRX)
READ:NOT READ

CC: Jeff Stryker (STRYKER@psg.ucsf.edu@INET@EOPMRX)
READ:NOT READ

TEXT:

Reply to: RE>>Query....

We did pass in the halls and I have been trying to organize a call with Helene--she's not easy to reach--and we're working on a conversation--keep you posted

Date: 7/24/96 5:55 PM

To: Tom Coates

From: Margaret Chesney

I think that they passed each other and acknowledged that they should talk but hadn't done so. Tom told me that he was going to call Helene. I have been away and he may have done this. He and I haven't had a chance to really follow-up yet. I'm cc'ing Tom on this as a reminder.

I saw Patsy F. at the meeting and told her how pleased we were about this concept and that we were looking forward to working on it. I didn't go into any detail. She said that she thinks that this is important and is glad that we are working together on it. It wasn't anything specific, more of a back and forth just acknowledging and being positive about the concept.

Date: 7/24/96 12:30 PM

To: Margaret Chesney

From: Jeffrey Levi

given how things have been going lately, I probably don't want to know the answer to this...but did Helene and Joe speak with you or Tom about our counseling and testing project while they were in Vancouver?

Thanks....hope you're well. (This is written from an alleged vacation.)

----- RFC822 Header Follows -----

Received: by quickmail.ucsf.edu with SMTP;24 Jul 1996 12:29:17 -0700

Received: from pmdf.eop.gov by gatekeeper.eop.gov; (5.65v3.2/1.1.8.2/17Oct95-0424PM)
id AA09242; Wed, 24 Jul 1996 14:35:41 -0400

Received: from mr.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01I7GDG1XPYO003QF7@PMDf.EOP.GOV> for Margaret_Chesney@quickmail.ucsf.edu;
Wed, 24 Jul 1996 14:35:46 -0400 (EDT)
Received: with PMDF-MR; Wed, 24 Jul 1996 14:36:10 -0400 (EDT)
Mr-Received: by mta DALE; Relayed; Wed, 24 Jul 1996 14:36:10 -0400
Mr-Received: by mta EOPMRX; Relayed; Wed, 24 Jul 1996 14:35:42 -0400
Alternate-Recipient: prohibited
Date: Wed, 24 Jul 1996 14:34:55 -0400 (EDT)
From: Jeffrey Levi <LEVI_J@a1.eop.gov>
Subject: Query....
To: Margaret_Chesney@quickmail.ucsf.edu
Message-Id: <E1861ZWKFVKVD7*/R=CD/R=A1/U=LEVI_J/@MHS.eop.gov>
Mime-Version: 1.0
Content-Type: TEXT/PLAIN; CHARSET=US-ASCII
Content-Transfer-Encoding: 7BIT
Posting-Date: Wed, 24 Jul 1996 14:36:00 -0400 (EDT)
Importance: normal
Priority: normal
Ua-Content-Id: E1861ZWKFVKVD7
X400-Mts-Identifier: [;01634142706991/2837652@CD]
A1-Type: MAIL
Hop-Count: 2

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE:25-JUL-1996 16:03:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01I7HUPBVA2O003VJF@PMDf.EOP.GOV> for
LEVI_J@a1.eop.gov; Thu, 25 Jul 1996 16:00:24 -0400 (EDT)

Received: from itsnet2.ucsf.edu by STORM.EOP.GOV (PMDF V5.0-7 #6879)
id <01I7HUOMGLUG00007K@STORM.EOP.GOV> for LEVI_J@a1.eop.gov; Thu,
25 Jul 1996 15:59:57 -0700 (MST)

Received: from quickmail.ucsf.edu by itsnet2.ucsf.edu (4.1/SMI-4.1)
id AA01261; Thu, 25 Jul 1996 13:01:07 -0700 (PDT)

X-Mailer: Mail*Link SMTP-QM 3.0.2

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Elizabeth E. Drye (DRYE_E) (OPD)

CREATION DATE/TIME:25-JUL-1996 13:45:47.36

SUBJECT: Notes from 8:15, Courtesy of Public Liason

TO: Carol H. Rasco (RASCO_C) (WHO)
READ:25-JUL-1996 14:41:35.55

TO: Jeremy D. Benami (BENAMI_J) (WHO)
READ:25-JUL-1996 14:05:55.99

TO: Janet B. Abrams (ABRAMS_J) (VPO)
READ:25-JUL-1996 15:12:20.43

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:25-JUL-1996 14:13:45.47

TO: Sandra L. Bublick-Max (BUBLICKMAX_S) (OPD)
READ:25-JUL-1996 18:58:49.77

TO: Dennis Burke (BURKE_D) (OPD)
READ:25-JUL-1996 15:06:50.43

TO: Michael Cohen (COHEN_M) (OPD)
READ:25-JUL-1996 14:29:03.89

TO: Julie E. Demeo (DEMEO_J) (OPD)
READ:25-JUL-1996 14:04:55.22

TO: Patsy Fleming (FLEMING_P) (WHO)
READ:25-JUL-1996 14:28:19.92

TO: Diana M. Fortuna (FORTUNA_D) (OPD)
READ:25-JUL-1996 13:45:46.11

TO: Lyndell Hogan (HOGAN_L) (OPD)
READ:25-JUL-1996 13:58:09.32

TO: Christopher C. Jennings (JENNINGS_C) (WHO)
READ:28-JUL-1996 14:00:19.05

TO: Dorothy L. Karayannis (KARAYANNIS_D)
READ:NOT READ

TO: Jennifer L. Klein (KLEIN_J) (OPD)
READ:25-JUL-1996 13:51:22.45

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:28-JUL-1996 14:40:24.86

TO: Cathy R. Mays (MAYS_C) (OPD)
READ:25-JUL-1996 13:47:18.28

TO: Rosalyn A. Miller (MILLER_RA) (OPD)
READ:NOT READ

TO: Bruce N. Reed (REED_B) (WHO)
READ:25-JUL-1996 14:54:18.64

TO: Diane Regas (REGAS_D) (OPD)
READ:25-JUL-1996 14:02:30.34

TO: Denise Ricketson (RICKETSON_D) (OPD)
READ:25-JUL-1996 13:55:04.85

TO: Jeanine D. Smartt (SMARTT_J) (OPD)
READ:25-JUL-1996 13:52:16.56

TO: Stephen C. Warnath (WARNATH_S) (OPD)
READ:25-JUL-1996 14:42:59.69

TO: Paul J. Weinstein, Jr (WEINSTEIN_P) (OPD)
READ:25-JUL-1996 14:04:43.02

TO: Jill Pizzuto (PIZZUTO_J) (OPD)
READ:25-JUL-1996 13:55:11.67

TEXT:

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: aidsnews@cdcnac.aspensys.com@INET@EOPMRX

CREATION DATE/TIME:25-JUL-1996 11:01:00.00

SUBJECT: CDC AIDS Daily Summary 07/25/96

TO: levi_j (levi_j@Al@CD) (WHO)

READ:28-JUL-1996 14:35:07.77

TEXT:

AIDS Daily Summary
July 25, 1996

The Centers for Disease Control and Prevention (CDC) National AIDS Clearinghouse makes available the following information as a public service only. Providing this information does not constitute endorsement by the CDC, the CDC National AIDS Clearinghouse, or any other organization. Reproduction of this text is encouraged; however, copies may not be sold, and the CDC National AIDS Clearinghouse should be cited as the source of this information. Copyright 1996, Information, Inc., Bethesda, MD

"Second Home Test for H.I.V. Is Approved"
"Doctor Is Accused of Injecting AIDS Virus"
"Federal Study of Lubricant Blasted"
"U.S. Patent to Be Received on Drugs to Treat HIV"
"Expansion of Home for Those With AIDS Virus Upheld"
"Aide Held in Theft at AIDS Facility"
"The Reliable Source: Now You Know"
"Virus Linked to Kaposi's Sarcoma--U.S. Study"
"Cost-Effectiveness of Short-Course Zidovudine to Prevent
Perinatal HIV Type 1 Infection in a Sub-Saharan African
Developing Country Setting"
"Double Push for New Vaccine Candidates"

"Second Home Test for H.I.V. Is
Approved" New York Times (07/25/96) P.
C9

A second home HIV test went on sale Wednesday after being approved by the Food and Drug Administration Monday. Like Johnson & Johnson's Confide, the Home Access Express test, sold by Home Access Health, is available via a toll-free number. Confide was introduced in Texas and Florida, and is now available in most of the country except New York and California. Home Access also expects to sell its test in drugstores later this year. Company spokesperson Kevin Johnson noted that all counselors on the toll-free results telephone line have "bachelors' degrees in a related discipline, such as

social-service work, psychology, and counseling," and half have advanced degrees. Moreover, Johnson said, all Home Access counselors have participated in a four-week company training program.

"Doctor Is Accused of Injecting AIDS Virus"

Wall Street Journal (07/25/96) P. A17

A Lafayette, La., doctor was indicted on a charge of attempted murder on Tuesday for allegedly trying to kill his girlfriend by injecting her with HIV. District Attorney Michael Harson said he would charge Richard J. Schmidt, a 48-year-old gastroenterologist, with murder if the woman dies of AIDS. The woman developed symptoms of AIDS two months after Schmidt gave her what he said was a vitamin injection. Harson said that Schmidt injected blood from an AIDS patient into the woman about a month before their relationship ended and that he had not had physical or sexual contact with her since the injection.

"Federal Study of Lubricant Blasted"

Washington Times (07/25/96) P. A3; Price, Joyce

Despite criticism from conservative groups, a federally funded study is being launched that will determine if nonoxynol-9, a widely used sexual lubricant, is safe for anal sex among homosexuals or whether it could increase the risk of HIV transmission. The \$300,000 study, under attack because it is limited to homosexual men engaged in a sexual practice that is illegal in many states, is being funded by the National Institute of Allergy and Infectious Diseases. AIDS activists are applauding the study, however, saying it is important because anal sex is still the leading mode of HIV transmission. During the 1980s, nonoxynol-9 was found to cause vaginal ulceration, thus increasing the risk of HIV transmission, in a study of Kenyan women. Because rectal tissue is thinner, the problem could be worse for passive participants in anal sex, according to Zeda Rosenberg of NIAID. The new study will evaluate the rectal use of the chemical in 35 homosexual couples.

"U.S. Patent to Be Received on Drugs to Treat HIV"

Wall Street Journal (07/25/96) P. B14

A patent covering VX-478 and related protease inhibitors will be granted to Vertex Pharmaceuticals, the company reported. Vertex is developing the drug, which is in Phase I and II clinical trials in the U.S., Europe, and Japan, with Glaxo Wellcome and Kissei Pharmaceuticals. Vertex's stock increased 10 percent in Wednesday's Nasdaq Stock Market trading, to close at \$28.125.

"Expansion of Home for Those With AIDS Virus Upheld"

Baltimore Sun (07/25/96) P. 3B

Despite opposition by the Mount Royal (Md.) Improvement Association, an area rowhouse for people who have HIV and their families has been cleared for expansion. The Maryland Court of Special Appeals upheld a Baltimore zoning board decision to allow the expansion, requested by D.M. Inc. and AIDS Interfaith

Residential Services.

"Aide Held in Theft at AIDS Facility"

Miami Herald (07/24/96) P. 1B; Gehrke, Donna

A volunteer at a Miami-area center for HIV-infected heterosexuals says he was under the influence of drugs when he took the group's funds, stole the director's car, ransacked her home, and took a road trip to Orlando. Jose Rodriguez was thought to be a hard-working, dedicated volunteer who was trusted as Director Sheri Kaplan's right-hand man. Kaplan discovered Rodriguez's actions upon her return from the recent International Conference on AIDS in Vancouver. Rodriguez, who turned himself in, is now in Dade County Jail on charges including forgery, grand theft, credit-card fraud, and car theft. Kaplan started the Center for Positive Connections last year after she learned she was HIV-positive. She wanted to offer counseling and social activities for other heterosexuals with the virus. Rodriguez, claiming to be HIV-positive, became an active volunteer and was trusted with Kaplan's home and car keys so he could feed her cat.

"The Reliable Source: Now You Know"

Washington Post (07/25/96) P. C3; Groer, Annie; Gerhart, Ann

Elizabeth Taylor, who criticized the government's AIDS policies Monday, will serve as grand marshal of the 1996 National AIDS Candlelight March in Washington, D.C., in October, James Millner of the Whitman-Walker Clinic said. Other celebrities expected at the event include: Sharon Stone, Rosie O'Donnell, Lily Tomlin, Judith Light, Greg Louganis, and Michael Feinstein.

"Virus Linked to Kaposi's Sarcoma--U.S. Study"

Reuters (07/24/96)

A form of the herpes virus is often the cause of Kaposi's sarcoma (KS), the skin tumors common in AIDS patients, researchers report in today's issue of the New England Journal of Medicine. Shou-Jiang Gao and colleagues at Columbia University found that of 40 gay men who developed KS after being infected with HIV, half developed signs of infection with the herpes virus known as KSHV, or Human Herpesvirus 8. The men developed antibodies for the virus 6 months to 75 months before the skin lesions appeared. The researchers suggest that the men who did not show evidence of KSHV infection may not have developed any antibodies to the virus.

"Cost-Effectiveness of Short-Course Zidovudine to Prevent Perinatal HIV Type 1 Infection in a Sub-Saharan African Developing Country Setting"

Journal of the American Medical Association (07/10/96) Vol. 276, No. 2, P. 139; Mansergh, Gordon; Haddix, Anne C.; Steketee, Mansergh, Gordon

Developing countries, especially in sub-Saharan Africa, have the highest rates of HIV infection in the world. Perinatal transmission is also especially high in these areas compared to developed countries. Zidovudine treatment of HIV-positive women and their infants, both during pregnancy and during the early

postnatal period, is able to significantly reduce perinatal HIV transmission. Researchers from the Centers for Disease Control and Prevention analyzed the cost-effectiveness of zidovudine programs in a sub-Saharan African setting, from the perspective of the health care system and of society. Gordon Mansergh and colleagues report that in a setting with 12.5 percent HIV seroprevalence, a national zidovudine program would reduce perinatal HIV incidence by 12 percent at a cost of \$1,115 per infant HIV infection prevented. The researchers conclude that such a program would lower the incidence of infant HIV infection in most sub-Saharan African countries and would also provide societal savings in some areas. Substantial initial investment is needed, however, and other immediate health care demands would have to be considered.

"Double Push for New Vaccine Candidates"

Nature (07/11/96) Vol. 382, No. 6587, P. 101; Macilwain, Colin

In an attempt to revive the nearly dead AIDS vaccine research effort, two new strategies were announced at the XIth International Conference on AIDS. William Paul, director of the Office of AIDS Research at the National Institutes of Health, pledged to "increase resources for research on vaccines" and to begin a "restructured, redirected vaccine research program." The International AIDS Vaccine Initiative (IAVA) promised to raise \$50 million over the next three years to help prepare vaccines for poor countries. Meanwhile, IAVA chair Seth Berkley of the Rockefeller Foundation, the financial backer of the initiative, called NIH's current low level of support for vaccine research "scandalous." Although 8 percent of NIH's AIDS budget, or \$100 million, goes to vaccine research every year, only about \$5 million is spent worldwide on preparing new candidate vaccines, Berkley noted. Vaccine development efforts in the pharmaceutical industry have been halted because of dim hopes of large-scale vaccine trials in the United States. For its first year, the IAVA has \$5 million, and it hopes to raise between \$8 million and \$12 million in 1997, and \$20 million to \$30 million in subsequent years.

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE:25-JUL-1996 11:01:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <0117HK9493JK002A28@PMDf.EOP.GOV> for
levi_j@a1.eop.gov; Thu, 25 Jul 1996 11:01:00 -0400 (EDT)
Received: from aspen3.aspensys.com (aspensys3.aspensys.com)
by STORM.EOP.GOV (PMDF V5.0-7 #6879) id <0117HK8QQK4000007K@STORM.EOP.GOV> for
levi_j@a1.eop.gov; Thu, 25 Jul 1996 11:00:42 -0700 (MST)
Received: by aspen3.aspensys.com (SMI-8.6/SMI-SVR4) id LAA16241; Thu,

25 Jul 1996 11:01:02 -0400

Errors-to: shelly_olim_at_aspenpo@smtpinet.aspensys.com

Precedence: bulk

Originator: aidsnews@cdcnac.aspensys.com

X-Comment: CDC National AIDS Clearinghouse

X-Listprocessor-version: 6.0c -- ListProcessor by Anastasios Kotsikonas

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:25-JUL-1996 10:40:18.27

SUBJECT: Research subcommittee

TO: Remote Addressee (KSF@s-3.com@INET@EOPMRX)
READ:NOT READ

CC: Remote Addressee (ScottHitt@aol.com@INET@EOPMRX)
READ:NOT READ

CC: Patsy Fleming (FLEMING_P) (WHO)
READ:25-JUL-1996 11:54:00.27

CC: Ursula Sanville (SANVILLE_U) (OPD)
READ:25-JUL-1996 11:50:46.71

TEXT:

A few things:

You should have heard from Daniel that the logistics stuff is fine. I think we won't start till 10 a.m. on the 8th.

Can you have disks of the subpanel reports from the Levine Committee sent to the Research subcommittee?

Next research subcommittee call is August 20th at 10 a.m. -- can you arrange and notify?

Also -- remembering how tough December is for hotel space, maybe we should start that process now so we can reach closure at the September meeting.

Thanks so much.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Dorothy K. Craft (CRAFT_D) (OPD)

CREATION DATE/TIME:25-JUL-1996 15:12:55.59

SUBJECT: AIDS action council

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:25-JUL-1996 16:49:29.06

TEXT:

dates -- well, I'll tell you when he cannot meet early august (as of now). He's pretty much here except for august 5 - 7 -- to be safe, the first two weeks of august aren't great, and the 14th doesn't look good. we can discuss in more detail -- i'd love to get a call from you, as always!!! thanks for the welcome and congrats! it's very fun this whole marriage thing! DKC

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: Margaret_Chesney@quickmail.ucsf.edu@INET@EOPMRX

CREATION DATE/TIME:25-JUL-1996 14:31:00.00

SUBJECT: Re: Query....

TO: Jeffrey Levi (LEVI_J@A1@CD) (WHO)

READ:25-JUL-1996 16:48:42.20

CC: Jeff Stryker (STRYKER@psg.ucsf.edu@INET@EOPMRX)

READ:NOT READ

CC: Tom Coates (Tom_Coates@quickmail.ucsf.edu@INET@EOPMRX)

READ:NOT READ

TEXT:

I think that they passed each other and acknowledged that they should talk but hadn't done so. Tom told me that he was going to call Helene. I have been away and he may have done this. He and I haven't had a chance to really follow-up yet. I'm cc'ing Tom on this as a reminder.

I saw Patsy F. at the meeting and told her how pleased we were about this concept and that we were looking forward to working on it. I didn't go into any detail. She said that she thinks that this is important and is glad that we are working together on it. It wasn't anything specific, more of a back and forth just acknowledging and being positive about the concept.

Date: 7/24/96 12:30 PM

To: Margaret Chesney

From: Jeffrey Levi

given how things have been going lately, I probably don't want to know the answer to this...but did Helene and Joe speak with you or Tom about our counseling and testing project while they were in Vancouver?

Thanks....hope you're well. (This is written from an alleged vacation.)

----- RFC822 Header Follows -----

Received: by quickmail.ucsf.edu with SMTP;24 Jul 1996 12:29:17 -0700

Received: from pmdf.eop.gov by gatekeeper.eop.gov;

(5.65v3.2/1.1.8.2/17Oct95-0424PM)

id AA09242; Wed, 24 Jul 1996 14:35:41 -0400

Received: from mr.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)

id <0117GDG1XPYO003QF7@PMDF.EOP.GOV> for Margaret_Chesney@quickmail.ucsf.edu;

Wed, 24 Jul 1996 14:35:46 -0400 (EDT)

Received: with PMDF-MR; Wed, 24 Jul 1996 14:36:10 -0400 (EDT)

Mr-Received: by mta DALE; Relayed; Wed, 24 Jul 1996 14:36:10 -0400

Mr-Received: by mta EOPMRX; Relayed; Wed, 24 Jul 1996 14:35:42 -0400

Alternate-Recipient: prohibited
Date: Wed, 24 Jul 1996 14:34:55 -0400 (EDT)
From: Jeffrey Levi <LEVI_J@a1.eop.gov>
Subject: Query....
To: Margaret_Chesney@quickmail.ucsf.edu
Message-Id: <E1861ZWKFVKVD7*/R=CD/R=A1/U=LEVI_J/@MHS.eop.gov>
Mime-Version: 1.0
Content-Type: TEXT/PLAIN; CHARSET=US-ASCII
Content-Transfer-Encoding: 7BIT
Posting-Date: Wed, 24 Jul 1996 14:36:00 -0400 (EDT)
Importance: normal
Priority: normal
Ua-Content-Id: E1861ZWKFVKVD7
X400-Mts-Identifier: [;01634142706991/2837652@CD]
A1-Type: MAIL
Hop-Count: 2

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE:25-JUL-1996 14:32:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <0117HRL2FNKW002CMP@PMDF.EOP.GOV> for
LEVI_J@a1.eop.gov; Thu, 25 Jul 1996 14:31:27 -0400 (EDT)

Received: from itsa.ucsf.EDU by STORM.EOP.GOV (PMDF V5.0-7 #6879)
id <0117HRKQGUBM00007K@STORM.EOP.GOV> for LEVI_J@a1.eop.gov; Thu,
25 Jul 1996 14:31:11 -0700 (MST)

Received: from quickmail.ucsf.edu (qmgtyw2.ucsf.EDU [128.218.80.208])
by itsa.ucsf.EDU (8.6.13/CDR4.26) with SMTP id LAA146284; Thu,
25 Jul 1996 11:31:28 -0700

X-Mailer: Mail*Link SMTP-QM 3.0.2

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Elizabeth E. Drye (DRYE_E) (OPD)

CREATION DATE/TIME:25-JUL-1996 15:12:22.56

SUBJECT: WEEKLY WEEKLY WEEKLY

TO: Elizabeth E. Drye (DRYE_E) (OPD)
READ:25-JUL-1996 15:18:34.55

TO: Jeremy D. Benami (BENAMI_J) (WHO)
READ:25-JUL-1996 19:35:16.71

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:25-JUL-1996 17:24:13.56

TO: Dennis Burke (BURKE_D) (OPD)
READ:25-JUL-1996 20:20:57.18

TO: Diane Regas (REGAS_D) (OPD)
READ:25-JUL-1996 15:15:52.65

TO: Patsy Fleming (FLEMING_P) (WHO)
READ:25-JUL-1996 17:26:02.58

TO: Diana M. Fortuna (FORTUNA_D) (OPD)
READ:25-JUL-1996 15:12:29.67

TO: Christopher C. Jennings (JENNINGS_C) (WHO)
READ:28-JUL-1996 14:00:24.09

TO: Jennifer L. Klein (KLEIN_J) (OPD)
READ:25-JUL-1996 16:14:26.29

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:28-JUL-1996 14:40:48.65

TO: Jill Pizzuto (PIZZUTO_J) (OPD)
READ:25-JUL-1996 15:34:10.34

TO: Stephen C. Warnath (WARNATH_S) (OPD)
READ:25-JUL-1996 15:17:11.32

TO: Paul J. Weinstein, Jr (WEINSTEIN_P) (OPD)
READ:25-JUL-1996 16:14:34.26

TO: Lyndell Hogan (HOGAN_L) (OPD)
READ:25-JUL-1996 16:09:47.73

TO: Jeanine D. Smartt (SMARTT_J) (OPD)
READ:25-JUL-1996 16:04:49.37

TO: Michael Cohen (COHEN_M) (OPD)
READ:25-JUL-1996 19:23:20.74

TO: Sandra L. Bublick-Max (BUBLICKMAX_S) (OPD)
READ:25-JUL-1996 18:59:04.57

TEXT:

Please save your weekly on the i drive and send me an e-mail letting me know it's done before you leave TODAY, THURSDAY, JULY 25. Thanks. (Sorry I forgot to remind you this morning).

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Elizabeth E. Drye (DRYE_E) (OPD)

CREATION DATE/TIME:25-JUL-1996 18:03:34.25

SUBJECT: WEEKLY REMINDER

TO: Elizabeth E. Drye (DRYE_E) (OPD)
READ:NOT READ

TO: Jeremy D. Benami (BENAMI_J) (WHO)
READ:25-JUL-1996 19:39:54.56

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:26-JUL-1996 09:21:55.75

TO: Dennis Burke (BURKE_D) (OPD)
READ:25-JUL-1996 18:03:51.06

TO: Diane Regas (REGAS_D) (OPD)
READ:26-JUL-1996 09:23:17.31

TO: Patsy Fleming (FLEMING_P) (WHO)
READ:25-JUL-1996 19:09:20.47

TO: Diana M. Fortuna (FORTUNA_D) (OPD)
READ:25-JUL-1996 18:08:54.03

TO: Christopher C. Jennings (JENNINGS_C) (WHO)
READ:28-JUL-1996 14:00:53.88

TO: Jennifer L. Klein (KLEIN_J) (OPD)
READ:25-JUL-1996 18:03:47.31

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:28-JUL-1996 14:42:33.33

TO: Jill Pizzuto (PIZZUTO_J) (OPD)
READ:25-JUL-1996 18:06:24.02

TO: Stephen C. Warnath (WARNATH_S) (OPD)
READ:25-JUL-1996 18:04:45.88

TO: Paul J. Weinstein, Jr (WEINSTEIN_P) (OPD)
READ:26-JUL-1996 10:11:30.93

TO: Lyndell Hogan (HOGAN_L) (OPD)
READ:25-JUL-1996 18:29:15.65

TO: Jeanine D. Smartt (SMARTT_J) (OPD)
READ:25-JUL-1996 18:04:13.12

TO: Michael Cohen (COHEN_M) (OPD)
READ:25-JUL-1996 19:31:29.94

TO: Sandra L. Bublick-Max (BUBLICKMAX_S) (OPD)
READ:25-JUL-1996 18:59:35.03

TEXT:

The weekly is looking pretty thin. It needs you.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:25-JUL-1996 10:32:22.45

SUBJECT: RE: NIH goals

TO: Ursula Sanville (SANVILLE_U) (OPD)

READ:25-JUL-1996 11:50:41.10

TEXT:

seems ok if it's ok with you

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: Margaret_Chesney@quickmail.ucsf.edu@INET@EOPMRX

CREATION DATE/TIME:25-JUL-1996 15:13:00.00

SUBJECT: Re: Query....

TO: Jeffrey Levi (LEVI_J@A1@CD) (WHO)
READ:25-JUL-1996 16:50:15.81

CC: Jeff Stryker (STRYKER@psg.ucsf.edu@INET@EOPMRX)
READ:NOT READ

CC: Tom Coates (Tom_Coates@quickmail.ucsf.edu@INET@EOPMRX)
READ:NOT READ

TEXT:

I think that they passed each other and acknowledged that they should talk but hadn't done so. Tom told me that he was going to call Helene. I have been away and he may have done this. He and I haven't had a chance to really follow-up yet. I'm cc'ing Tom on this as a reminder.

I saw Patsy F. at the meeting and told her how pleased we were about this concept and that we were looking forward to working on it. I didn't go into any detail. She said that she thinks that this is important and is glad that we are working together on it. It wasn't anything specific, more of a back and forth just acknowledging and being positive about the concept.

Date: 7/24/96 12:30 PM

To: Margaret Chesney

From: Jeffrey Levi

given how things have been going lately, I probably don't want to know the answer to this...but did Helene and Joe speak with you or Tom about our counseling and testing project while they were in Vancouver?

Thanks....hope you're well. (This is written from an alleged vacation.)

----- RFC822 Header Follows -----

Received: by quickmail.ucsf.edu with SMTP;24 Jul 1996 12:29:17 -0700

Received: from pmdf.eop.gov by gatekeeper.eop.gov;

(5.65v3.2/1.1.8.2/17Oct95-0424PM)

id AA09242; Wed, 24 Jul 1996 14:35:41 -0400

Received: from mr.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)

id <0117GDG1XPYO003QF7@PMDF.EOP.GOV> for Margaret_Chesney@quickmail.ucsf.edu;
Wed, 24 Jul 1996 14:35:46 -0400 (EDT)

Received: with PMDF-MR; Wed, 24 Jul 1996 14:36:10 -0400 (EDT)

Mr-Received: by mta DALE; Relayed; Wed, 24 Jul 1996 14:36:10 -0400

Mr-Received: by mta EOPMRX; Relayed; Wed, 24 Jul 1996 14:35:42 -0400

Alternate-Recipient: prohibited
Date: Wed, 24 Jul 1996 14:34:55 -0400 (EDT)
From: Jeffrey Levi <LEVI_J@a1.eop.gov>
Subject: Query....
To: Margaret_Chesney@quickmail.ucsf.edu
Message-Id: <E1861ZWKFVKVD7*/R=CD/R=A1/U=LEVI_J/@MHS.eop.gov>
Mime-Version: 1.0
Content-Type: TEXT/PLAIN; CHARSET=US-ASCII
Content-Transfer-Encoding: 7BIT
Posting-Date: Wed, 24 Jul 1996 14:36:00 -0400 (EDT)
Importance: normal
Priority: normal
Ua-Content-Id: E1861ZWKFVKVD7
X400-Mts-Identifier: [;01634142706991/2837652@CD]
A1-Type: MAIL
Hop-Count: 2

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:25-JUL-1996 15:14:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <0117HT2A75CG0044LE@PMDF.EOP.GOV> for
LEVI_J@a1.eop.gov; Thu, 25 Jul 1996 15:13:35 -0400 (EDT)

Received: from itsa.ucsf.EDU by STORM.EOP.GOV (PMDF V5.0-7 #6879)
id <0117HT1W3Z9A00007K@STORM.EOP.GOV> for LEVI_J@a1.eop.gov; Thu,
25 Jul 1996 15:13:16 -0700 (MST)

Received: from quickmail.ucsf.edu (qmgtyw2.ucsf.EDU [128.218.80.208])
by itsa.ucsf.EDU (8.6.13/CDR4.26) with SMTP id MAA114326; Thu,
25 Jul 1996 12:13:31 -0700

X-Mailer: Mail*Link SMTP-QM 3.0.2

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Elizabeth E. Drye (DRYE_E) (OPD)

CREATION DATE/TIME:25-JUL-1996 15:14:59.75

SUBJECT: 8:15 meeting (trying again)

TO: Jeremy D. Benami (BENAMI_J) (WHO)
READ:25-JUL-1996 19:35:26.13

TO: Janet B. Abrams (ABRAMS_J) (VPO)
READ:27-JUL-1996 11:38:21.09

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:25-JUL-1996 17:27:33.77

TO: Sandra L. Bublick-Max (BUBLICKMAX_S) (OPD)
READ:25-JUL-1996 18:59:19.57

TO: Dennis Burke (BURKE_D) (OPD)
READ:25-JUL-1996 15:15:00.61

TO: Michael Cohen (COHEN_M) (OPD)
READ:25-JUL-1996 19:24:45.58

TO: Julie E. Demeo (DEMEO_J) (OPD)
READ:25-JUL-1996 15:45:25.80

TO: Patsy Fleming (FLEMING_P) (WHO)
READ:25-JUL-1996 17:26:26.97

TO: Diana M. Fortuna (FORTUNA_D) (OPD)
READ:25-JUL-1996 16:05:47.22

TO: Lyndell Hogan (HOGAN_L) (OPD)
READ:25-JUL-1996 16:10:22.90

TO: Christopher C. Jennings (JENNINGS_C) (WHO)
READ:28-JUL-1996 14:00:27.71

TO: Dorothy L. Karayannis (KARAYANNIS_D)
READ:NOT READ

TO: Jennifer L. Klein (KLEIN_J) (OPD)
READ:25-JUL-1996 16:15:21.51

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:28-JUL-1996 14:41:12.42

TO: Cathy R. Mays (MAYS_C) (OPD)
READ:25-JUL-1996 15:21:43.11

TO: Rosalyn A. Miller (MILLER_RA) (OPD)
READ:NOT READ

TO: Bruce N. Reed (REED_B) (WHO)
READ:25-JUL-1996 19:36:00.67

TO: Diane Regas (REGAS_D) (OPD)
READ:25-JUL-1996 15:19:42.95

TO: Denise Ricketson (RICKETSON_D) (OPD)
READ:25-JUL-1996 15:21:06.78

TO: Jeanine D. Smartt (SMARTT_J) (OPD)
READ:25-JUL-1996 15:20:14.95

TO: Stephen C. Warnath (WARNATH_S) (OPD)
READ:25-JUL-1996 15:17:41.90

TO: Paul J. Weinstein, Jr (WEINSTEIN_P) (OPD)
READ:25-JUL-1996 16:14:49.42

TO: Jill Pizzuto (PIZZUTO_J) (OPD)
READ:25-JUL-1996 15:34:36.72

TEXT:

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:25-JUL-1996 11:30:00.00

ATT BODYPART TYPE:B

ATT CREATOR: Barbara D. Woolley

ATT SUBJECT: Staff Meeting

ATT TO: Elizabeth E. Drye (DRYE_E)

TEXT:

===== END ATTACHMENT 1 =====

===== ATTACHMENT 2 =====

ATT CREATION TIME/DATE:25-JUL-1996 09:01:00.00

ATT BODYPART TYPE:B

ATT CREATOR: Doris O. Matsui

ATT SUBJECT: Senior Staff Summary

ATT TO: Cheri M. Carter (CARTER_CM)

ATT TO: Marilyn DiGiacobbe (DIGIACOBBE_M)

ATT TO: Jay K. Footlik (FOOTLIK_J)
ATT TO: Robert B. Johnson (JOHNSON_R)
ATT TO: Floydetta McAfee (MCAFEE_F)
ATT TO: Ruby G. Moy (MOY_R)
ATT TO: Betsy Myers (MYERS_B)
ATT TO: Christa T. Robinson (ROBINSON_C)
ATT TO: Lee A. Satterfield (SATTERFIEL_L)
ATT TO: Brian Scott (SCOTT_B)
ATT TO: FAX (92734876,BOB JONES) (TLXA1MAIL _F:92734876\C:BOB JONES\\)
ATT TO: Suzanna Valdez (VALDEZ_S)
ATT TO: Daniel Wexler (WEXLER_D)
ATT TO: William White (WHITE_WI)
ATT TO: Barbara D. Woolley (WOOLLEY_B)
ATT TO: Marilyn Yager (YAGER_M)
ATT TO: Holly Carver (CARVER_H)

TEXT:

POTUS Schedule: First he is in New York today-- * will have a briefing with various agencies involved in the TWA crash and WILL MEET WITH THE FAMILIES. He will make an announcement on improving airport security with a VP commission to bring back recommendations in 45 days. He then goes to Atlanta for the Games-- *meet with Women's Basketball team *Watch Gynastics *Interview with Bob Costas.

Legislative: House--completed Commerce State and Justice, working on Energy and Water with final passage this morning, then moving on to Campaign Finance Reform.

Senate--Passed Food Safety. Working on Ag Approp, then onto Foreign ops. VA/HUD also this week.

Welfare Conference this morning beginning at 11:00 AM. It will go to floor next week. Kennedy/Kassebaum inching closer.

Dole in Pennsylvania today--he has been emphasizing women and business entrepreneurship. He is in Maine tomorrow with Bush. He plans to say something about the 6th Anniv of ADA---(Bill, you should check to see if radio address is going to have something about this. Also let them know what we are doing around this. There is an expectation that surrogates say something.)

Vice President in Tennessee today, announcing another welfare waiver.

===== END ATTACHMENT 2 =====

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005. email	From: Donald Abrams, To: Jeffrey Levi, Re: Clint's Theory (1 page)	07/25/1996	Personal Misfile

COLLECTION:

Clinton Presidential Records
Automated Records Management System [Email]
WHO ([Jeffrey Levi...])
OA/Box Number: 500000

FOLDER TITLE:

[07/23/1996 - 07/26/1996]

2018-0759-F
jn424

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Diane Ikemiyashiro (IKEMIYASHI_D) (WHO)

CREATION DATE/TIME:25-JUL-1996 11:14:54.35

SUBJECT: Going away party for Seth Masket

TO: Jennifer L. Klein (KLEIN_J) (OPD)
READ:25-JUL-1996 13:49:30.50

TO: Christopher C. Jennings (JENNINGS_C) (WHO)
READ:28-JUL-1996 13:57:51.66

TO: Ellen S. Seidman (SEIDMAN_E) (OPD)
READ:25-JUL-1996 12:28:45.05

TO: Douglas S. Sheorn (SHEORN_D) (WHO)
READ:25-JUL-1996 11:26:50.95

TO: Thomas A. Kalil (KALIL_T) (WHO)
READ:26-JUL-1996 09:32:40.33

TO: Kristin A. Schneeman (SCHNEE_K) Autoforward to: Remote Addressee (Kristin A.
Schneeman@LNGATE@EOPMRX) (VPO)
READ:NOT READ

TO: Alice E. Shuffield (SHUFFIELD_A) (OMB)
READ:26-JUL-1996 09:30:24.22

TO: Jeffrey D. Goldstein (GOLDSTEIN_J) (OMB)
READ:25-JUL-1996 19:02:48.17

TO: Floydetta McAfee (MCAFEE_F) (WHO)
READ:25-JUL-1996 12:18:18.20

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:25-JUL-1996 17:20:21.22

TO: Diana M. Fortuna (FORTUNA_D) (OPD)
READ:25-JUL-1996 11:15:13.59

TO: Marilyn Yager (YAGER_M) (WHO)
READ:26-JUL-1996 10:31:00.34

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:28-JUL-1996 14:39:01.27

TO: Jeremy D. Benami (BENAMI_J) (WHO)
READ:25-JUL-1996 14:03:11.24

TO: Sara C. Emery (EMERY_S) (WHO)
READ:25-JUL-1996 11:54:08.70

TO: G. Timothy Saunders (SAUNDERS_GT) (WHO)
READ:25-JUL-1996 11:39:23.78

TO: Joni Stevens (PR_U=JSTEVENS@PR_L=WHMOOEOb@MRP@OPUS)
READ:NOT READ

TO: Barbara D. Woolley (WOOLLEY_B) (WHO)
READ:25-JUL-1996 11:29:29.48

TO: John B. Emerson (EMERSON_J) (WHO)
READ:25-JUL-1996 16:22:20.22

TEXT:

All of you are welcome to join the Office of Presidential Correspondence in wishing Seth Masket a fond farewell. Seth will be moving to Northern California to pursue other exciting endeavors. The festivities will take place this Friday, July 26, in room 93 (OEOB) between 3:00 - 5:00 p.m. We hope to see you there.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Ursula Sanville (SANVILLE_U) (OPD)

CREATION DATE/TIME:25-JUL-1996 10:00:27.64

SUBJECT: fyi

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:25-JUL-1996 10:36:49.87

TEXT:

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:25-JUL-1996 09:58:00.00

ATT BODYPART TYPE:B

ATT CREATOR: Ursula Sanville

ATT SUBJECT: Re: FW: NIH Goals for National Strategy

ATT TO: Wertheimer, Wendy (WERTHEIW@od31eml1.od.nih.gov@INET@EOPMRX)

TEXT:

I thought there was another issue too -- the one you raise here has been addressed.

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Seth E. Masket (MASKET_S) (WHO)

CREATION DATE/TIME:25-JUL-1996 12:30:37.55

SUBJECT: My successor

TO: Douglas S. Sheorn (SHEORN_D) (WHO)
READ:25-JUL-1996 13:19:15.79

TO: Seth E. Masket (MASKET_S) (WHO)
READ:25-JUL-1996 12:31:00.35

TO: Ellen S. Seidman (SEIDMAN_E) (OPD)
READ:25-JUL-1996 12:42:03.74

TO: Jennifer L. Klein (KLEIN_J) (OPD)
READ:25-JUL-1996 13:51:04.37

TO: Christopher C. Jennings (JENNINGS_C) (WHO)
READ:28-JUL-1996 13:59:50.01

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:25-JUL-1996 17:21:03.43

TO: Thomas A. Kalil (KALIL_T) (WHO)
READ:26-JUL-1996 09:33:11.36

TO: Deborah L. Fine (FINE_D) (OPD)
READ:25-JUL-1996 12:42:23.68

TO: Diana M. Fortuna (FORTUNA_D) (OPD)
READ:25-JUL-1996 12:49:44.83

TO: Marilyn Yager (YAGER_M) (WHO)
READ:26-JUL-1996 10:33:24.28

TO: Barbara D. Woolley (WOOLLEY_B) (WHO)
READ:25-JUL-1996 13:46:22.82

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:28-JUL-1996 14:39:34.57

TO: John B. Emerson (EMERSON_J) (WHO)
READ:25-JUL-1996 16:28:56.45

TO: Jeremy D. Benami (BENAMI_J) (WHO)
READ:25-JUL-1996 14:05:45.69

TEXT:
Thank you again for all your help over the past three years.
(God, has it been that long? Wow.) Anyway, I'd like to introduce

you to my replacement. Her name is Sarah Freeman, and she used to be a speechwriter with B'nai B'rith and a publications writer with AmeriCorps. She's been volunteering this week, and she's very excited to get started on Monday and work with all of you. (I only told her nice things about you.)

She'll have my same phone number and issue assignments, so feel free to go to her with the same things you would have discussed with me. I've tried to give her a good introduction, but she's new to the White House, so play nice.

That's all from here. I hope to see all of you or at least speak with you before I'm gone tomorrow. Bye for now!

-Seth

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Patsy Fleming (FLEMING_P) (WHO)

CREATION DATE/TIME:26-JUL-1996 19:36:55.96

SUBJECT: Re: Research subcommittee

TO: Jeffrey Levi (LEVI_J@A1@CD) (WHO)

READ:NOT READ

TEXT:

stop working!

I leave for Dulles Monday at 10:00. Skip the DPC meeting so we can talk before I go. Have a good weekend.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeremy D. Benami (BENAMI_J) (WHO)

CREATION DATE/TIME:26-JUL-1996 17:43:20.75

SUBJECT: Issue Briefs

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:26-JUL-1996 17:44:22.66

TO: Sandra L. Bublick-Max (BUBLICKMAX_S) (OPD)
READ:26-JUL-1996 18:34:31.11

TO: Dennis Burke (BURKE_D) (OPD)
READ:26-JUL-1996 19:23:36.37

TO: Michael Cohen (COHEN_M) (OPD)
READ:29-JUL-1996 11:06:05.85

TO: Elizabeth E. Drye (DRYE_E) (OPD)
READ:26-JUL-1996 18:02:08.10

TO: Patsy Fleming (FLEMING_P) (WHO)
READ:26-JUL-1996 18:22:14.64

TO: Diana M. Fortuna (FORTUNA_D) (OPD)
READ:29-JUL-1996 09:34:24.18

TO: Lyndell Hogan (HOGAN_L) (OPD)
READ:26-JUL-1996 18:25:12.20

TO: Christopher C. Jennings (JENNINGS_C) (WHO)
READ:26-JUL-1996 21:05:42.61

TO: Dorothy L. Karayannis (KARAYANNIS_D)
READ:NOT READ

TO: Jennifer L. Klein (KLEIN_J) (OPD)
READ:26-JUL-1996 17:51:34.01

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:26-JUL-1996 19:36:58.09

TO: Diane Regas (REGAS_D) (OPD)
READ:26-JUL-1996 17:58:04.85

TO: Jeanine D. Smartt (SMARTT_J) (OPD)
READ:26-JUL-1996 17:51:29.21

TO: Stephen C. Warnath (WARNATH_S) (OPD)
READ:26-JUL-1996 21:33:42.71

TO: Paul J. Weinstein, Jr (WEINSTEIN_P) (OPD)
READ:26-JUL-1996 18:32:56.52

TEXT:

Just want to be clear what I envisioned as the product for the issue brief documentation.

I think each issue brief should have a bulleted 1-2 page list of the cites for each fact use, in order. So just run down the issue brief and in bullet form provide the cite and/or a one-sentence explanation (i.e., this is the most expansive report ever done because it is the only report ever done).

Then compile a file of copies of each of the actual sources documents (or at least the relevant page(s)).

Keep a copy of the whole file for yourself and give one copy to Dorothy by c.o.b. Monday. If you don't have all the actual materials by Monday, provide what you do have and then feed the rest to her as you get it.

I will be out early next week - so please help Dorothy meet this deadline. Thanks.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jeffrey Levi (LEVI_J) (WHO)

CREATION DATE/TIME:26-JUL-1996 19:33:08.49

SUBJECT: Re: Research subcommittee

TO: Farrell, Kimberly (KSF@s-3.com@INET@EOPMRX)
READ:NOT READ

CC: Patsy Fleming (FLEMING_P@A1@CD) (WHO)
READ:NOT READ

CC: Ursula Sanville (SANVILLE_U@A1@CD) (OPD)
READ:NOT READ

CC: ScottHitt (ScottHitt@aol.com@INET@EOPMRX)
READ:NOT READ

TEXT:
thanks for doing all this; let's talk december after actg.

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Diana M. Fortuna (FORTUNA_D) (OPD)

CREATION DATE/TIME:26-JUL-1996 16:44:50.14

SUBJECT: FYI

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:26-JUL-1996 16:46:35.11

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:26-JUL-1996 19:34:35.06

TEXT:

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE:26-JUL-1996 12:01:00.00

ATT BODYPART TYPE:B

ATT CREATOR: Jeremy D. Benami

ATT SUBJECT: drugs/welfare reform

ATT TO: Bruce N. Reed (REED_B)

ATT TO: Kenneth S. Apfel (APFEL_K)

ATT CC: Christopher C. Jennings (JENNINGS_C)

ATT CC: Carol H. Rasco (RASCO_C)

ATT CC: Diana M. Fortuna (FORTUNA_D)

TEXT:

As you know, I am staying far away from the welfare issue, but. .

Are we flagging the Gramm amendment re drugs as a major concern?

I just want to flag for all of you that the calls I am getting from treatment groups/homeless providers are PANICKED. Their reading of the amendment is that it will shut down drug treatment in the country. Without access to SSI and Medicaid, treatment programs could not exist - and obviously by definition almost all of their clients have convictions for various drug offenses. I understand that McCaffrey is on the case - calling Gramm, etc. - but I hadn't seen it in any of our lists, letters, etc. so I wanted to be sure we were putting this on a priority list for change.

Thanks. I will now return to my state of non-involvement!!

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Ursula Sanville (SANVILLE_U) (OPD)

CREATION DATE/TIME:26-JUL-1996 12:26:51.05

SUBJECT: Strategy update

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:26-JUL-1996 19:34:05.44

TEXT:

Just spoke to Patsy. Jeremy has read the Strategy through the prevention section and didn't understand what the complaints were about on HHS' part. However, e felt it read more like a report than a Strategy, i.e. no action plan, implemetation, etc. Jeremy said he would call Kevin and Patsy promised to follow-up with Jeremy. I'll keep you posted.

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: KSF@s-3.com@INET@EOPMRX

CREATION DATE/TIME:26-JUL-1996 08:26:00.00

SUBJECT: Re: Research subcommittee

TO: Jeffrey Levi (LEVI_J@A1@CD) (WHO)
READ:26-JUL-1996 19:32:00.21

CC: Patsy Fleming (FLEMING_P@A1@CD) (WHO)
READ:26-JUL-1996 09:27:06.54

CC: Ursula Sanville (SANVILLE_U@A1@CD) (OPD)
READ:26-JUL-1996 10:32:56.51

CC: ScottHitt (ScottHitt@aol.com@INET@EOPMRX)
READ:NOT READ

TEXT:

The call for Aug. 20 is set and everyone has been notified. The dial in number is (800) 403-2031, host access: 805553, participant access: 512853.

I will send the factsheets to everyone on Monday. Scott said he will have a tentative agenda I can distribute after Aug. 7.

When I send out the factsheets, I will also include the Panel Reports diskette in the Research Committee members' (and Tom Henderson's) packets.

Good idea about December. I contacted several hotels yesterday and have already found four downtown hotels that have space and the per diem. It looks like the dates of December 11 - 13 and 15 - 17 are what most hotels seem to have. How do these look to you? (On our end we only have the ACTG meeting Dec. 7 - 10 and Hanukkah is Dec. 6.) I will send you a complete summary at the end of next week if that is OK with you (ACTG is Sunday through Tuesday of this week). (I haven't run the December meeting by Linda yet since she is out of the office and is still somewhat ill. But, Peggy will mention it to her next time she checks in with us...)

|From: Jeffrey Levi
|To: KSF
|Cc: ScottHitt; Patsy Fleming; Ursula Sanville
|Subject: Research subcommittee
|Date: Thursday, July 25, 1996 10:42AM

| A few things:

| You should have heard from Daniel that the logistics stuff is
| fine. I think we won't start till 10 a.m. on the 8th.

Can you have disks of the subpanel reports from the Levine Committee sent to the Research subcommittee?

Next research subcommittee call is August 20th at 10 a.m. -- can you arrange and notify?

Also -- remembering how tough December is for hotel space, maybe we should start that process now so we can reach closure at the September meeting.

Thanks so much.

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:26-JUL-1996 08:27:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)

by PMDF.EOP.GOV (PMDf V5.0-4 #6879) id <0117IT58XXDC004505@PMDf.EOP.GOV>; Fri, 26 Jul 1996 08:26:45 -0400 (EDT)

Received: from SSSHQ5 (206.65.240.10) by STORM.EOP.GOV (PMDf V5.0-7 #6879)

id <0117IT4WBJCS00007K@STORM.EOP.GOV>; Fri, 26 Jul 1996 08:26:28 -0700 (MST)

X-Mailer: Worldtalk (NetConnex V4.00a)/MIME

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (EXTERNAL MAIL)

CREATOR: aidsnews@cdcnac.aspensys.com@INET@EOPMRX

CREATION DATE/TIME:26-JUL-1996 10:34:00.00

SUBJECT: CDC AIDS Daily Summary 07/26/96

TO: levi_j (levi_j@A1@CD) (WHO)

READ:28-JUL-1996 14:44:23.95

TEXT:

AIDS Daily Summary
July 26, 1996

The Centers for Disease Control and Prevention (CDC) National AIDS Clearinghouse makes available the following information as a public service only. Providing this information does not constitute endorsement by the CDC, the CDC National AIDS Clearinghouse, or any other organization. Reproduction of this text is encouraged; however, copies may not be sold, and the CDC National AIDS Clearinghouse should be cited as the source of this information. Copyright 1996, Information, Inc., Bethesda, MD

"Pa. Program Offers 2 More AIDS Drugs for Working Poor"

"Poor TB Care Worse Than None"

"Courts Tough on Those Who May Expose Others to AIDS, Study Says"

"The FDA Can Work Better"

"Report Blasts FDA's Blood Regulation"

"AIDS and Elderly: Age Is No Escape"

"Tuberculosis on Rise in Kenya"

"Venezuela Registers Nearly 3,500 Deaths from AIDS"

"Serum HIV-1 RNA Levels and Time to Development of AIDS in the Multicenter Hemophilia Cohort Study"

"Pa. Program Offers 2 More AIDS Drugs for Working Poor"

Philadelphia Inquirer (07/26/96) P. B2; Collins, Huntly

Two more powerful new protease inhibitors will be provided at no cost to low-income, uninsured AIDS patients in Pennsylvania, the state Welfare Department announced Thursday. Crixivan and Norvir will be added to the list of 58 AIDS drugs, including the protease inhibitor Invirase, now provided by the \$5.7 million program. To be eligible for the free drugs, HIV-infected patients must earn less than \$30,000 a year. Each patient may receive just one of the protease inhibitors, which, when combined with older AIDS drugs, are able to suppress the level of HIV in the bloodstream. The drugs are covered by private insurers and Medicaid, but the uninsured are not covered in many states.

"Poor TB Care Worse Than None"

USA Today (07/26/96) P. 2D; Manning, Anita

Tuberculosis (TB) programs that are not managed well do more harm than good, researchers at the University of California San Francisco and Stanford University Medical Center report today in the journal Science. UCSF's Sally Blower and Philip C. Hopewell, and Stanford's Peter Small, evaluated the World Health Organization's TB control programs and report that the number of TB cases could be reduced by 80-90 percent by 2000 if WHO meets its goals of identifying 70 percent of cases worldwide and curing 85 percent of those identified. In their report, the researchers warn that unless TB patients are treated with a full six-month drug regimen, they can develop and spread drug-resistant strains. Small called the report a vehicle to raise awareness about the need for increased resources.

"Courts Tough on Those Who May Expose Others to AIDS, Study Says"

Houston Chronicle (07/25/96) P. 21A; Epstein, Aaron

The courts of the 1990s are ruling against HIV-positive individuals who expose others to the virus, even if the risk is remote, a new legal study says. Lawrence Gostin, a Georgetown University law professor, based his findings on 310 AIDS cases since January 1991. Judges have not discriminated against people with AIDS in schools, workplaces, and housing projects, but Gostin says they increasingly rule against HIV-positive individuals in insurance disputes and in health-care settings where exposure to blood is possible. For example, several courts have held that HIV-positive surgeons could be kept from operating despite a low risk of transmitting the virus to patients. At a briefing on the study on Wednesday, Gostin said that lawmakers and judges need to be educated about the risks of transmission. The study noted that in criminal cases, people with HIV have been convicted for spitting, biting, hitting, and other behaviors which did not carry significant risk of transmission. Moreover, Gostin said, insurance disputes involving access to care, ceilings on coverage, and other issues are generally decided in favor of the insurance company.

"The FDA Can Work Better"

Washington Post (07/26/96) P. A27; Mikulski, Barbara; Kassebaum, Nancy

In a commentary in the Washington Post, Senators Barbara Mikulski (D-Md.) and Nancy Kassebaum (R-Kan.) object to a July 17 Post editorial that criticized their year-long efforts to reform the Food and Drug Administration. They argue that the legislation developed by the Senate Labor and Human Resources Committee has not been rushed to the Senate floor, as the editorial suggested, but is the result of careful consideration. They also note that the FDA's success in speeding-up approval of AIDS drugs, in response to pressure from the AIDS community, was a basis for further improvement. Objecting to the editorial's suggestion that the bill would put too much regulatory power in the private sector, the authors say it would only encourage cooperation throughout the approval process, thus avoiding costly

delays.

"Report Blasts FDA's Blood Regulation"

Philadelphia Inquirer (07/26/96) P. A3; Shaw, Donna

A new Congressional report criticizes the Food and Drug Administration for not regulating the blood-products industry effectively and not adequately protecting Americans from tainted blood. The report said that 15 years after AIDS was first identified, the agency still does not have an effective recall system for contaminated blood products. It recommended that a fund be created to help people who "suffer adverse consequences" from tainted blood- and plasma-based therapies, but fails to mention the estimated 10,000 hemophiliacs infected with HIV in the 1980s from blood-clotting products. Moreover, Corey Dubin, president of the Committee of Ten Thousand, an activist group for HIV-infected hemophiliacs, denounced the report for its exclusion of people already infected. Legislation is pending to provide \$1 billion to compensate HIV-infected hemophiliacs, but the bill is said to have poor chances.

"AIDS and Elderly: Age Is No Escape"

Chicago Tribune (07/25/96) P. 1-1; Lade, Diane C.

In Florida, at least 3,991 people over age 50 have contracted HIV from unprotected sex and died of AIDS. Sexual contact is the most common way people over age 50 are infected with HIV, accounting for 60 percent of cases in Florida since 1981. Heterosexual sex is the most common mode of transmission among those 65 or older and was responsible for 24.6 percent of all cases documented in Florida since 1981. While people aged 30-39 comprise 45 percent of the state's AIDS cases, the disease is spreading in the senior population at a rapid rate. Nationally, the percentage of AIDS cases in people over 50 increased 11 percent from 1993 to 1994. E. Bentley Lipscomb, secretary of Florida's Department of Elder Affairs, says the problem stems from lack of education as well as a neglect to target HIV programs to the elderly population.

"Tuberculosis on Rise in Kenya"

Xinhua News Agency (07/25/96)

In Kenya, tuberculosis cases increased to 4,000 in 1995, up from 400 10 years earlier, a government official said Thursday. The Kenyan Minister for Health attributed the rise to the spread of HIV. An estimated 1 million Kenyans have the virus, which is often associated with TB. The minister was speaking at the opening of a new TB clinic.

"Venezuela Registers Nearly 3,500 Deaths of AIDS"

Xinhua News Agency (07/25/96)

Out of 5,796 AIDS cases in Venezuela, 3,496 people have died, a health official announced Thursday. Alejandro Villarroel, medical director of the International Foundation of Combat Against AIDS in Venezuela, urged the public to be aware of the threat of the disease.

"Serum HIV-1 RNA Levels and Time to Development of AIDS in the Multicenter Hemophilia Cohort Study"

Journal of the American Medical Association (07/10/96) Vol. 276, No. 2, P. 105; O'Brien, Thomas R.; Blattner, William A.; Waters, David; et al.

Research suggests that HIV-infected individuals with higher levels of viral RNA may develop AIDS more quickly than those with lower viral levels, but the time from infection to AIDS has not been quantified for various HIV-1 RNA levels. The link between the amount of HIV-1 RNA during early chronic HIV-1 infection and future disease progression is important to understand the pathogenesis of HIV-1. Dr. Thomas R. O'Brien of the National Cancer Institute and colleagues evaluated HIV-1 RNA levels and disease progression in 165 patients enrolled in the Multicenter Hemophilia Cohort Study. The patients' ages at time of seroconversion ranged from 1 year to 66 years. The viral levels were similar for patients younger than 17 and for those aged 18 to 34, but they were higher for individuals aged 35 or older. At 10 years after seroconversion, 72 percent of patients with the highest initial viral load had progressed to AIDS, while none of the patients with the lowest viral loads had developed the disease. The authors conclude that the HIV-1 RNA level during early chronic HIV-1 infection is a strong, age-independent predictor of disease progression.

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:26-JUL-1996 10:35:00.00

ATT BODYPART TYPE:D

TEXT:

RFC-822-headers:

Received: from storm.eop.gov (storm.eop.gov)

by PMDF.EOP.GOV (PMDf V5.0-4 #6879) id <01171XLXIQG00037NJ@PMDf.EOP.GOV> for levi_j@a1.eop.gov; Fri, 26 Jul 1996 10:34:44 -0400 (EDT)

Received: from aspen3.aspensys.com (aspensys3.aspensys.com)

by STORM.EOP.GOV (PMDf V5.0-7 #6879) id <01171XLJ4B9I00007K@STORM.EOP.GOV> for levi_j@a1.eop.gov; Fri, 26 Jul 1996 10:34:25 -0700 (MST)

Received: by aspen3.aspensys.com (SMI-8.6/SMI-SVR4) id KAA05768; Fri, 26 Jul 1996 10:34:47 -0400

Errors-to: shelly_olim_at_aspenpo@smtpinet.aspensys.com

Precedence: bulk

Originator: aidsnews@cdcnac.aspensys.com

X-Comment: CDC National AIDS Clearinghouse

X-Listprocessor-version: 6.0c -- ListProcessor by Anastasios Kotsikonas

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Ursula Sanville (SANVILLE_U) (OPD)

CREATION DATE/TIME:26-JUL-1996 17:30:57.31

SUBJECT: National Strategy

TO: Jeffrey Levi (LEVI_J) (WHO)

READ:26-JUL-1996 19:38:20.89

TEXT:

Here you go

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE:26-JUL-1996 17:30:00.00

ATT BODYPART TYPE:p

ATT CREATOR: Ursula Sanville

TEXT:

PRINTER FONT 10_POINT_COURIER

TOP ODD

The National AIDS Strategy

Draft for ONAP Review, 7.22.96

PRINTER FONT 14_POINT_ROMAN

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The Strategy as a Catalyst for Change

PRINTER FONT 12_POINT_ROMAN_ITALIC

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The Social Impact

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The Evolving Challenge of the HIV/AIDS Epidemic

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Goal of the National Strategy

Development of the Strategy

Common Objectives and Opportunities for Progress

Implementation

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II. OVERVIEW OF FEDERAL EFFORTS

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Introduction

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Prevention
Research
Care and Services
International Activities
Translation of Research into Practice
Civil Rights

III. APPENDICES

PRINTER FONT 12_POINT_ROMAN

Appendices A - F (Prevention, Research, Care and
Services, International Activities,
Translation of Research into Practice,
Civil Rights)

Appendix G Budget Tables

PRINTER FONT 12_POINT_ROMAN_ITALIC

IV. FIGURES, ACRONYMS, AND MEMBERS OF THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS

PRINTER FONT 12_POINT_ROMAN

Figure 1 Death Rates from Leading Causes of
Death in Persons Aged 25

-44 Years,
USA, 1982

-1993

Figure 2 Cumulative U.S. AIDS Cases: 2/83
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TOP EVEN

The National AIDS Strategy
Draft for ONAP Review, 7.22.96

Acronym List

Members of the Interdepartmental Task Force on HIV and
AIDS

TOP EVEN

The National AIDS Strategy
Draft for ONAP Review, 7.22.96

PRINTER FONT 14_POINT_ROMAN_ITALIC

Message from the Director of the Office of National
AIDS Policy

PRINTER FONT 10_POINT_COURIER

The epidemic of HIV and AIDS constitutes a public health crisis of
unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP)
was created by President Clinton to provide a national focus and direction for
the government's response to HIV and AIDS. More recently, President Clinton
asked ONAP to develop a comprehensive National Strategy that would chart the
Administration's direction in responding to the HIV/AIDS national and
international pandemic. This was as a result of the President's commitment to
promote efficient and collaborative policy and program efforts.
The development of a National AIDS Strategy is an historic undertaking. No

previous administration has undertaken so broad a planning effort that: (1) involves all Federal Departments and Agencies that engage in HIV

-related

efforts; (2) reaches out to communities and the private sector; and, (3) identifies areas where the Nation should place its most concerted efforts. Combating HIV disease will require nothing less than the best innovative and cooperative efforts of State, local and federal governments, the private sector, and infected and affected communities and individuals. The urgency of the crisis requires that we build upon what we have already learned, joining together with one another to develop a new, more unified and collaborative approach to addressing the epidemic.

The Strategy was developed through consultation with, and guidance from, many groups and individuals. I would like to thank, in particular, the members of the Interdepartmental Task Force on HIV and AIDS (IDTF) for the time and attention that they, and their staffs, contributed to the development of the Strategy. The IDTF is a group consisting of representatives from executive branch Departments and Agencies that conduct HIV

-relevant work.

In developing the document, we depended heavily upon groups outside of government as well -- they, too, have been, and will continue to be, essential partners in developing solutions that capitalize on the opportunities for progress that are now before us. The recommendations provided by the Presidential Advisory Council on HIV and AIDS (PAC), the advocacy community, participants in the White House Conference on HIV and AIDS, service providers on the front lines of the epidemic, and many HIV

-positive persons, their

families, friends and care givers have been central to identifying areas for focused attention. The insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing the National Strategy.

This document is a snapshot of where we are and where we think we need to go. Collaboration is one of the hallmarks of this Administration's approach to AIDS policy and Strategy serves as a reference point for lengthier dialogues and collaborative efforts between the public and private sectors.

It is important to remember that our efforts would not have been possible without leadership and direction at the highest levels of government. While the challenges of HIV/AIDS that are facing us cannot be solved by government

TOP ODD

The National AIDS Strategy

Draft for ONAP Review, 7.22.96

or the private sector acting alone, more than ever in the history of this epidemic, we need innovative ideas, careful planning, and the strength of public

-private partnerships to bring our strategy to fruition.

The epidemic challenges us on many fronts. Because the most common transmission routes are sexual activity and drug use, topics difficult for

many Americans to confront directly, HIV has challenged this country to look at things that are difficult to face.

There is also fear -- fear of contracting this disease and unwarranted fear of those who are infected. Fifteen years into the epidemic, persons living with HIV still endure daily prejudice and discrimination based upon their HIV status. We are further challenged by the inadequacies of a social and health care infrastructure that is, in many ways, woefully unprepared to address the needs of HIV

-infected persons. Moreover, the safety net provided by programs such as Medicaid and Medicare is threatened with fundamental programmatic changes and reductions in funding. Scientifically, we have made much progress, but the virus continues to be a formidable adversary, challenging the best and brightest among us to find a cure and a vaccine. AIDS also brings to light many of the cross

-cutting problems that exist in our Nation's patchwork of health care, legal, and social service systems. For example, AIDS orphans are a hidden epidemic within the larger context of HIV/AIDS. Some are HIV

-infected, all are HIV

-affected. Many of these children already have or will become wards of the state, shuffled between foster and group homes, often separated from their siblings. They often fall through the cracks of a system that is not prepared to care for them. We are seeing an increasing number of grandparents becoming parents of their grandchildren, even as they deal with the illness and death of their own child. The myriad of Federal and State Agencies (i.e.) charged with overseeing child welfare issues, coupled with a legal code not designed to dispense compassionate remedies for these orphaned children, has created a bureaucratic nightmare for dying parents seeking to provide a safe and caring home for their children. There is a need to be sure parental rights are maintained as long as possible, but also to facilitate the orderly and legal transfer of custody upon incapacitation or death of a child's parent(s). Despite the many difficulties, AIDS has also brought forth an outpouring of compassion and caring. In my many meetings around the country with persons living with HIV, I have been inspired by numerous examples of great personal courage. I have been impressed by the dedication with which many communities and individuals have overcome obstacles in preventing infections and caring for those who are sick. By example, it demonstrates that, as a Nation, we, too, can collectively rise to meet the most difficult challenges placed in our path. Those Americans living with HIV, and others who are at

-risk of infection, their families, and their communities, deserve a thoughtful, effective, and aggressive strategy to combat the disease. Today we are facing great challenges, but we are also facing equally great opportunities. While AIDS is a terrible tragedy that has already affected far too many people around the world, I believe it is a disease that we can defeat -- just as we have eradicated polio from the western hemisphere and smallpox from the world. The National Strategy for HIV and AIDS lays a foundation for the public

-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will be able to win the battle against HIV and AIDS.

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Preface

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The Need for a National Strategy for HIV and AIDS

The National Strategy for HIV and AIDS has been developed to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector.

Since the discovery of the first AIDS cases in the early 1980s, the epidemic of HIV and AIDS has posed a series of unique challenges. The challenges today are very different from those that we faced ten or even five years ago. We now know the risk factors and the etiologic agent, and we have tests to diagnose infection and protect the blood supply. We are developing new and more powerful therapies that offer hope for treatment and prevention.

Scientists now believe that a vaccine is possible. Nonetheless, the epidemic continues. More people are infected every year, in every geographic area, and in every age range. Racial and ethnic minorities are disproportionately represented among existing and new cases of HIV infection. And youth are at increasing risk. Internationally, the epidemic is threatening the economic stability of a number of developing nations.

The changing face of HIV and AIDS, coupled with a period of overall fiscal restraint and a trend toward managed health care programs, require new approaches and

solutions. The National Strategy must incorporate innovative ideas, careful planning, and the strength of public

-private partnerships.

The Strategy as a Catalyst for Change

The National Strategy is intended to serve the public, the President, the Congress, the members of the Interdepartmental Task Force on HIV/AIDS, and Presidential Advisory Council on HIV and AIDS. The text that follows will serve as a blueprint that will: document the baseline of current efforts government

-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS.

The Strategy does not prescribe a fixed sequence of steps by which the entire plan, and its identified opportunities, are to be accomplished. The goals, common objectives, and opportunities for progress are intended to serve as a focus for our attention and efforts. The development of a functional implementation plan will be the responsibility of the Office of National AIDS Policy in partnership with the Interdepartmental Task Force on HIV/AIDS, the Presidential Advisory Council on HIV and AIDS, private sector organizations, and the community.

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I. INTRODUCTION

Scope of the HIV/AIDS Pandemic

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The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and worldwide. While we have made significant progress in understanding the disease and developing treatments since the first case was identified by the CDC in June of 1981, with this progress comes the challenge of preventing new infections, ensuring access to new treatments, and assuring that health care professionals know how to care for their patients. Still, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding, but still limited, inventory of available treatments.

An Expanding Public Health Threat

As of December 1995, the Centers for Disease Control and Prevention (CDC) reported 513,486 cases of AIDS among persons in the U.S.; 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death among all Americans to the 8th. It is now the leading cause of death among Americans aged 25 to 44. (See Figure 1.) In 1995 alone, approximately 74,000 new cases of AIDS were reported to the CDC. More than 46,000 AIDS related deaths were reported to the CDC in 1994. The CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 800,000 and one million Americans are currently living with HIV.

As the epidemic in the United States has evolved, the demographics of the epidemic have been shifting. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half of all new cases. Among the populations being more heavily affected now are young gay men, women, and heterosexual injecting drug users and their partners as well as non

-injecting drug users (i.e., crack cocaine and alcohol). Although gay men no longer represent the majority of new cases, this groups represents the majority of persons living with HIV and AIDS. In 1995, nearly 14,000 women were reported with AIDS and now women comprise 14 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new pediatric AIDS cases were reported. It is however hoped that with greater use of AZT by HIV

-positive mothers during pregnancy and delivery, and administration to their babies after birth, the number of new cases in newborns can be reduced. As the geographic diversity of the disease has widened, the impact of the disease on the country as a whole has increased.

Adolescents are at special risk. The CDC estimates that one in four new HIV infections in the U.S. occur among young people. A significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier stages in their lives. This fact, coupled with the disturbing number of adolescents who are prone to high risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color have been disproportionately affected by the epidemic. In 1995, African

-Americans accounted for 40 percent of newly reported AIDS cases, while representing approximately 12 percent of the general population. Hispanics represented 19 percent of new cases reported in 1995, although this group represents only 9 percent of the general population. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of December 1995 these groups comprised 52 percent of cumulative AIDS cases. AIDS is no longer just an urban problem. The HIV/AIDS pandemic is spreading to non

-urban areas, including dramatic increases in certain regions of the South and Midwest. In fact, between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South. PRINTER FONT 12_POINT_ROMAN
Morbidity and Mortality Weekly Report. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.

While most cases are still reported from urban areas, the rate of reported cases in non

-metropolitan areas is increasing faster than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and the U.S. territories. (See Figure 2.)

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Internationally, the toll of the epidemic is greater still. The World Health Organization (WHO) estimates that since the beginning of the epidemic, 4.5 million cases of AIDS have occurred worldwide. It has estimated that as of mid

-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the pandemic. WHO also projects that by the year 2000 between 30

-40 million people will have been infected with HIV.

The Social Impact

Prejudice and discrimination are still experienced by people living with HIV, their families, and their loved ones. Persons with HIV have been denied medical and dental services, emergency medical treatment, and health insurance. They have been discharged from their jobs and evicted from their homes. *Many persons living with HIV have been the target of violence, rejected by their families, and suffered discrimination because of their HIV status.

AIDS is a disease that most often affects people in the prime of life. It kills people during their most productive years. That it is the leading cause

of death among Americans 25 to 44 is particularly significant since this is the age group that constituted 54% of the civilian labor force in 1992.PRINTER FONT 12_POINT_ROMAN

Communication, Department of Labor. Premature deaths due to AIDS result in the loss of many productive years of life and in many cases deprive young children of their parents. In 1994, HIV infection was the fourth leading cause of years of potential life lost before age 65.

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AIDS has consistently risen in the rankings as a cause of death, while rates for disease such as cancer and heart disease have been comparatively stable. Direct lifetime medical care after diagnosis for an HIV

-infected person costs

more than care for patients with cancer or heart disease, specifically: \$61,211 for heart diseasePRINTER FONT 12_POINT_ROMAN

For 5 years of care after initial heart attack.

Source: American Journal of Cardiology, 1990. , \$25,000 to 84,000 for Cancer Depending on stage diagnosed -- early or late.

Source: Swartz & Rollins, Business and Health, 1985, 85, 24

-6., and \$119,000 for HIV/AIDS Journal of the American Medical Association, July 28, 1993. Add page number/complete reference.

And although cancer and heart disease costs may be attributable to striking older and frailer persons, overall DHHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer and heart disease than for AIDS. In FY 1995 DHHS spent approximately: \$38.0 billion for heart disease, \$17.5 billion for cancer, and \$6.0 billion for AIDS.

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In developing countries, the pandemic threatens to reverse decades of progress in strengthening national economies and improving the health status and social well

-being of millions of women, men, and children. In some African nations, 95 percent of hospital beds are occupied by AIDS patients. Moreover, the WHO estimates that 10 to 15 million children will be orphaned due to AIDS by the year 2000. The human toll has been staggering and is likely to continue.

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The Evolving Challenge of the HIV/AIDS Epidemic

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The four decades prior to the report of the first AIDS case in the early 1980s encompassed a period of unprecedented success in controlling infectious diseases. The emergence of HIV, and the subsequent epidemic of HIV and AIDS, has posed an evolving series of unique scientific, economic, and social challenges, both domestic and international. Today the challenges we face with the epidemic are very different from challenges we faced previously. In the early years of the epidemic, significant scientific resources were dedicated towards understanding how the disease was transmitted and identifying its underlying cause. Thanks to this work, we now know the risk factors and the etiologic agent for HIV, and we have a test to ascertain HIV

serostatus and can, therefore, protect the blood supply with a high degree of certainty.

Building on the knowledge gained from those discoveries, more resources were subsequently directed towards achieving a deeper understanding of HIV

-related

immunology and pathogenesis, and, developing therapies for HIV infection and its associated opportunistic infections and malignancies. New and more powerful therapies that offer new hope for treatment and prevention have been developed. Scientists now believe that a vaccine is possible. Current day discoveries also create new challenges for the future. We now face new scientific challenges in developing a vaccine and the new generation of therapeutics for HIV its associated and opportunistic infections and malignancies.

Since the beginning of the epidemic, behavioral research designed to understand the behavioral, social, cognitive, and biological factors that place individuals at risk for acquiring HIV infection has provided important insights for prevention efforts. Practical experience has also taught us that prevention efforts can be effective. However, behavioral research remains a relatively young science and there are currently more questions than answers. The challenge before us now lies in expanding the scientific underpinnings that will allow us to design more effective prevention programs that will reach even more individuals at risk for infection.

The progress in developing therapies and prevention programs has also created new problems for the health care delivery system. As a result of improved therapies, people with AIDS now live twice as long as they did a decade ago. Due to NIH

-sponsored research we now have the ability to reduce the risk of perinatally acquired HIV infection by treating women with AZT during pregnancy and their babies after birth. The recent approval of a new class of therapies, protease inhibitors, will again change the direction of HIV/AIDS treatment and prevention. Ensuring access to these therapies is the challenge that confronts us now. We need to improve our efforts in providing people with care earlier in their infection so they can receive the new treatments and we need, as well, to ensure that health care professionals are well

-trained and know the best way to provide that care.

Ensuring access to prevention services and medical care for the growing number of people who need, or will need, health care is an enormous task. There are societal and economic changes that are influencing the ways in which the country addresses the issues of health care access and cost. There is a trend towards decentralizing the role of the Federal government in health care and

placing more responsibility at the State and local levels, coupled with a movement to managed care systems. These changes will influence efforts to strengthen prevention efforts and ensure health care and services for people with HIV/AIDS.

From a societal perspective, while we have made tremendous progress in overcoming fear and discrimination, we still have a long way to go. There are no grounds for discriminating against persons with HIV infection and yet such action has thwarted access to health care, health insurance, housing, employment, and even funeral services. We must continue in our vigilance to

ensure that the protections provided under the law are extended to all HIV

-infected persons.

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Goal of the National Strategy

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The goal of the National AIDS Strategy is to capitalize upon the progress which has been made in fighting the epidemic and to catalyze new and strengthened collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector. To realize this ambition we will need innovative ideas, careful planning, and the strength of public

-private partnerships to make these plans a reality.

The text and appendices that follows will serve as a blueprint that will: document the baseline of current efforts government

-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges occur.

Development of the Strategy

The National Strategy for HIV and AIDS presented here is broader in scope than any prior planning efforts. To date, planning has been focused primarily in the Public Health Service (PHS)PRINTER FONT 12_POINT_ROMAN

The Public Health Service Agencies within DHHS with responsibility for a range of activities and programs associated with the HIV epidemic are: the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), the Agency for Health Care Policy and Research (AHCPR), the Food and Drug Administration (FDA), and the Indian Health Service (IHS). Information regarding these agencies can be found in the Appendices., Department of Health and Human Services, as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome (AIDS), Public Health Reports 100:453

-455, September

-October,

1985., the "Coolfont" Coolfont Report. A PHS plan for the Prevention and Control of AIDS and the AIDS Virus. Public Health Reports 101:341

-348, July

-August 1986. and "Charlottesville" Report of the Second Public Health Service AIDS Prevention and Control Conference. Public Health Reports. Vol. 103 Supplement No.1 (Revised). 1988. reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States The Public Health Service Strategic Plan to Combat HIV & AIDS in the United States. U.S. Department of Health and Human Services. 1992.. There have also been planning efforts on the part of various Agencies and Departments, such as the Department of State's United States International Strategy on HIV/AIDS, the congressionally

-mandated annual NIH plan for HIV

-related

research, and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS. Recommendations have also been issued by a number of groups, including the National Commission on AIDS AIDS: An Expanding Tragedy. The Final Report of the National Commission on AIDS. Washington, DC. 1993. and the Presidential Advisory Council for HIV and AIDS. However, until now there has not been a national plan that provides for a government

-wide coordinated effort encompassing not just Public Health Service activities, but also that incorporates areas such as housing, health care, and civil rights.

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Effective planning requires a genuine commitment from participants to work together toward clearly defined goals. Therefore, the strategy for HIV and AIDS has been developed by the Federal Departments and Agencies that support HIV

-related

activities along with the counsel of HIV

-infected persons and

their advocates, the private sector, and the Presidential Advisory Council on HIV and AIDS.

Through the Interdepartmental Task Force on HIV and AIDS (IDTF), a formal request went out for the executive branch Agencies to identify their activities, goals, and objectives. These pertinent data have been compiled uniformly and are contained within the appendices of the strategy. The IDTF members, with their specialized knowledge of a broad range of HIV

-related

issues, have been crucial in identifying areas requiring special attention.

There has also been a reliance on groups outside of government -- the same groups that have been and will continue to be essential partners in developing solutions and capitalizing on the opportunities for progress that lay before us now. The recommendations provided by the Presidential Advisory Council on

HIV and AIDS (PAC) have been invaluable. The advice and counsel of the activist and advocacy communities, participants in the White House Conference on HIV and AIDS, individuals on the front lines of the epidemic, and many HIV

-infected persons and their families, friends, and care givers have been essential in identifying areas for focused attention. And finally, the insights provided by the National Commission on AIDS, the Institute of Medicine of the National Research Council, the General Accounting Office, and the reports of the Office of

Technology Assessment have also been extraordinarily helpful in developing this Strategy.

Common Objectives and Opportunities for Progress

Based on the consultations, the following national objectives are established:

? To provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected;

? To provide solid support for effective prevention strategies so as to reduce the number of new infections each year until there are no new infections; and,

? To ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards.

Alternative language: To ensure that persons living with HIV are not subject to discrimination and receive services that are caring, ethical, and in accordance with legal standards.

Also through the consultations, it became clear that there was consensus regarding the major challenges facing us today, and that these challenges warranted focused attention. There was also a judgment that these challenges represent opportunities for progress -- opportunities to take steps today to find a cure and a vaccine, reduce the number of new infections, and care for those who are infected.

Based on this counsel, opportunities for progress are presented and discussed within each substantive section (i.e., prevention, research, care and services, international activities, translation of research into clinical practice, and civil rights) of the Strategy. (See section on Organization of the Strategy below.) It is these opportunities that will require consideration and broad

-based input in the development of implementation plans if we are to meet the challenges they present.

Implementation

First, it is important to realize that this document is a snapshot of where we are and where we think we need to go. The Strategy serves as a reference point for the lengthier dialogues

and a foundation for future collaborative planning efforts between the public (i.e., Federal, State, and local governments),

and private (i.e., persons living with HIV, AIDS service organizations, the advocacy and activist community, businesses, pharmaceutical and biotechnology companies, academia, health care providers, and insurers, etc.) sectors that will be absolutely essential.

Each issue raised in the Strategy will require specially tailored approaches and implementation plans. In some cases significant progress has already been made, in others much work remains. Some of these challenges can be resolved with the cooperation of a small number of Agencies and organizations, while others will require extensive thoughtful effort on the part of many committed participants in order to craft workable solutions. It will also be important to build on the less comprehensive planning efforts that have taken place and complement current planning activities.

Organization of the National AIDS Strategy

The National AIDS Strategy is organized into the following substantive areas: prevention, research, care and services, international activities, translation of research into practice, and civil rights.

Information and discussion of Federal activities can be found in three locations within the document. First, discussion on each substantive area addresses broad policy issues and new Federal objectives in terms of the national goals and opportunities for progress. Second, each substantive section has a corresponding appendix that provides information on individual Agency goals, objectives, funding levels, constituency involvement, and unmet needs. And third, funding tables can be found in Appendix G. Current Agency activities have not been arranged around administrative structures, but by area. In cases where a single Agency may have responsibility for more than one area, such as prevention and research, documentation of their activities will be found in the respective substantive sections. In some cases there are cross

-cutting issues that could fall into several categories, such as internationally

-based treatment and prevention efforts. In this case, programs that are specifically targeted towards geographic regions of the world are included in the international section.

The type of information provided in the appendices varies depending upon the type of efforts Departments and Agencies sponsor. Support for HIV/AIDS activities falls into two general categories: in the first, HIV/AIDS activities are an essential part of the mission; in the second category, HIV

-related activities are not an explicit part of the mission but are indirectly supported or receive collateral benefit from Agency supported work and/or policies. There are a number of Agencies for whom AIDS

-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA)), while other Agencies maintain programs and activities that support a broad range of activities, of which HIV

-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ)). Data are presented, therefore, in a manner consistent with an Agency's level of involvement.

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II. OVERVIEW OF FEDERAL EFFORTS

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Introduction

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The scope and nature of the HIV/AIDS epidemic have brought State, local, and Federal involvement into many HIV

-related activities.

The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In 1985 the Federal government spent \$212 million for AIDS research, surveillance, and care. With the dramatic increase in cases, by 1995 that figure had reached \$6.8 billion. (See Appendix G). Congress also took note of the rapid increase in cases of HIV and AIDS and passed legislation that sought to address the needs of HIV

-infected persons and their families, and the Nation's need to find a cure and a vaccine, including the Ryan White Comprehensive AIDS Resources Emergency Act (CARE) Act and the NIH Revitalization Act of 1993.

Currently, Federally sponsored activities include direct support for research, training, prevention and education, housing, medical care, support services, information dissemination, enforcement of civil rights, and assistance to international organizations and other nations. While Federal Agencies are responsible for responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for surveillance, prevention, research, and health care responsibilities carried out by State and local governments, academic institutions, private foundations, health care institutions and community

-based organizations.

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PREVENTION

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The Nation's prevention goal is to develop effective prevention strategies that will reduce the number of new infections each year until there are no new infections. Achieving this goal will require a dedicated alliance between the Federal government, States, local governments, communities, businesses, the academic community, professional and non

-governmental organizations, families, health care professionals, and individuals. Achieving this ambitious end will require a clear definition of the different roles and responsibilities of the Federal government, and an ongoing dialogue with its partners in the public and private sectors about the responsibilities each has in reaching this goal.

We know that HIV prevention works. We also know that the task of preventing HIV transmission faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.PRINTER FONT 12_POINT_ROMAN

This section will address primary prevention activities. Other aspects of prevention, such as secondary prevention (i.e., preventing complications of HIV infection), development of topical microbicides, the behavioral components of vaccine research, and international prevention activities will be discussed in the following research, care and services, and international activities sections. The Centers for Disease Control and Prevention (CDC) estimates that approximately 800,000 to 1 million Americans are presently HIV

-infected, many of whom are unaware of their HIV status. Moreover, the CDC estimates that approximately 40,000 to 60,000 Americans will become infected each year. Many more Americans who are not presently infected are at risk for acquiring HIV. HIV infection is a unique prevention challenge because of the virus' virulence, the long period of time when people may not be aware they are infected, long duration of infectiousness, nearly always fatal prognosis, and potential for exponential spread. Moreover, HIV is transmitted primarily as a result of personal and private behaviors -- sex and drug use. To be effective, HIV prevention programs must reach tens of millions of Americans who are characterized by a diversity of age, race, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors.

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Prevention activities are currently supported by several Federal Agencies. (See Appendix A.) Most Federal prevention efforts are funded by Department of Health and Human Services (HHS), although other Departments such as the Department of Defense (DOD), and

the Department of Veterans Affairs (VA) also support prevention activities. These efforts reflect a continuum from surveillance to research to social marketing initiatives. Agency activities are also reflective of their respective missions. For example, the Centers for Disease Control and Prevention (CDC), the Agency with primary Federal HIV

-prevention responsibilities, supports a wide range of surveillance and prevention projects, many in partnership with States, local governments, and community

-based organizations. Other Agencies focus on specific aspects of prevention. The National Institutes of Health (NIH) supports biomedical, behavioral, and social science prevention research. The National Institute on Drug Abuse (NIDA, NIH) and the Substance Abuse and Mental Health Services Administration (SAMSHA) support efforts to prevent HIV infection among drug users, while other Agencies support primary prevention efforts as part of medical care, such as at the veterans and military hospitals and clinics. The Health Resources and Services Administration (HRSA) also encourages broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services for low

-income medically underserved persons. HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program. The efforts of Federal Agencies as well as government

-supported research conducted at universities and private organizations, have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain. We know from both research and community experience that developing prevention programs that are effective requires knowledge of who is becoming infected and of the behaviors that are enabling transmission, an understanding of the motivations for those behaviors, and an understanding of how best to reach people with messages that will ensure lasting behavior change. Prevention priorities must be guided toward gaining knowledge that will improve our efforts to develop effective prevention programs. We need to improve our understanding about the major modes of transmission, close gaps in scientific knowledge, including identifying effective prevention models and strategies, and work towards eliminating gaps in program areas.

Opportunities for Progress

Modes of Transmission

An important aspect of strengthening prevention activities is to have a clearer understanding of who is being infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the HIV epidemic continues to spread in the United States among people who engage in injection drug use, which includes the sharing of drug paraphernalia, and/or

having sex with an injecting drug user, and their sexual partners, young and minority men having sex with men, through heterosexual transmission and perinatal transmission. Moreover, the youth of our country are becoming infected at an alarming rate -- 50 percent of new infections in the United States are in persons under 25 years of age. It is likely that many Americans, aged 25 to 44, for whom HIV is the leading cause of death, became infected as adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. In 1995, African

-Americans accounted for 40 percent of newly reported AIDS cases and Hispanics represented 19 percent of new cases. Over 50 percent of women with HIV/AIDS are African American or Hispanic. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic, and assess the effectiveness of prevention interventions.

Seroprevalence surveys provide information on the level of HIV infections in selected "sentinel" populations. As the Federal Agency with primary responsibility for monitoring the epidemic, CDC's AIDS case and case death reporting system provides useful data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV

-related opportunistic infections.

There are, however, opportunities for refinement. While effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not capture sufficient "front

-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. (These data must be collected with the appropriate confidentiality protections.) Collection of these data are needed as part of an

enhanced effort to link surveillance and epidemiological data to priority setting, in addition to the design and evaluation of prevention programs.

The CDC has recognized the value of this approach and has incorporated data collection design into its community planning process. These shifts in data needs coupled with fiscal restrictions may also require that the CDC reevaluate and reconfigure its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategiesPRINTER FONT 12 POINT ROMAN

External Review of HIV Prevention Strategies by the
CDC Advisory Committee on the Prevention of HIV

Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994., the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

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Prevention ResearchPRINTER FONT 12_POINT_ROMAN
Information on NIH

-supported behavioral and
epidemiological research relevant to primary prevention
can be found in Appendix B: Research.

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Factors that place individuals at risk for acquiring HIV infection are a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity we must not assume we intuitively know which interventions will work, but instead base our efforts on sound research findings and evaluation. Experience has taught us that prevention efforts can be effective, but when they are it is because the intervention incorporates findings from both experience and relevant research. Many significant scientific questions exist in the field of HIV

-related behavioral research. The three main areas where gaps in knowledge have been identified are basic behavioral research, intervention research, and social marketing research.

Basic Behavioral Research. Information provided by the conduct of basic behavioral research should serve as the foundation for prevention programs. Basic behavioral research, similar to basic research in other areas of scientific inquiry, seeks to explain the determinants and causes underlying biological, behavioral, and social processes. HIV

-related risk

-taking behavior is often
complex and influenced by a host of individual and environmental factors.

To capitalize on what is known and improve HIV prevention programs that are targeted to reach a diversity of Americans, more information on the determinants of HIV

-associated sexual and

drug

-using behaviors is needed. For example, although much has been learned about the basic biology of substance abuse, further elucidation of the mechanisms underlying addictive behavior may assist in the development of new therapeutic approaches to addiction, which may in turn reduce the number of new infections.PRINTER FONT 12_POINT_ROMAN

AIDS and Behavior: An Integrated Approach. Judith D. Auerbach, Christina Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine, National Academy

Press, Washington, D.C., 1994. p.79. And although we have some information on relevant risk

-taking
behaviors, more information about knowledge, attitudes,
decision

-making processes, and beliefs about AIDS and other sexually transmitted diseases (STDs) is much needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying what approaches may be most effective for an individual or a community. AIDS and Behavior: An Integrated Approach. Judith D.

Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.

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Intervention Research. A second major gap is research to improve prevention interventions, i.e., research that concentrates on modifying behaviors, such as those related to drug use and sexual practices. We know from other behavior

-influenced diseases (such as hypertension) and practices (such as cigarette smoking and wearing seatbelts) that basic information about what motivates a person to exhibit these behaviors can be incorporated into intervention research to advance approaches to reducing unhealthy behaviors.

In HIV and AIDS, this intervention research can focus on both individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has identified several significant predictors of changes in sexual and drug

-using behaviors among gay men, adolescents, and heterosexual adults.PRINTER FONT 12_POINT_ROMAN
AIDS and Behavior: An Integrated Approach. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994. Studies have shown that community

-based HIV risk reduction
programs that are gender relevant and culturally sensitive can be effective. JAMA article used in PRIM&R speech A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment. Don C. Des Jarlais, Holly Hagan, Samuel R. Friedman, Patricia Friedmann, David Goldberg, Martin Frischer, Steven Green, Kerstin Tunving, Bengt Ljungberg, Alex Wodak, Michael Ross, David Purchase, Margaret E. Millson, Ted Myers. Maintaining Low HIV Seroprevalence in Populations of Injecting Drug Users. JAMA, October 18, 1995 -- Vol. 274, No. 15. pp 1226

-1231.

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However, despite this evidence of success, there is more that we need to know if we are to develop effective prevention programs for a diversity of Americans. We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research on interventions that lead to sustained behavior change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data

-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Enhancing the dialogue between researchers in these two related fields will invariably improve the development of effective prevention interventions.

Social Marketing Research. It is important that the findings from basic behavioral and intervention research be incorporated into prevention programs. Agencies supporting social marketing activities need to build on current knowledge in addition to strengthening efforts to understand barriers to the implementation and replication of promising prevention programs. Given the highly innovative nature of these endeavors, the CDC must consider providing broader technical assistance and training to community organizations. Moreover, a community

-based effort that would test prevention models in a real

-world setting should be carefully considered. We know from efforts in other countries that HIV

-related social marketing efforts can be successful. However, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can be employed in the design and implementation of prevention interventions. There are good models for prevention interventions that are not making

their way to those on the front lines of the epidemic. Community

-based organizations, which are responsible for developing a large portion of the prevention programs often do not, or are not able to, take advantage of current knowledge about program effectiveness.

Prevention Programs

In order to stop new infections, the results of basic behavioral, intervention and social marketing research must serve as the foundation for prevention intervention programs that reach people at risk for acquiring or transmitting HIV. Presently, the Federal government supports a range of programs that address the disparate needs of a number of at

-risk populations. However, the shifting demographics of the epidemic coupled with restricted resources has resulted in gaps in program areas that limit the Nation's ability to prevent new infections. It is therefore important that prevention planners carefully prioritize their efforts based on local epidemiology.

Community Involvement. For prevention interventions to be effective they must reach communities at risk and be responsive to their unique needs. And for individuals to take control of their own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves.

One of the most important innovations in the prevention area is community planning. The community planning process is an outstanding model of a Federal

-local partnership. Through this effort, it is possible to establish joint goals for the prevention of HIV that will meet Federal standards while remaining responsive to local needs. However, this process is early in its development and requires significant, ongoing leadership and technical assistance from the CDC if it is to fulfill its potential for effective priority setting and decision making.

Substance Abuse Prevention and Treatment. Injection drug use is one of the major forces driving the epidemic. One third of all new cases are directly or indirectly related to this mode of transmission. Limiting the impact of substance abuse on the epidemic will require efforts on several fronts.

First, we need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV in this country are

overlapping and highly interrelated, however, care and prevention services for HIV and substance are not. It is vital to continue and strengthen efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

A second avenue for controlling the spread of HIV among substance abusers is enrollment into drug treatment programs. Substance abuse treatment is a form of HIV prevention. Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use. There is also substantial evidence that use of non

-injectable drugs such as alcohol and crack cocaine can adversely influence risk

-taking behavior.

SAMHSA supports the urgent need for the integration of substance abuse prevention and treatment and HIV prevention services for those who use drugs, however, SAMSHA recognizes that there is a "hardcore" segment of the population that refuses treatment and will not practice HIV prevention. The need to encourage prevention and treatment for this population is critical.

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse, and increased outreach efforts to encourage active substance users to seek treatment. We also need to ensure that drug treatment services are available in sufficient numbers for a range of addictions for those in need of such services.

This would include services that accept pregnant women or women with children, indigent members of the community and adolescents. Work on this issue has begun and will continue. The CDC has an initiated State

-by

-State discussion, including meetings with State Legislators and the National Conference of State Legislatures regarding HIV prevention issues. SAMHSA's new Knowledge Development Application (KDA) Program will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. In addition, CDC, HRSA, NIDA, and SAMSHA are co

-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.

Treatment for Sexually Transmitted Diseases and Tuberculosis. Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV

transmission, even by as much as 20 fold. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups. PRINTER FONT 12_POINT_ROMAN

Heiner Grosskurth, Frank Mosha, James Todd, Extra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Changalucha, Angus Nicoll, Gina ka

-Gina,
James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. The Lancet, Vol. 346, August 26, 1995., Maria Wawer, Science. 9.08.95, vol. 269, No. 5229 These data suggest treating STDs can be an effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs. NIH

-supported

research to further understanding of the effect of STD treatment on HIV transmission is underway and should continue.

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HIV positive people are at very high for developing of M. tuberculosis (TB) disease. People infected with both HIV and TB are more likely to develop TB disease than people who infected with only TB. Studies suggest that the risk of developing TB disease is 7 to 10 percent each year for persons who are infected with both TB and HIV, whereas the risk is 10 percent over a lifetime for persons not infected with HIV.PRINTER FONT 12_POINT_ROMAN

Personal communication from CDC Division TB Elimination. In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with TB.

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Further, there is strong evidence that the HIV epidemic has contributed to the increase in the number of TB cases.

Geographic areas that have been most affected by the HIV epidemic have also reported the largest increase in TB cases. Moreover, from 1985 to 1992, the largest increase in TB cases among people ages 25 to 44, the age group most affected by the HIV epidemic. Epidemiology of Tuberculosis, Self

-Study Module on

Tuberculosis, Module Number 2, Division of Tuberculosis, Nation Center for HIV, STD, and TB Prevention, the Centers for Disease Control and Prevention.

It is important that Federal and State efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element, and, that HIV prevention programs incorporate STD prevention and treatment efforts. Moreover, the traditional model of targeting most STD prevention efforts towards

individuals who have already contracted one STD is not necessarily effective for HIV prevention. Enhanced and innovative linkages between STD and HIV prevention need to be established. The newly organized National Center for HIV/STD/TB Prevention at CDC reflects the importance of integrating these inter

-dependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

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. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at risk persons, including youth, women, and ethnic minorities. To assure that all persons seeking HIV testing can have access to such services, the CDC's

counseling and testing guidelines should acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC

-funded sites.

Incorporating a patient's sexual and drug using history when a medical history is taken, offering HIV

-related counseling and voluntary testing, and providing prevention education to HIV positive individuals so they do not infect others is also important. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Training should be made available to improve primary care providers' skill, comfort level and sensitivity in these areas.

Achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments.

Prisoners. Populations in prisons are at high risk for both substance abuse and HIV disease. Moreover, there is often a high prevalence of both HIV and substance abuse behaviors in people entering prison.

Given that the incarcerated population is often at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity to reach these persons. Studies have found that programs using peer counselors have been effective in delivering HIV treatment and prevention

messages. Research has also shown that individuals who are well informed about HIV and substance abuse issues do modify their risk

-taking behaviors. It is important the Federal government build upon the knowledge and opportunity that currently exists and further improve HIV prevention efforts for incarcerated persons.

Evaluation. It is important to assess the effectiveness of the prevention interventions that have or will be implemented. Prospectively set performance measures can be used as a basis for evaluation and program improvement. Incorporating effectiveness measures must become a routine part of all Federally

-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic. Achieving this will also require careful examination of what programs should be continued, what activities need to be initiated, and an awareness that a reconfiguration of some program priorities may be required.

RESEARCHPRINTER FONT 12_POINT_COURIER

This section focus primarily on biomedical and health services research. Discussion of behavioral and social science research is presented in the Prevention section.

One of the Federal government's goals is to provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected. It is research that will enable us to reach these goals and until they are a reality, the Federal government must provide solid ongoing support for basic and clinical research. Achieving this goal will require committed collaborative efforts among the Federal government, universities, researchers, the advocacy community, persons living with HIV and those at risk for infection, communities where research is conducted, charitable organizations, pharmaceutical companies, biotechnology firms, and other parts of the private sector. It will also require an ongoing dialogue between the public and private sectors. At present, a number of Federal Agencies play a significant role in U.S. AIDS research efforts. (See Appendix B.) These endeavors range from basic molecular research to clinical research to health services research. The National Institutes of Health (NIH) supports the largest portion of these efforts. NIH supports HIV

-related activities in the areas of natural history and epidemiology, etiology and pathogenesis, drug discovery and therapeutics, vaccines, behavior and social sciences, and research training. The Veterans Administration (VA) also supports a broad range basic and applied research efforts. As part of its mission to protect and maintain a viable fighting force, the Department of Defense supports clinical vaccine and therapeutic research. The Agency for Health Care Policy and Research (AHCPR) funds health services research to help determine which medical approaches are the most cost effective. The Department of Energy (DOE), through its support of technologically advanced equipment, provides the opportunity for Federal and private researchers to share resources and thereby analyze molecular structures that, without such equipment would not be possible. The Centers for Disease Control and Prevention (CDC) monitors and assesses modes of and risk factors for transmission through epidemiologic and laboratory studies. The Agency also supports facilities employing sophisticated methods for identifying viral variants.

Contributions of Research

The Nation has already realized benefits of supporting research in general, and HIV

-related research specifically. The effort to understand HIV and AIDS has led to, and will continue to result in, scientific strides that benefit research on many other diseases. AIDS research has accelerated study of the human

immune system. This basic immunologic information is being applied to research to better understand and treat many other diseases, such as cancer and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and has provided a new paradigm for treatment of viral diseases. Advances made in the treatment and prevention of the opportunistic infections that complicate HIV disease have had an impact on the care of patients with other immunodeficiency states who are susceptible to many of the same pathogens. The research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, or the treatment of diseases caused by heightened immune responses. HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent of Kaposi's sarcoma. Such approaches may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti

-HIV

therapies have improved our understanding of more viral diseases and led to development of treatments for many other diseases. Efforts to develop drugs for the treatment of HIV has accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV

-related wasting has provided important information for research on nutritional disorders, metabolic

abnormalities, and gastrointestinal dysfunctions. Due in great part to Federally

-sponsored research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti

-retroviral drugs. One of the recent research advances has been the development of new class of drugs, protease inhibitors. When used in combination with other types

of anti

-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream, and possibly improve a person's clinical status and reduce transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV

-related conditions can prolong and improve the quality of life of persons living with HIV. In addition, the Food and Drug Administration, through its expedited review and accelerated approval programs, is now approving drugs faster than ever before and faster than any European nation. However, despite these advances, many complex biomedical and behavioral challenges remain. Identifying the most promising scientific avenues, and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities, requires a considered and coordinated effort.

Opportunities for Progress

Coordinating Federal Research. Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing this massive Federal effort requires coordination efforts at two levels -- one within NIH and the second among the Departments and Agencies supporting HIV research.

Within the NIH, the Agency with the largest portfolio, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, evaluate, and fund the AIDS research activities of these ICDs the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. The law requires that the OAR develop a yearly NIH plan and budget for AIDS research and receive directly from the

President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.

It is crucial that the authority granted OAR in the revitalization legislation, including the consolidated appropriation, be supported and maintained. With such a large research enterprise involving almost every area of clinical medicine and scientific investigation, it is essential that there is oversight and accountability so the most promising approaches are vigorously pursued, gaps in research areas are identified, and the individual Institutes have both the scientific and administrative assistance they need to effectively collaborate with other NIH institutes.

Add language about the Levine Report?

It is also clear that while NIH supports a significant portion of HIV

-related research, other Agencies and Departments support a broad spectrum of research related to HIV and AIDS. Multiple Federal Departments and Agencies have responded with research initiatives that bring to bear their unique capabilities and strengths.

Moreover, this research is often carried out collaboratively. For example, the CDC, FDA, DoD, and NIH hold monthly discussions on protecting the country's blood supply. The DoD and NIH collaborate in the conduct of clinical trials, and there exist strong linkages between basic and applied biomedical studies on HIV disease sponsored by the DoD, NIH, and VA. In addition, the CDC and VA jointly sponsor surveillance studies on the incidence of HIV

-related opportunistic infections.

For the government to effectively support a diversity of promising approaches, these research efforts must also be well

-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy coordinated an inter

-departmental working group, chaired by the Director of the Office of AIDS Research, whose charge it was to develop a coordinated plan and budget specifically for HIV and AIDS research across all Agencies Departments.

The first Federal Biomedical and Behavioral Research Plan and

Budget for HIV and AIDS was completed in April 1996. The development of this plan brought together representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans Affairs. This plan provides an initial blueprint to focus and coordinate existing Federal HIV/AIDS research initiatives and thereby utilize available resources more efficiently and effectively. It also serves as a foundation for continued planning and evaluation.

Vaccine Development. Several major challenges currently face the U.S. and the world in the HIV vaccine development effort. The first is to surmount the daunting scientific and social challenges, and the second is to ensure the development and testing of promising vaccine candidates.

On the scientific level, researchers presently hold two major views regarding the most promising approaches to vaccine development. Some scientists maintain that there is not sufficient information about the virus to warrant efficacy trials and there is a need to gather more basic science information to guide us. Others assert that only clinical efficacy trials in humans will provide the answers that will lead to the development

of a successful candidate. This group believes that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding, and, that in the face of a global emergency testing in people should begin immediately. Both groups have valid arguments.

The issues driving this debate are scientific and social, and stem from the contrasting ways different parts of the world are experiencing the epidemic. Some regions of the world have already experienced the devastating consequences of the epidemic while, in other areas, the epidemic is in its early stages. Some governments have shown a greater interest than others in preparing for vaccine trials as a method of slowing the growth of the epidemic in their countries. Both the social and scientific issues must be considered when planning trials. Given the State of scientific knowledge, there is some consensus that both the basic and empirical avenues can and should be pursued. Both approaches face significant obstacles and it is clear that developing a vaccine cannot be accomplished by the government or the private sector working apart -- a public

-private partnership
will be needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for

vaccines, the Vice President convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue. In addition to effective collaboration with private sector partners, it is also vital that the Federal effort be well

-coordinated. The Federal linkages that were strengthened during the development of the Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS should be utilized in furthering coordination.

Microbicides. Many scientists believe that in the absence of a vaccine, the development of a safe, effective, female

-controlled
mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections, could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. In the U.S., the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs

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Alan B. Stone, and Penelope J. Hitchcock. Vaginal
Microbicides for Preventing the Transmission of HIV.
AIDS 1994, 8 (suppl 1):S285

-S293.. An easily available and inexpensive microbicide could provide a prevention option for millions of women worldwide.

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Condoms, the barrier methods that are currently available, have limitations. Most require consent, if not active participation of the male partner, and therefore cannot be independently used at the discretion of the female partner. Although epidemiological studies have demonstrated that the correct and consistent use of condoms will reduce the risk of acquiring and transmitting HIV and other STDs there are many situations in which interpersonal, social, or cultural barriers interfere with a woman's ability to successfully negotiate condom use. The need for a method that can be employed by women is based on the prevalence of non

-consensual sex, sex without condom use, and HIV risk behaviors that occur without partner knowledge. The development of this important prevention option will depend on strong support for basic and clinical research. Microbicides are a promising approach, but will require preliminary Federal support before they reach a stage where the pharmaceutical or

biotechnology industries can assume a lead role. Discussions among Federal Agencies, the private sector, and advocacy groups have been ongoing and should continue in order to identify areas for worthwhile collaboration and hasten the pace of development. Examining the Impact of HIV on Youth. HIV

-related research has made great strides on many fronts, however, adolescents have not received the full benefit of research discoveries. To date, HIV research efforts have primarily focused two specific populations: infants and adults. But scientific information exists to indicate that HIV may behave differently in infected adolescents. Adolescent treatment approaches may vary from those used for adult or infants. Because little definitive research has been conducted to date with HIV

-positive adolescents, the specific impact of puberty on the course of HIV infection has not yet been determined. Behavioral trends that play a key factor in treatment and prevention have also not been sufficiently studied. Adolescents must become a bigger part of the research process. The NIH and the Food and Drug Administration should examine options for lowering barriers to participation and continue to encourage sponsors to enroll adolescents, when feasible and appropriate, in HIV/AIDS clinical trials. There is also need for adolescent

-relevant information on the part of clinicians and researchers. The Adolescent Medicine HIV/AIDS Research Network, cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the

National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA) serves as an important model of collaboration in this area of research. The network has been developed to improve our understanding of disease and health in adolescents; several PHS agencies have cooperatively established the Adolescent Medicine HIV/AIDS Research Network. The Public Health Service should continue to develop in collaboration with researchers, clinicians, and the infected and affected community, clinical practice guidelines and expeditiously disseminate the latest information on state

-of

-the

-art therapies, options for trials and eligibility criteria for entry into them, and health care and prevention techniques to U.S. and international communities affected by HIV/AIDS.

Clinical Effectiveness Research. Due in part to the FDA's

accelerated approval programPRINTER FONT 12_POINT_ROMAN

The accelerated approval regulation permits companies to seek approval of drugs for serious or life

-threatening diseases when the drug provides meaningful therapeutic benefit over existing therapies. Under these procedures, the FDA may approve drugs based on surrogate endpoints, such as CD4+ cell counts that reasonably predict that a drug provides clinical benefit. The company is then required to confirm this clinical benefit through additional human studies to be completed after marketing approval. The accelerated approval regulation provides for removal of the drug from the market if further studies do not confirm the clinical benefit of the therapy., the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding long

-term clinical effectiveness are unavailable. For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is appropriate to switch or add therapies.

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If these studies are not done there will be little data describing which of the available treatments is more effective and for whom, and under what circumstances. As a result,

patients may be receiving less effective treatments or combinations of treatments, and Federal programs such as Medicaid and Medicare and private insurers may be paying for treatment strategies that are not optimally effective.

With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that post

-marketing

effectiveness studies, currently mandated through regulation are carried out. In order for the results to be relevant to as many persons as possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. To develop a mechanism for conducting such studies, the Vice President has initiated discussions to examine possible options. Participants include pharmaceutical firms, public and private payors and insurers, researchers, the FDA, the NIH, and the advocacy community. Public

-Private Partnerships. As has been noted previously, a key role for the Federal government is to act in partnership with the private sector and support areas where there is a market failure,

i.e., areas where industry is unlikely to pursue research that would be beneficial to the public health. Vaccine development is one such area, but there are others. The Department of Defense has been successful in developing partnerships in the conduct of vaccine trials and this effort should be strengthened. As noted previously, microbicides (i.e., chemical barrier methods for preventing HIV transmission) are a promising approach, but will require preliminary Federal support before they reach a stage where the private sector can assume a lead role.

It is also unlikely that the free market system will push the implementation of head

-to

-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health and Veteran's Administration have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry and these efforts should continue. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships including the NIH, studies of alternative therapies have been conducted; these are important efforts that should continue.

It is cost effective for the government to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. For

example, the Department of Energy has supported sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource that has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development.

Research: An Investment for the Future. And finally, research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine.

At present, the NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other

Departments and Agencies, such as the Department of Defense and Veteran's Administration also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue this investment.

PRINTER FONT 12_POINT_COURIER_OBLIQUE CARE & SERVICES

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One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. 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.

Background

Persons living with HIV finance needed health care services through a variety of mechanisms. Currently, nearly 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care. For the remainder, their lives often depend on the Federal health care safety net.

For those who qualify, care and services are provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community that have admirably served those living with HIV. Taken together, these efforts form a valuable if incomplete safety net for some of the most vulnerable people in our Nation.

After Medicaid, the centerpiece of this safety net is programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). It was established

to fill gaps in coverage and build systems of care to create access to health care for people living with HIV/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and States primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title IIIb of the Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal reducing HIV

-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community

-based family

-centered

system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs.

Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service/DHHS which provides health care for HIV

-infected Native Americans and Alaska Natives.

Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV positive persons in Federal prisons.

Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

Opportunities for Progress

The challenge before us today, especially in light of the restricted fiscal environment, is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. To achieve this, AIDS care and service programs must build upon past successes, continue to improve prioritization efforts, improve accountability, and increase the cost

-effectiveness of services they provide.

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.

Integrated Continuum of Care. Many health care providers believe that one of the most potentially effective approaches to treating HIV positive persons, in addition to reducing the spread of infection, lies in providing people access to an integrated continuum of health care services. This includes counseling and testing, comprehensive health care, home health care, and access to substance abuse treatment and prevention services.

One of the most powerful methods of recruiting people into primary care is knowledge of serostatus -- persons who know they are HIV positive are more likely to seek health care. Counseling and testing services can serve as a gateway to this care.

Unfortunately, the majority of Americans who may be at risk for HIV infection do not know whether or not they are HIV positive. There is a need to develop better outreach education in order to encourage people to come in for counseling and testing and link them to appropriate services as needed. Without the linkage of testing to medical care, the opportunity to prolong life is lost. Linking an HIV

-positive person with care also provides an opportunity for education about behaviors which may reduce their chances of infecting others. For example, this can mean offering addiction treatment or offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission.

As noted in the Prevention Section, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local and Federal governments.

Housing Services. Housing is an important element in the effort to provide comprehensive care for persons living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person with HIV/AIDS has diminished access to programs and services and a diminished

opportunity to live a productive life. It is estimated that up to 50 percent of persons living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.PRINTER FONT 12_POINT_ROMAN
Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

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Persons living with HIV face significant obstacles locating affordable housing. The private market alone does not consistently meet the basic housing needs of persons living with HIV and their families, as housing must often be provided in connection with specialized services that enhance an individual's or family's ability to live independently. In addition, persons living with HIV must also overcome reduced housing options due to unfounded fears and prejudice regarding AIDS.

Housing assistance is an area that requires significant community involvement and support if it is to be successful. Many communities are part of new efforts to comprehensively plan for the housing needs of their residents, including assessing and addressing the needs of residents living with HIV/AIDS. The HOPWA program was created in 1992 to provide communities with a tool to meet the increased need for resources, effective planning, and coordination with existing public and private efforts. The program is representative of HUD's "Continuum of Care" approach to building local systems to address homelessness. Moreover, it is estimated that the cost of providing housing services in a HOPWA

-funded residential facility is far less than the average day in the hospital.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. In addition, the Community Development Block Grant (CDBG) and the HOME affordable housing program as well as Public Housing programs are key resources that are available to communities, contingent on eligibility, space availability and local priorities.

Providing consistent funding for the housing component of the safety net with programs such as community

-oriented programs

HOPWA must be a Federal priority. Moreover, integrating housing services into other programs and ensuring a shared responsibility between Federal, State, local governments and community

organizations is another important step in assisting communities

to build seamless systems of support for our most vulnerable citizens. Efforts are underway to improve inter

-departmental

coordination and should continue.

Prisoners. There are also groups of people, such as prisoners, who are not served by these traditional safety net programs.

Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons. Identifying the HIV positive prisoners and ensuring them access to quality care for incarcerated persons is especially challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that appropriate care is provided.

They also may have difficulties regarding confidentiality, trust, and less access to research opportunities.

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, and improving discharge planning. These efforts can serve to improve discharge planning for HIV positive prisoners at the time of their release from prison.

Program Coordination. For care and services to have the most beneficial impact they should be offered as part of a continuum of care. For organizations on the front lines of the epidemic, building a comprehensive integrated program requires applying to numerous Federal Agencies. For example, 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.

Evaluation. Strong Federal support for these safety net programs must go hand

-in

-hand with improved accountability and priority setting. Evaluating current activities can provide valuable information for planners and those on the frontlines of the epidemic. It can assist us in providing better care to persons living with HIV. In an era of limited resources coupled with a demand for cost effective services of high quality, we must use all the tools available to us if we are to help those persons living with HIV.

Quality of Care. Federally supported programs can and should consistently provide quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV positive persons is possible, but quality care is not consistently available throughout the health care system. Establishing a standard

-of

-care and ensuring consistency in care delivery will require increased training for health care professionals and more accountability through the use of performance measures for quality care.

A Federal program that has achieved success in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection.

However, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV positive persons. Achieving this goal will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

PRINTER FONT 12_POINT_COURIER_OBLIQUE INTERNATIONAL ACTIVITIES PRINTER FONT 12_POINT_COURIER

AIDS is a global pandemic. In the United States it is estimated that between 800,000 and 1 million people are currently infected with HIV. The World Health Organization (WHO) estimates that 18.5 million adults and over 1.5 million children are currently infected worldwide and there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

The pandemic jeopardizes decades of economic and social advances in many developing nations. In Africa and Asia, economic advances are threatened, and in some cases, may be reversed due to the pandemic of HIV and AIDS. Socio

-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in

the volumes of imports and exports, and a reduction in receipts from tourism.PRINTER FONT 12_POINT_ROMAN
HIV/AIDS Policy Guidance. U.S. Agency for
International Development. September 1995. In many countries, governments will be forced to cope with
increasing numbers of cases, weakened health care systems, a
deleterious economic impact on the most productive segments of
society, and the reduction in the number of healthy men and women
able to serve in the government and the military.

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At present several Federal Agencies are working at slowing the
AIDS epidemic internationally. (See Appendix D.) The Department
of State has worked with other Departments, Agencies, and
non

-governmental organizations to develop a framework to guide
U.S. foreign policy in the global efforts against HIV and AIDS.
The major areas identified for U.S. leadership are: preventing
new infections; reducing the personal and social impact of the
pandemic; and mobilizing and unify national and international
efforts. The U.S. Agency for International Development (USAID)
also has a leadership role in the global HIV effort through
development assistance, research and policy formation. USAID
focuses its strategy on developing prevention programs based on
proven interventions, addressing social, cultural, regulatory and
economic issues related to HIV/AIDS and other sexually
transmitted infections, and developing and testing new
interventions and methods to prevent transmission and mitigate
the impact of the epidemic. The U.S. Information Agency (USIA)
supports programs that promote dissemination of U.S. policies and
information related to HIV and AIDS; and the Peace Corps trains a
portion of its volunteers to directly address HIV

-related

concerns in their countries of placement. In addition, several
Agencies support research overseas, including the National
Institutes of Health, the Centers for Disease Control and
Prevention, and the Department of Defense (DOD). The DOD is
conducting clinical trials of candidate HIV vaccines in Thailand
and NIH (working in collaboration with USAID), supports basic
scientific studies on social and behavioral aspects of AIDS in
developing countries. The results of the studies ultimately will
be used to develop interventions to reduce behaviors that place
individuals at risk for contracting HIV infection.

Opportunities for Progress

International Leadership. The United States has established a
global leadership role in combatting the epidemic. This
leadership must continue. The U.S. strongly supports the newly
established Joint and Co

-sponsored United Nations Programme on AIDS (UNAIDS).PRINTER FONT 12_POINT_ROMAN

Until recently, the United Nations' response to
HIV/AIDS was carried out primarily by the World Health
Organization's Global Programme on AIDS. On January 1,
1996 the U.N. launched UNAIDS, co

-sponsored by six U.N. agencies to strengthen coordination and focus support for HIV/AIDS activities at the global and country levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multisectoral responses to the pandemic. Moreover, the U.S. is a member of the governing body of UNAIDS.

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The U.S. also supports efforts to more effectively make use of available resources as well as to encourage non

-traditional donor countries to provide much needed contributions. Supporting UNAIDS and its innovative programmatic efforts, and its goal of working to increase the availability of therapeutics (and vaccines when developed) 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. In addition to financing the development of large scale, comprehensive AIDS prevention programs in many countries, USAID has gained valuable insights and lessons from experiences from these countries and is applying them to U.S. populations. Based on the "Lessons without Borders Project" initiative brings

lessons learned abroad home to inner city and rural areas with problems similar to those experienced overseas. This initiative creates linkages between U.S. community organizations and international projects. The U.S., through its various Agencies will continue to build and strengthen networks that will facilitate leadership, coordination and transnational approaches to AIDS prevention and control programs and AIDS related research; exchange culturally and linguistically appropriate educational and training materials; and demonstrate the bidirectionality of USAID international programs and its potential impact on US based programs, and U.S. based non

-governmental organizations. 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. Other Agencies, such as NIH and CDC, also support international activities. These differences in focus present challenges in effectively

planning, coordinating, and evaluating the overall U.S. international effort. Therefore, in order to improve this endeavor, the Agencies supporting international activities must develop a mechanism for identifying and coordinating this effort.

PRINTER FONT 12_POINT_COURIER_OBLIQUE
TRANSLATION OF RESEARCH INTO PRACTICE
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An important element in our fight against AIDS is ensuring that hard won research advances are translated into practice (i.e., ensuring that new knowledge is incorporated into the standard practice of clinicians, service providers, and health educators caring for persons living with HIV). The increasing presence of HIV in every community necessitates that all health care providers become knowledgeable about assessing risk, promoting prevention, and caring for persons with HIV.

Improving the translation of research advances into daily clinical practice will require an ongoing collaborative effort on the part of the Federal government, individual health care providers, medical schools, professional organizations, international organizations, health centers and hospitals, and other parts of the private sector.

Information dissemination activities fall under the missions of several Agencies. (See Appendix E.) The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the general public. DHHS supports and directs the International HIV/AIDS Clinical Conference Call series which disseminates critical, state

-of

-the

-art clinical care information to primary
care providers via live worldwide audio tele

-conferencing. NIH
also supports publicly available computerized databases such as
AIDSDRUGS, AIDSTRIALS, and AIDSLINE. In addition the toll

-free

1

-800 TRIALS

-A AIDS Clinical Trials Information Service (ACTIS)
is co

-sponsored by NIH, CDC, and FDA. The Centers for Disease
Control and Prevention (CDC) disseminates information through
hotlines such as its toll

-free 1

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-HIV

-0440 HIV/AIDS Treatment

Information Service (ATIS) and the AIDS Information Clearinghouse.

The CDC also issues guidelines for health professionals through its Morbidity and Mortality Weekly Report; such guidelines have included The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women. The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV

-related clinical practice guidelines for clinicians and companion pamphlets for their patients; an example of these materials is clinician guidelines for the evaluation and management of early HIV infection. The Health Resources and Services Administration has also developed guidances for its CARE

Act grantees, funds an AIDS warmline that responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers.

Opportunities for Progress

Due in part to Federally

-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place over the last 15 years. However, despite these successes, there are still areas for improvement. For example, an AHCPR

-supported study indicated that primary care physicians may miss significant HIV

-related symptoms during patient examinations.PRINTER FONT 12_POINT_ROMAN

Douglas S. Paauw, Marjorie D. Wenrich, J. Randall Curtis, Jan D. Carline, Paul G. Ramsey. Ability of Primary Care Physicians to Recognize Physical Finding Associated with HIV Infection. JAMA. 1995; 274:1380

-1382. Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care. Colombotos, J., Messeri, P., McConnell, M.B., et al:

Physicians, Nurses, and AIDS: Findings From a National Study. Rockville, MD: Agency for Health Care Policy and Research; 1995. Grant No. HS06359. (NTIS Publication PB95

-129185)

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We are also at a stage in the epidemic where research advances are coming frequently. In the case of the NIH study that demonstrated it is possible to block perinatal transmission by administering a specific AZT regimen to the mother and baby, it became clear that this scientific breakthrough required a change in the standard of care and action by a number of Federal Agencies. This change also required the development of new testing and counseling guidelines to reflect the new options available to women. And it meant that for patients enrolled in Medicaid and Medicare to receive access to this therapeutic regimen, a policy change on the part of the Health Care Financing Administration (HCFA) was required.

State of the Art Guidelines. One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy for their patients. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients be provided in a timely manner.

The Federal government currently supports a number mechanisms for periodically assessing advances in clinical care. It is essential that these assessment efforts continue and that crucial information is widely disseminated. This will require collaboration with industry, government, and professional groups. Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within the DHHS, the Office of HIV/AIDS Policy (OHAP) has the lead responsibility for coordinating the HIV

-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough 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, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

Improved information dissemination efforts are also needed in the area of primary prevention models. As noted in the prevention section, models of effective prevention interventions have been developed, but often this valuable information is not reaching those persons developing, implementing, and evaluating prevention programs. Here again, the Public Health Service must take the lead in ensuring that information that can be used to stem the

tide of new infections reaches those who can make a difference.

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CIVIL RIGHTS

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One of the Nation's common goals is to ensure that services provided to persons living with HIV caring, ethical, and in accordance with legal standards. Discrimination based on HIV status is illegal and morally wrong.

Discrimination undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control.

Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, consequently do not take advantage of care that could help them live longer, healthier lives. In addition, opportunities to educate people are lost. Discrimination can also wrongfully deny persons access to housing, insurance, employment, and health care.

The Federal government and some States have enacted laws that protect persons with HIV from discrimination on the basis of their infection. 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). 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. In addition, the Department of Health and Human Service's (DHHS) Office of Civil Rights (OCR) is responsible for implementing portions of the ADA, including investigating and resolving Title II complaints of discrimination by health care and social service programs. Federal Agencies and recipients of Federal funds are prohibited from discriminating against people with disabilities under Section 504 the Rehabilitation Act of 1973. The DHHS' Office of Civil Rights is also responsible for enforcing Section 504 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies. The Health Care Financing Administration (HCFA) also enforces regulations regarding the

treatment of HIV

-infected persons.

Opportunities for Progress

Enforcement of Federal Laws. 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 those against clinicians who have refused to care for HIV

-positive 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. Federal Policies. The Federal government must also actively work to remedy any of its own existing discriminatory policies. 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. Leadership. The United States has made progress in fighting discrimination. However, the enactment of laws is insufficient to end discrimination. 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.

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Footnotes

===== END ATTACHMENT 1 =====

RECORD TYPE: PRESIDENTIAL (ALL-IN-1 MAIL)

CREATOR: Jill Pizzuto (PIZZUTO_J) (OPD)

CREATION DATE/TIME:26-JUL-1996 18:25:07.62

SUBJECT: CHR highlights attached

TO: Jeremy D. Benami (BENAMI_J) (WHO)
READ: 1-AUG-1996 09:08:34.73

TO: Christopher C. Jennings (JENNINGS_C) (WHO)
READ:26-JUL-1996 21:07:03.74

TO: Jennifer L. Klein (KLEIN_J) (OPD)
READ:26-JUL-1996 19:05:10.06

TO: Cathy R. Mays (MAYS_C) (OPD)
READ:29-JUL-1996 10:25:26.66

TO: Denise Ricketson (RICKETSON_D) (OPD)
READ:29-JUL-1996 07:41:37.37

TO: Lyndell Hogan (HOGAN_L) (OPD)
READ:26-JUL-1996 18:27:16.53

TO: Stephen C. Warnath (WARNATH_S) (OPD)
READ:26-JUL-1996 21:34:14.71

TO: Paul J. Weinstein, Jr (WEINSTEIN_P) (OPD)
READ:26-JUL-1996 18:33:34.70

TO: Diana M. Fortuna (FORTUNA_D) (OPD)
READ:29-JUL-1996 10:09:09.80

TO: Carol H. Rasco (RASCO_C) (WHO)
READ:26-JUL-1996 19:14:50.59

TO: Janet B. Abrams (ABRAMS_J) (VPO)
READ:27-JUL-1996 12:27:31.82

TO: Dorothy L. Karayannis (KARAYANNIS_D)
READ:NOT READ

TO: Patsy Fleming (FLEMING_P) (WHO)
READ:26-JUL-1996 18:26:03.97

TO: Jeffrey Levi (LEVI_J) (WHO)
READ:26-JUL-1996 19:36:11.86

TO: Elizabeth E. Drye (DRYE_E) (OPD)
READ:28-JUL-1996 17:15:48.34

TO: Deborah L. Fine (FINE_D) (OPD)
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TO: Dennis Burke (BURKE_D) (OPD)
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TO: Diane Regas (REGAS_D) (OPD)
READ:26-JUL-1996 19:58:17.53

TO: Jill Pizzuto (PIZZUTO_J) (OPD)
READ:26-JUL-1996 18:30:58.91

TO: Julie E. Demeo (DEMEO_J) (OPD)
READ:29-JUL-1996 10:38:05.22

TO: Molly Brostrom (BROSTROM_M) (WHO)
READ:26-JUL-1996 18:55:50.87

TO: FAX (9-720-4732,Elworth, Larry) (TLXA1MAIL_ \F:9-720-4732\C:Elworth, Larry\\)
READ:NOT READ

TEXT:

PRINTER FONT 12_POINT_ROMAN
TO: DPC STAFF
FR: JILL PIZZUTO
RE: CHR CALENDAR HIGHLIGHTS

August 1st:
12:05p Depart BWI
12:45p Arrive Nashville, TN
* personal trip
August 2

-5:
AR / personal trip
August 5:
11:40p Return/Arrive DC
August 6:
12:00p Intern lunch, RM 211
August 7:
9:00a Rural Strategy & Policy Development meeting
p.m. Paralympic Prep
August 8:
10:00a Disability Policy Review & Employment meeting
11:45a Swearing

-In Ceremony for Madeline May Kunin
US Ambassador to Switzerland
1:30p Child welfare meeting
August 11:
4:00p Depart DC

5:46p Arrive Atlanta
*Participating in Paralympic Congress
August 11

-16
August 16:
9:07p Return DC