

WITHDRAWAL SHEET

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Date: 3/25/04

DOCUMENT NO. & TYPE	SUBJECT/TITLE	DATE	RESTRICTION
1. Note	To Carol Rasco from Phil re: AIDS Coordinator position, 1p	nd	P5, P6/B6
2. Letter	To POTUS from Michael Montani re: AIDS cure, 2p (partial)	7/12/93	P6/B6

P1 National security classified information [(a)(1) of the PRA].

P2 Relating to 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.

RESTRICTIONS

B1 National security classified information [(b)(1) of the FOIA].

B2 Release could disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA].

B3 Release would violate a Federal statute [(b)(3) of the FOIA].

B4 Release would disclose trade secrets or confidential commercial financial information [(b)(4) of the FOIA].

B6 Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA].

B7 Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA].

B8 Release would disclose information concerning the regulation of financial institutions [(b)(9) of the FOIA].

B9 Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA].

THE WHITE HOUSE
WASHINGTON

How interested?

Coordination

AIDC - Grants / business

ESD - Jobs

DFA - Catching up

DHS

Vets

Ed

Vo-Tech

Health

G-7 - Csk Tony Lake
AIDS

1. Sandy Thurman ^{Chico}
AIDS Algoita #2

Dorothy Whitmore

Mgr of Houston

690
76940

THIS FORM MARKS THE FILE LOCATION OF ITEM NUMBER 1
LISTED IN THE WITHDRAWAL SHEET AT THE FRONT OF THIS FOLDER.



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D. C. 20201

To: Carol Rasco
From: Donna E. Shalala
Re: AIDS Advisor

I would like to recommend the following individuals (in alphabetical order) for consideration as AIDS Advisor. Each is acceptable to the Department and I know or have interviewed each. (Resumes are attached.)

1. Ruby Hearn: Vice President, The Robert Wood Johnson Foundation; a skilled manager of health initiatives on a national scale; most of her experience is in areas other than AIDS, such as children's health and drug abuse treatment.
2. Jeff Levi: Policy Director, AIDS Action Council (DC) and founder of the National Gay and Lesbian Task Force; extremely knowledgeable about AIDS policies and politics; very high credibility with the AIDS and gay communities; though we have confidence in his abilities, he has never had responsibilities on this scale; in discussions with him he displayed a clear vision of the leadership and coordinating functions that we have envisioned for the role.
3. Lee Smith: Corporate Vice President, Levi Strauss and Chairman, National Leadership Coalition on AIDS (business/labor group which works with employers to assist them in developing more humane policies toward employees who are HIV+); a good public spokesperson on the issue as well as a strong bureaucratic actor (his business background would be an asset); with less visibility on the issue so AIDS groups may not be as positive initially as they would be about the other candidates; not particularly familiar with AIDS policies/politics in Washington.

If one of these three is chosen, I would strongly recommend a pairing with a deputy with medical training and a background in this issue. Three possibilities we have discussed include: Dr. Sandra Hernandez (Assistant Clinical Professor, University of California at San Francisco and the former Director, AIDS Office San Francisco Department of Health), Dr. Harvey Makadon (Division of General Medicine at Beth Israel Hospital in Boston) and Dr. Gabriel Torres (Director of AIDS Services at St. Vincent's Hospital in New York City). There are, of course, other candidates for this position.

Yale University

file w/ AIDS czar
search files
Gerald Friedland, M.D.
Director
AIDS Program
Department of Internal Medicine
School of Medicine
333 Cedar Street
P.O. Box 3333
New Haven, Connecticut 06510-8056
Campus address:
Welch Center
335 Congress Avenue
Telephone:
203 737-2450
Fax: 203 737-2240

July 7, 1993

Carol Rasko
Director Domestic Policy Council
The White House
Washington, D.C. 20500

Dear Ms. Rasko:

Thank you very much for your time and interest in discussing the position of AIDS Policy Coordinator with me. As I mentioned in our last phone conversation, it was a great honor to be considered for this position.

I wish the newly appointed coordinator and you good luck in the next several years in working to combat the HIV/AIDS epidemic. If I could be of any help in furthering an HIV/AIDS agenda as we've discussed, I would be most willing.

Sincerely,



Gerald H. Friedland, M.D.
Director, AIDS Program
Professor of Medicine and
Epidemiology and Public Health

GHF:kl

THE WHITE HOUSE
WASHINGTON
September 14, 1993

file AIDS

MEMORANDUM FOR NORMAN CANTERBURY, P.D.

FROM: Carol H. Rasco, ^{Director} Assistant to the President for Domestic Policy

SUBJECT: HIV/AIDS Education Partnership Date

Thanks so much, Norman, for the information on the program for HIV/AIDS education utilizing pharmacists. I have asked Kris Gebbie, AIDS Policy Coordinator, to contact you directly to set up the requested meeting as her office is the appropriate one to work with you on this project.

Thanks again for sharing this exciting concept!

cc: Kristine Gebbie
AIDS Policy Coordinator
1750 17th Street, NW - Suite 1060
Washington, DC 20503

TRANSMISSION REPORT

THIS DOCUMENT (REDUCED SAMPLE ABOVE)
WAS SENT

**** COUNT ****
1

*** SEND ***

NO	REMOTE STATION I.D.	START TIME	DURATION	#PAGES	COMMENT
1.	5013725246	9-14-93 14:03	1'08"	1	

TOTAL 0:01'08" 1

XEROX TELECOPIER 7020

Arkansas Pharmacists Association

417 South Victory • Little Rock, Arkansas 72201 • 372-5250

SEP 13 REC'D

Norman Canterbury, P.D.
Executive Vice President



"Our 2nd Hundred Years"



FAX COVER SHEET

TO: Carol Raso

FROM: Norman Canterbury, P.D. ←

DATE: 9-10-93

THIS MESSAGE CONSISTS OF 8 PAGES (INCLUDING COVER.) IF YOU HAVE ANY QUESTIONS, PLEASE CALL ME AT (501) 372-5250.

FAX# (501) 372-0546

TYPE MEMO & FAX:

To:

From: CHR (I need to personally sign)

Subj: HIV/AIDS Education Partnerships

Date

Thanks so much, Norman, for the information on the program for HIV/AIDS education utilizing pharmacists. I have asked Kris Helbie (list title) to contact you directly to set up the

requested meeting as her office is the appropriate one to work with you on this project.

Thanks again for sharing this exciting concept!

cc: Kris Gervie

(Roy - explain to her he is Arkansasan w/ whom we worked while Gov. as well as (gag!) he is named "Norman" after my great-aunt "Norma" !!!

THE WHITE HOUSE

WASHINGTON

September 14, 1993

MEMORANDUM FOR NORMAN CANTERBURY, P.D.

FROM: Carol H. Rasco, ^{CH} Assistant to the President for Domestic Policy

SUBJECT: HIV/AIDS Education Partnership Date

Thanks so much, Norman, for the information on the program for HIV/AIDS education utilizing pharmacists. I have asked Kris Gebbie, AIDS Policy Coordinator, to contact you directly to set up the requested meeting as her office is the appropriate one to work with you on this project.

Thanks again for sharing this exciting concept!

cc: Kristine Gebbie
AIDS Policy Coordinator
1750 17th Street, NW - Suite 1060
Washington, DC 20503

THIS FORM MARKS THE FILE LOCATION OF ITEM NUMBER 2
LISTED IN THE WITHDRAWAL SHEET AT THE FRONT OF THIS FOLDER.

THE FOLLOWING PAGE HAS HAD MATERIAL REDACTED. CONSULT THE
WITHDRAWAL SHEET AT THE FRONT OF THIS FOLDER FOR FURTHER
INFORMATION.

THE WHITE HOUSE
WASHINGTON

file AIDS

Ray -
I was asked to deliver this
to the President -

I suggest a very brief
reply of "thanks for writing"
I've referred your letter
to Kristine Galindo, Nat'l
AIDS Policy Coordinator, &

Thanks
Kristine

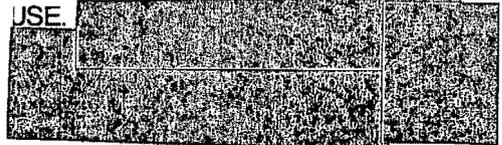
DS!

CURRENTLY BEING STALLED BY THE
I USED IN EUROPE FOR DECADES. IT
OR MANY DIFFERENT DISEASES.

NATIONAL INC. (MZEI). MZEI HAS
IALS BUT THEY ARE STALLED AT

THIS LETTER AND THE
WITH NO HOPE, I BEG YOU TO
MAN TRIALS COULD BE BROUGHT TO

OTHER UNDERGROUND LOCATIONS
USE.



WLD BE MOST HAPPY TO FORWARD IT
STANCE OR IF I CAN ANSWER ANY

MICHAEL MONTANI

ENCLS

CC:

HILLARY CLINTON, HEALTH CARE TASK FORCE CHAIRMAN

Carol -
Do you agree? ^{MD} 2/9/03
Ray

Yes, the letter
should actually be from
Kris saying ~~MD~~ Pres.
referred to her.

MICHAEL MONTANI

P6/(b)(6)

PRESIDENT WILLIAM CLINTON
THE WHITE HOUSE

JULY 12, 1993

DEAR MR. PRESIDENT,

A CURE FOR AIDS!

YES IT IS TRUE MR. PRESIDENT! THERE IS A CURE THAT IS CURRENTLY BEING STALLED BY THE FDA. IT IS CALLED OZONE/ OXYGEN GAS. OZONE HAS BEEN USED IN EUROPE FOR DECADES. IT IS NONTOXIC AND OFFERS HELP TO THE SICK INDIVIDUAL FOR MANY DIFFERENT DISEASES.

OZONE HAS BEEN PATENTED IN THE US BY MEDIZONE INTERNATIONAL INC. (MZEI). MZEI HAS BEEN WORKING FOR SEVEN YEARS TO GET INTO HUMAN TRIALS BUT THEY ARE STALLED AT EVERY JUNCTURE!

MR. PRESIDENT, I PRAY THAT YOU WILL HAVE TIME TO READ THIS LETTER AND THE ENCLOSURES. FOR THE SAKE OF ALL THE AIDS PATIENTS WITH NO HOPE, I BEG YOU TO INTERCEDE WITH THE FDA. WITH YOUR INTERCESSION, HUMAN TRIALS COULD BE BROUGHT TO FRUITION.

IT IS CURRENTLY BEING USED SUCCESSFULLY IN MIAMI AND OTHER UNDERGROUND LOCATIONS AROUND THE COUNTRY. PEOPLE ARE SURVIVING WITH ITS USE.

I HAVE FURTHER DOCUMENTATION IF YOU REQUIRE IT I WOULD BE MOST HAPPY TO FORWARD IT TO YOU. MR. PRESIDENT, IF I CAN BE OF ANY FURTHER ASSISTANCE OR IF I CAN ANSWER ANY QUESTIONS PLEASE DO NOT HESITATE TO CALL OR WRITE.

SINCERELY,

MICHAEL MONTANI

ENCLS

CC:

HILLARY CLINTON, HEALTH CARE TASK FORCE CHAIRMAN



file
Department of Justice

*K. Melbie -
fyi in case you
SEP - 9 RECD didn't
receive.
CJR*

ADVANCE FOR RELEASE AT 5 P.M. EDT
SUNDAY, SEPTEMBER 12, 1993

BJS
202-307-0784

50 PERCENT OF PRISON INMATE DEATHS IN NORTHEAST CAUSED BY AIDS
28 PERCENT CAUSED BY AIDS NATIONWIDE DURING 1991

More than half of the prison inmate deaths in the nation's Northeastern states during 1991 were caused by the Acquired Immune Deficiency Syndrome (AIDS), according to a Bureau of Justice Statistics (BJS) report released today. Nationwide, 28 percent of the 1,863 state prisoners who died in custody died from AIDS--513 men and 15 women.

In New Jersey 69 percent of the inmate deaths were AIDS-related deaths, as were 66 percent in New York, 44 percent in Florida, 33 percent in Maryland and 30 percent in North Carolina and Massachusetts, BJS said.

In 1991, the latest year for which the data are available, 2.2 percent of the 792,000 men and women in federal and state prisons were infected with the human immunodeficiency virus (HIV) that causes AIDS. Of these, 0.6 percent exhibited HIV symptoms, and 0.2 percent had confirmed AIDS.

Lawrence A. Greenfeld, Acting Director of BJS, the Department of Justice's statistical agency, said the findings came from the annual reports of local, state and federal

correctional authorities and from in-depth interviews with a nationally representative sample of almost 14,000 state prisoners nationwide.

"The states reporting the highest percentage of HIV positive inmates were New York (13.8 percent), Connecticut (5.4 percent), Massachusetts (5.3 percent), New Jersey (4 percent), Rhode Island (3.5 percent) and Georgia (3.4 percent)," Greenfeld said.

In a nationally representative survey of state prisoners about half the inmates reported that they had been tested for HIV infection and were willing to share the results with the interviewers. Among tested prisoners who said they had never used drugs, 0.8 percent were HIV positive, as were 2.5 percent who said they had used drugs at least once, 4.9 percent who said they had used needles to inject drugs and 7.1 percent who said they had shared needles.

About 25 percent of all state prison inmates reported they had used a needle to inject illegal drugs, and about half of them had previously shared a needle with others.

An estimated 6.8 percent of Hispanic women were HIV positive, as were 3.5 percent of Hispanic men. Among black inmates, 3.5 percent of the women and 2.5 percent of the men were HIV positive. Among white inmates, 1.9 percent of the women and

1 percent of the men were HIV positive.

Inmates 35 to 44 years old had an infection rate of 3.7 percent and were more likely than those in other age groups to be HIV positive.

Prisoners sentenced for drug, property or public order offenses (such as gambling or weapons violations) were more likely to be HIV positive than were violent offenders.

All the states as well as the District of Columbia and the federal Bureau of Prisons test inmates for the HIV virus either routinely or for specific reasons. Seventeen jurisdictions test all prisoners, at admission, upon release or during custody. Thirty-nine test if asked to do so by the inmate, and 40 test if an inmate exhibits symptoms of HIV infection.

Single copies of the special report "HIV in U.S. Prisons and Jails" (NCJ-143292) as well as other BJS statistical bulletins and reports may be obtained from the National Criminal Justice Reference Service, Box 6000, Rockville, Maryland 20850. The telephone number is 1-800-732-3277.

Data from the tables and graphs used in many BJS reports can be made available to news organizations in spreadsheet files on 5½" and 3½" diskettes by calling (202) 307-0784.

#



Bureau of Justice Statistics Special Report

HIV in U.S. Prisons and Jails

Caroline Wolf Harlow, Ph.D.
BJS Statistician

In 1991, 2.2% of Federal and State prison inmates — 17,479 of 792,176 inmates held in U.S. prisons — were infected with the human immunodeficiency virus (HIV) that causes AIDS. Of the total prison population 0.6% exhibited symptoms of HIV infection, including 0.2% with confirmed AIDS.

This report uses data from three Bureau of Justice Statistics (BJS) data series. Some information on prisoners with HIV comes from the annual reports made by State and Federal correctional authorities (National Prisoner Statistics or NPS). Other data on prisoner characteristics and drug use resulted from interviews with inmates (1991 Survey of Inmates in State Correctional Facilities). Jail data were provided by the Nation's 503 largest jail jurisdictions (1992 Annual Survey of Jails).

Additional findings about HIV in U.S. prisons and jails include the following:

- State prisons reported 2.3% of inmates were HIV positive, and Federal Prisons reported 1.0%.
- Of HIV-positive inmates in State or Federal prison, 9.6% had confirmed AIDS. In State prisons in the West, 21.1% of HIV cases had AIDS.

- All prison jurisdictions tested at least some inmates for HIV; 17 tested all prisoners.

- In 1991, 28% of all deaths in State and Federal prisons were attributable to AIDS. Between July 1, 1991, and June 30, 1992, 24% of deaths in jails were AIDS related.

- In 1991, about 51% of State prison inmates reported having been tested for HIV and knowing the results.

- In 1991, among those prison inmates tested, an estimated 3.3% of women, 3.7% of Hispanics, and 3.7% of those between age 35 and 44 tested positive to HIV.

- In 1991, an estimated 0.8% of tested prison inmates who said they never used drugs were HIV positive, as were 2.5% who ever used drugs, 4.9% who used needles to inject drugs, and 7.1% who shared needles.

September 1993

Because of their comparatively high rates of drug abuse, jail and prison inmates are at greater risk of contracting AIDS. In 1991 an estimated 1 in 4 State prisoners had been using cocaine or crack in the month before their imprisonment offense and about 1 in 10 reported use of heroin or other opiates. During their lives, nearly 1 in 4 State prisoners had used a needle to inject illegal drugs.

This report provides the most recent information from BJS statistical programs covering State prisons and the largest jails nationwide on AIDS testing and the prevalence of AIDS and HIV seropositivity. It also provides information from State prisoners reporting on their personal characteristics and how these relate to HIV test results.

Nationwide, prison authorities in 1991 reported that 2.2% of those confined in State and Federal facilities had tested positive for HIV. That same year, in a nationally representative sample survey of State prisoners, 2.2% were estimated to be HIV positive, based upon interviews with prisoners. These comparable rates suggest that important and useful information about HIV exposure can be reliably obtained from prisoners.

On behalf of the Bureau, I express appreciation to authorities at the Centers for Disease Control for guidance in developing questions in our collection instruments and to State and local correctional authorities who supplied data. I also thank the nearly 14,000 inmates participating in our survey in 1991.

Lawrence A. Greenfeld
Acting Director

Data sources

The NPS-1 program includes midyear and yearend numbers and movements of prison inmates, provided to BJS by the departments of corrections in the 50

States and the District of Columbia and by the U.S. Bureau of Prisons. In 1991 questions were added to the yearend report to determine the numbers of HIV-positive prisoners and the department policies on testing for the virus.

The 1991 Survey of Inmates in State Correctional Facilities questioned a nationally representative sample of almost 14,000 State prisoners about current offenses, prior drug use and treatment, personal characteristics, and other aspects of their life. Questions on whether prisoners had ever been tested for HIV and the results of the test were included in the interviews.

The Annual Survey of Jails obtains data on populations and movements of jail inmates. The sample includes all jail jurisdictions with 100 or more inmates and a sample of smaller jurisdictions. The 503 large jail jurisdictions provide figures on deaths in jails. In 1992, the jurisdictions that were the largest in 1991 were asked to indicate their policies for testing for HIV and numbers of HIV prisoners they were holding on June 30, 1992. (For further description of data sources, see *Methodology*.)

Prevalence of HIV infection in U.S. prisons

In 1991, 2.2% of Federal and State prison inmates were reported to have the human immunodeficiency virus that causes AIDS (table 1). In State prisons, 2.3% of inmates were reported testing HIV-positive; in Federal prisons, 1.0%. Of the total prison population, 0.6% showed symptoms of HIV infection, including 0.2% with confirmed AIDS.

States reporting the highest percentage of prisoners infected with HIV were New York (13.8%), Connecticut (5.4%), Massachusetts (5.3%), New Jersey (4.0%), Rhode Island (3.5%), and Georgia (3.4%). Twenty-nine States reported less than 1.0%. The percentage of inmates in prison on December 31, 1991, and known to be HIV positive is related in part to the testing policies of the individual prisons or departments of corrections.

States in the Northeast led the country in the percentage of inmates known to be infected with the HIV (8.1%). Five of the six States with the highest rates of HIV-positive prisoners were in the Northeast. By contrast, States in the Midwest and West had less than 1% of prisoners with HIV.

Table 1. Inmates in custody of State or Federal correctional authorities known to be positive for the human immunodeficiency virus, yearend 1991

Jurisdiction	Type of HIV infection/AIDS cases				HIV/AIDS cases as a percent of total custody population
	Total	Asymptomatic	Symptomatic	Confirmed AIDS	
U.S. total	17,479	12,765	3,032	1,682	2.2%
Federal	630	422	91	117	1.0
State	16,849	12,343	2,941	1,565	2.3
Northeast	10,247	7,420	1,922	905	8.1%
Connecticut	574	229	264	81	5.4
Maine	1	1	0	0	.1
Massachusetts	484	100	362	22	5.3
New Hampshire	18	8	6	4	1.2
New Jersey	756	0	694	62	4.0
New York	8,000	6,833	474	693	13.8
Pennsylvania	313	247	34	32	1.3
Rhode Island	98	0	88	10	3.5
Vermont	3	2	0	1	.3
Midwest	1,128	733	268	127	.7%
Illinois	299	216	66	17	1.0
Indiana	62	60	0	2	.5
Iowa	19	17	0	2	.5
Kansas	13	1	6	6	.2
Michigan	390	124	194	72	1.1
Minnesota	14	13	1	0	.4
Missouri	127	125	0	2	.8
Nebraska	11	10	1	0	.4
North Dakota	1	1	0	0	.2
Ohio	152	129	0	23	.4
South Dakota	--	--	--	--	--
Wisconsin	40	37	0	3	.5
South	4,314	3,513	513	288	1.5%
Alabama	178	178	0	0	1.1
Arkansas	68	59	5	4	.9
Delaware	85	78	0	7	2.6
District of Columbia	--	--	--	--	--
Florida	1,105	1,015	0	90	2.4
Georgia	807	774	10	23	3.4
Kentucky	27	25	0	2	.3
Louisiana	100	100	0	0	.7
Maryland	478	324	135	19	2.5
Mississippi	106	106	0	0	1.3
North Carolina	170	116	35	19	0.9
Oklahoma	74	64	0	10	.7
South Carolina	316	298	0	18	2.0
Tennessee	28	0	20	8	.3
Texas	615	251	307	57	1.2
Virginia	152	121	0	31	.9
West Virginia	5	4	1	0	.3
West	1,160	677	238	245	.7%
Alaska	9	7	0	2	.4
Arizona	84	74	0	10	.5
California	714	407	136	171	.7
Colorado	82	37	41	4	1.0
Hawaii	19	17	1	1	.8
Idaho	10	3	3	4	.5
Montana	7	7	0	0	.5
Nevada	117	72	39	6	2.0
New Mexico	10	10	0	0	.3
Oregon	24	11	12	1	.4
Utah	35	0	5	30	1.3
Washington	42	32	0	10	.5
Wyoming	7	0	1	6	.6

--Not reported.

Source: National Prisoner Statistics-1.

Table 2. Testing policies for the antibody to the human immunodeficiency virus that causes AIDS, by jurisdiction, 1991

All incoming inmates	All inmates currently in custody	All inmates at time of release	High risk groups	Upon inmate request	Upon clinical indication of need	Upon involvement in incident	Random sample	Other
Alabama	Rhode Island	Alabama	Arkansas	Alaska	Alaska	California	Arkansas	Hawaii ^c
Colorado	Utah	Federal	Connecticut	Arizona	Arizona	Florida	Dist. of Col.	Illinois
Georgia	Wyoming	Missouri	Dist. of Col.	Arkansas	California	Hawaii ^b	Federal	Mississippi
Idaho		Nevada	Illinois	California	Colorado	Kentucky	Maryland	New Jersey
Iowa		Wyoming	Indiana	Colorado	Connecticut	Louisiana	Massachusetts	New Mexico ^c
Michigan			Kentucky	Connecticut	Delaware	Maryland	New York	North Carolina
Mississippi			Minnesota	Delaware	Dist. of Col.	Massachusetts	Wyoming	Oregon
Missouri			New York	Dist. of Col.	Federal	Michigan		South Carolina
Nebraska			North Carolina	Federal	Florida	Minnesota		Tennessee ^a
Nevada			Ohio	Florida	Georgia	Missouri		Washington
New Hampshire			South Carolina	Georgia	Hawaii ^b	New Hampshire		Wisconsin ^c
North Dakota			South Dakota	Hawaii	Illinois	New Jersey		
Oklahoma			Tennessee ^a	Indiana	Indiana	New Mexico		
Rhode Island			Texas	Kansas	Kansas	New York		
Utah			West Virginia	Kentucky	Kentucky	Ohio		
Wyoming				Louisiana	Louisiana	South Carolina		
				Maine	Maryland	Tennessee ^a		
				Maryland	Massachusetts	Texas		
				Massachusetts	Michigan	Virginia		
				Michigan	Minnesota	Wyoming		
				Minnesota	Mississippi			
				Missouri	Missouri			
				New Hampshire	Montana			
				New York	New Hampshire			
				North Carolina	New Jersey			
				Ohio	New Mexico			
				Oregon	North York			
				Pennsylvania	North Carolina			
				Rhode Island	Ohio			
				South Carolina	Oregon			
				South Dakota	Pennsylvania			
				Tennessee ^a	Rhode Island			
				Texas	South Carolina			
				Vermont	Tennessee ^a			
				Virginia	Texas			
				Washington	Virginia			
				West Virginia	Washington			
				Wisconsin	West Virginia			
				Wyoming	Wisconsin			
					Wyoming			

Note: States could report more than one policy.
Source: National Prisoner Statistics-1.

^aFollowing CDC guidelines, counseling and inmate consent.

^bUpon inmate consent.

^cIncoming inmates upon consent.

Of the inmates who tested HIV-positive, 73.0% of them were asymptomatic and 17.3% had symptoms but had not developed AIDS. The remaining 9.7% had AIDS. The West had the highest percentage of HIV-positive inmates with confirmed AIDS (21.1%), compared to the Northeast (8.8%), Midwest (11.3%), and South (6.7%).

Prison policies for testing for HIV

All the States, the District of Columbia, and the U.S. Bureau of Prisons tested inmates for HIV on some basis (table 2).

Seventeen jurisdictions tested all prisoners, either at admission, release, or during custody. The remaining 35 jurisdictions tested at least some inmates.

Thirty-nine of the 52 jurisdictions tested if asked by an inmate and 40 if an inmate exhibited symptoms suggestive of HIV infection.

Testing policy	Number of jurisdictions
All incoming inmates	16
All inmates currently in custody	3
All inmates at time of release	5
High risk groups	15
Upon inmate request	39
Upon clinical indication of need	40
Upon involvement in incident	20
Random sample	7
Other	10

Note: Detail adds to more than total because a jurisdiction may have more than one policy.

Deaths in prison

During 1991, for every 1,000 inmates, 2.5 deaths occurred in State correctional facilities (table 3). Among the 10 States with the largest prison populations, New York had the highest rate of death, about 5.6 deaths per 1,000 inmates.

Table 3. Number of prison deaths per 1,000 inmates for all States and the 10 States with the largest prison populations, 1991

Jurisdiction	Total prison population 6/30/91	Total deaths, 1991	Rate of deaths per 1,000 inmates in 1991 midyear population*
All States	735,198	1,863	2.5
California	101,995	135	1.3
New York	56,530	318	5.6
Texas	50,611	111	2.2
Florida	46,233	133	2.9
Michigan	35,324	56	1.6
Ohio	33,715	41	1.2
Illinois	28,941	55	1.9
Georgia	23,300	62	2.7
Pennsylvania	22,710	83	3.7
New Jersey	22,346	96	4.3

*To calculate a rate of inmate deaths per 1,000 inmates, the midyear population is used as an approximation to the average population 'exposed to risk' of death during the year.
Source: National Prisoner Statistics-1.

AIDS-related deaths

Of the 1,863 deaths of prison inmates in 1991, 528 — or 28% — died of AIDS (table 4). In New York and New Jersey two-thirds of the reported deaths were caused by AIDS. These 2 States also had the largest number of AIDS related deaths, 210 in New York and 66 in New Jersey. Twenty-one States had no AIDS-related deaths.

Of inmates who died of AIDS in prison, 3% were women. Eleven of the 15 women who died of AIDS were imprisoned in the Northeast.

Extent of HIV testing of State prison inmates

Based on interviews with State prison inmates for the 1991 Survey of Inmates in State Correctional Facilities, about half of State prison inmates knew they had been tested for the HIV and reported the result of the test.

HIV testing	Percent of State prison inmates
Reported HIV-test results	51.2%
Had never been tested	32.2
Did not know if they had been tested	9.0
Had been tested but did not know the results	7.5
Refused to report whether they had been tested or refused to report the test results	.1
Total number of inmates	711,643

Source: Survey of Inmates in State Correctional Facilities, 1991

Table 4. AIDS-related deaths reported for State prisons, 1991

Jurisdiction	Total deaths	AIDS-related deaths			AIDS-related deaths as a percent of all deaths
		Total	Male	Female	
U.S. total*	1,863	528	513	15	28.3%
Northeast	612	315	304	11	51.5%
Connecticut	75	11	11	0	14.7
Maine	4	0	0	0	0
Massachusetts	27	8	8	0	29.6
New Hampshire	6	0	0	0	0
New Jersey	96	66	66	0	68.8
New York	318	210	199	11	66.0
Pennsylvania	83	19	19	0	22.9
Rhode Island	3	1	1	0	**
Vermont	0	0	0	0	0
Midwest	236	20	20	0	8.5%
Illinois	55	10	10	0	18.2
Indiana	27	5	5	0	18.5
Iowa	3	0	0	0	0
Kansas	10	2	2	0	20.0
Michigan	56	--	--	--	0
Minnesota	10	0	0	0	0
Missouri	20	0	0	0	0
Nebraska	2	0	0	0	0
North Dakota	0	0	0	0	0
Ohio	41	2	2	0	4.9
South Dakota	7	0	0	0	0
Wisconsin	5	1	1	0	**
South	775	148	145	3	19.1%
Alabama	52	0	0	0	0
Arkansas	22	1	1	0	4.5
Delaware	6	2	2	0	**
District of Columbia*	--	--	--	--	--
Florida	133	59	57	2	44.4
Georgia	62	13	13	0	21.0
Kentucky	22	2	2	0	9.1
Louisiana	35	0	0	0	0
Maryland	42	14	13	1	33.3
Mississippi	16	1	1	0	6.3
North Carolina	46	14	14	0	30.4
Oklahoma	32	3	3	0	9.4
South Carolina	49	12	12	0	24.5
Tennessee	37	1	1	0	2.7
Texas	111	18	18	0	16.2
Virginia	106	8	8	0	7.5
West Virginia	4	0	0	0	0
West	240	45	44	1	18.8%
Alaska	1	0	0	0	0
Arizona	34	4	4	0	11.8
California	135	38	37	1	28.1
Colorado	10	1	1	0	10.0
Hawaii	2	1	1	0	**
Idaho	7	1	1	0	**
Montana	8	0	0	0	0
Nevada	9	0	0	0	0
New Mexico	5	0	0	0	0
Oregon	15	0	0	0	0
Utah	4	0	0	0	0
Washington	9	0	0	0	0
Wyoming	1	0	0	0	0

**Not calculated on fewer than 10 deaths.

--Not reported.

*The Federal Bureau of Prisons and the departments of corrections for the District of Columbia and Michigan did not report whether inmates died from AIDS-related causes.

Source: National Prisoner Statistics-1.

Table 5. State prison inmates ever tested for the human immunodeficiency virus and results, by selected characteristics, 1991

Characteristic	Percent of all inmates who were ever tested	Tested inmates who reported results	
		Number	Percent who were HIV positive
All inmates	51.2%	364,515	2.2%
Sex			
Male	50.3%	338,608	2.1%
Female	66.8	25,907	3.3
Race/Hispanic origin			
White non-Hispanic	52.6%	132,594	1.1%
Black non-Hispanic	52.1	168,873	2.6
Hispanic	46.0	54,563	3.7
Other	50.5	8,485	.9
Sex and race/Hispanic origin			
Male			
White non-Hispanic	51.7%	123,020	1.0%
Black non-Hispanic	51.2	156,866	2.5
Hispanic	45.2	51,103	3.5
Female			
White non-Hispanic	68.3%	9,574	1.9%
Black non-Hispanic	67.3	12,007	3.5
Hispanic	62.7	3,460	6.8
Age			
24 or younger	50.2%	78,242	.8%
25-34	53.1	172,772	2.1
35-44	51.1	82,614	3.7
45-54	47.0	21,832	1.9
55 or older	41.0	9,105	.7
Offense			
Violent	47.9%	157,224	1.4%
Property	56.8	99,103	2.7
Drug	52.4	78,729	3.2
Public-order	52.1	25,266	2.1
Criminal history			
No previous sentence	47.6%	63,879	1.3%
Violent recidivists	50.3	171,302	2.0
Nonviolent recidivists	55.6	124,044	2.8

Source: Survey of Inmates in State Correctional Facilities, 1991.

Women were more likely than men to know if they had been tested and whether the results were positive or negative — as were non-Hispanics compared to Hispanics, those under age 45 compared to older prisoners, offenders imprisoned for property, drug, or public-order offenses compared to those in prison for violent offenses, and recidivists compared to first timers (table 5).

HIV test results, by inmate characteristics

For inmates reporting test results, a higher percentage of women than men tested HIV positive (3.3% to 2.1%). Hispanics were more likely than blacks and blacks were more likely than whites to have antibodies to HIV (3.7%, 2.6%, and 1.1%).

An estimated 6.8% of Hispanic women were HIV positive, as were 3.5% of black women and 3.5% of Hispanic men. Among white inmates, 1.9% of the women and 1% of the men were positive.

Inmates 35 to 44 years of age were more likely than those in other age groups to be HIV positive; 3.7% were positive.

Inmates in prison for drug, property, and public-order offenses were more likely than violent offenders to be HIV positive.

Recidivists were more likely to be HIV positive than inmates who had not previously served a sentence to either probation or a term in a correctional facility.

Table 6. State prison inmates testing positive for the human immunodeficiency virus, by drug and needle use, sex, race/Hispanic origin, age, and offense

Characteristic	Percent of State prison inmates who tested positive to HIV and who				
	Never used drugs	Ever used drugs	Used drugs in the month before offense	Used a needle to inject drugs	Shared a needle to inject drugs
All inmates	.8%	2.5%	2.8%	4.9%	7.1%
Sex					
Male	.7%	2.4%	2.7%	4.7%	6.7%
Female	.9	3.8	4.6	6.7	10.0
Race/Hispanic origin					
White non-Hispanic	.3%	1.2%	1.5%	2.4%	3.7%
Black non-Hispanic	1.1	2.9	3.2	7.2	11.1
Hispanic	.6	4.3	5.2	8.2	11.3
Age					
24 or younger	0	1.0%	.8%	.8%	2.0%
25-34	1.3	2.3	2.7	4.6	5.8
35-44	.9	4.3	5.2	7.0	10.3
45-54	.8	2.5	2.7	4.4	5.4
55 or older	2	2.1	0	0	0
Offense					
Violent	.9%	1.5%	1.4%	2.7%	3.8%
Property	.9	3.0	3.4	5.2	5.7
Drug	2	3.6	4.5	8.5	15.4
Public order	1.0	2.3	2.9	4.5	9.0

Note: See appendix table 1, page 8, for sample sizes upon which percentages are based. Source: Survey of Inmates in State Correctional Facilities, 1991.

HIV results, by drug and needle use

About a fourth of all State prison inmates had used a needle to inject illegal drugs.* About 4 in 10 inmates who had used drugs in the month before the offense for which they were sentenced had injected drugs at some time; about 2 in 10 had ever shared a needle.

For inmates reporting test results, drug users had higher positive HIV rates than inmates who never used drugs (2.5% versus 0.8%) (table 6). Needle use further increased the likelihood of being HIV positive; 4.9% of inmates who had used needles to inject drugs and 7.1% who had shared needles were HIV positive.

*See Survey of State Prison Inmates, 1991, BJS report, NCJ-136949, March 1993, p. 25.

Although women and men who never used drugs had the same HIV rates (less than 1%), those women who used drugs and who used needles had higher infection rates than men with the same drug practices. Ten percent of women and

6.7% of men who had ever shared needles when using drugs were HIV positive.

Of those who reported sharing needles to inject illegal drugs, 1 in 10 black inmates, Hispanic inmates, and inmates between ages 35 and 44 were HIV positive. Over 15% of those sentenced for drugs and who had shared needles were HIV positive.

HIV test results, by type of prison

Maximum, medium, and minimum security level prisons had essentially the same rates of HIV infection (table 7). Inmates held in prisons with unclassified security levels, such as facilities for classification or reception, reported a positive rate of 11.6%.

Percentages of HIV-positive prisoners increased with the size of the prison. The HIV-positive rate in facilities holding fewer than 500 was 1.1%, compared to 2.8% in prisons with 2,500 or more.

HIV testing policies in the largest jail jurisdictions

The jail jurisdictions that were among the 25 largest in 1991 were asked what testing policies they were following. Sixteen jurisdictions tested when ordered by a court, and 12 checked high risk groups. Two jurisdictions tested all inmates at admission in at least one facility: Philadelphia, Pennsylvania, and Fulton County (Atlanta), Georgia.

Deaths in 503 large jail jurisdictions

AIDS-related deaths in local jails, 1991-92

Cause of death	Number
Total	445
AIDS	107
Other	338

Of the 445 deaths during the year ending June 30, 1992, in jail jurisdictions with average daily inmate populations of 100 or more, 24% were reported to be AIDS related.

Table 7. State prison inmates testing positive for human immunodeficiency virus, by security level and size of facility, 1991

State prison characteristic	Number of inmates reporting test results	Percent positive
Security level		
Maximum	89,440	2.0%
Medium	183,172	2.0%
Minimum	85,804	2.1%
Unclassified*	6,099	11.6%
Prison size		
Fewer than 500	72,097	1.1%
500-999	121,166	2.2%
1,000-2,499	117,094	2.5%
2,500 or more	54,159	2.8%

*Pre-release, work release, or medical facilities. Source: Survey of Inmates in State Correctional Facilities, 1991.

Table 8. Policies determining testing for the antibody to the human immunodeficiency virus in the 25 largest jail jurisdictions, 1992

One or more facilities in the 25 largest jail jurisdiction testing					
All inmates at admission	Random samples of inmates while in custody	High risk groups	Upon inmate request	Upon court order	Upon involvement in incident
Fulton Cty., GA Philadelphia, PA	Riverside Cty., CA Sacramento Cty., CA San Diego Cty., CA Broward Cty., FL Fulton Cty., GA New York City, NY	Alameda Cty., CA Riverside Cty., CA Sacramento Cty., CA San Bernardino Cty., CA Santa Clara Cty., CA Dade Cty., FL Fulton Cty., GA Orleans Parish, LA* New York, NY Shelby Cty., TN Bexar Cty., TX* Dallas Cty., TX*	Maricopa Cty., AZ Alameda Cty., CA Kern Cty., CA Los Angeles Cty., CA* Los Angeles Cty., CA* Orange Cty., CA Riverside Cty., CA Sacramento Cty., CA San Bernardino Cty., CA San Diego Cty., CA Santa Clara Cty., CA Washington, DC* Washington, DC* Broward Cty., FL* Dade Cty., FL Dade Cty., FL Orange Cty., FL* Fulton Cty., GA Orleans Parish, LA* Baltimore City, MD New York City, NY Philadelphia, PA Shelby Cty., TN Bexar Cty., TX* Dallas Cty., TX* Harris Cty., TX* Tarrant Cty., TX	Alameda Cty., CA Kern Cty., CA Los Angeles Cty., CA* Orange Cty., CA Riverside Cty., CA Sacramento Cty., CA San Bernardino Cty., CA San Diego Cty., CA Santa Clara Cty., CA Washington, DC* Broward Cty., FL* Dade Cty., FL Orange Cty., FL* New York, NY Bexar Cty., TX* Harris Cty., TX*	Alameda Cty., CA Los Angeles Cty., CA* Orange Cty., CA Riverside Cty., CA Sacramento Cty., CA San Bernardino Cty., CA San Diego Cty., CA Broward Cty., FL* Dade Cty., FL Orleans Parish, LA*

*Jurisdictions in which all facilities reported following the same policy to test for the HIV or in which authorities reported jurisdiction-wide policies. All other jurisdictions had one or more facilities with different testing policies. In some jurisdictions, facilities that differed were following policies not presented in the table. Cook County, Illinois, provided no information.

Methodology

Data sources

The data collection series National Prisoner Statistics has counted prisoners since 1926. The series provides annual summary measures of the movement of persons into and out of prison systems. At midyear and yearend, departments of corrections in the 50 States, the District of Columbia, and the Federal prison system are asked to provide basic numbers describing their prison population.

The Annual Survey of Jails was begun in 1982. For this survey complete enumerations of the Nation's jails are conducted every 5 years. The most recent census was in 1988. The sample for the 1992 survey was based on that census.

A local jail is a facility that holds inmates beyond arraignment, usually for more than 48 hours, and is administered by local officials. Specifically excluded from the counts of the Annual Survey of Jails are temporary lockups that house persons for less than 48 hours, physically separate drunk tanks, and other holding facilities that did not hold persons after they had been formally charged. Excluded from the Annual Survey of Jails and instead included in the National Prisoner Statistics series are Federal- or State-administered facilities, and the combined jail-prison systems of Alaska, Connecticut, Delaware, Hawaii, Rhode Island, and Vermont. Included in the Annual Survey of Jails are five locally operated jails in Alaska and eight jails that were privately operated under contract for local governments.

The 1992 Annual Survey of Jails included 1,113 jails in 795 jurisdictions. A jurisdiction is a county, municipality, township, or regional authority that administers one or more local jails. The jails in 503 large jurisdictions were automatically included in the survey because the average daily inmate population in these jurisdictions was 100 or more in the 1988 census. The jurisdictions with large jail populations accounted for 814 jails and 362,217 inmates, or 81% of the estimated inmate population on June 30, 1992.

In 1992, the 25 jail jurisdictions that were the largest in 1991 were asked if any inmates were tested for HIV, and, if so, on what basis were inmates tested. They

Appendix table 1. Denominators for percents presented in table 6

	State prison inmates				
	Never used drugs	Ever used drugs	Used drugs in the month before offense	Used a needle to inject drugs	Shared a needle to inject drugs
All inmates	66,048	298,373	191,422	105,082	50,509
Sex					
Male	61,668	276,884	176,639	95,219	45,254
Female	4,380	21,489	14,784	9,883	5,255
Race/Hispanic origin					
White non-Hispanic	22,492	110,102	70,639	50,737	24,996
Black non-Hispanic	33,244	135,535	84,228	31,400	13,374
Hispanic	8,849	45,714	32,026	19,928	10,331
Age					
24 or younger	13,651	64,592	42,818	12,729	4,499
25-34	23,494	149,190	96,677	49,532	23,143
35-44	14,027	68,531	43,409	36,255	18,807
45-54	8,323	13,509	7,671	5,941	3,583
55 or older	6,554	2,551	847	625	476
Offense					
Violent	35,846	121,379	76,276	38,498	19,293
Property	13,762	85,261	55,908	37,120	17,912
Drug	9,723	69,006	47,846	21,841	10,136
Public-order	5,095	20,157	9,811	6,874	2,854

were also asked the number of males and females who were asymptomatic, symptomatic, and full-blown AIDS victims.

The 1991 Survey of Inmates in State Correctional Facilities uses personal interviews of a representative sample of prison inmates to gather detailed information on prison inmates. Data are collected on personal and criminal justice characteristics of prison inmates.

The sample for the Survey of Inmates in State Correctional Facilities was a two-stage selection. In the first stage 277 prisons were selected from a universe of 1,239 State prisons. In the second stage interviewers visited each selected facility and systematically selected a sample of male and female inmates using predetermined procedures. As a result, approximately 1 in every 52 male inmates and 1 in every 11 female inmates were selected. A total of 13,986 interviews were completed, yielding an overall response rate of 93.7%.

The data reported from the BJS surveys supplement those collected in a survey series sponsored by the National Institute of Justice and the Centers for Disease Control and Prevention. A forthcoming report *1992 Update: HIV/AIDS in Correctional Facilities*, will present findings from the seventh in the series, which did not cover 1991. The 1992 update contains reporting about prevalence, testing, treatment, and education for HIV and AIDS in Federal, State, and 31 large city/county

correctional systems. A subsequent report will summarize collected information on testing, treatment, and education for tuberculosis in correctional settings.

Accuracy of the estimates

All data collection series are subject to nonsampling error. Nonsampling error can be attributed to many sources, such as nonresponse, differences in the interpretation of questions, recall difficulties, and processing errors. The full extent of nonsampling error is never known. Surveys, such as the Survey of Inmates in State Correctional Facilities, are also subject to sampling error. Sampling error is the variation that may occur by chance because a sample rather than a complete enumeration of the population was conducted.

The sampling error, as measured by an estimated standard error, varies by the size of the estimate and the size of the base population. Estimates of the standard errors have been calculated for the 1991 survey of inmates (see appendix table and *Survey of State Prison Inmates, 1991*). These estimates may be used to construct confidence intervals around percentages in this report. For example, the 95-percent confidence interval around the percentage of inmates who tested positive for HIV is approximately 2.2% plus or minus 1.96 times 0.05% (or 1.7% to 2.7%).

These standard errors may also be used to test the significance of the difference between two sample statistics by pooling the standard errors of the two sample estimates. For example, the standard error of the difference between black and white inmates in the percent testing positive for HIV would be .547% (or the square root of the sum of the squared standard errors for each group). The 95-percent confidence interval around the difference would be 1.96 times .547% (or 1.1%). Since the difference of 1.5% (2.6% minus 1.1%) is greater than 1.1%, the difference would be considered statistically significant.

All comparisons using data from the Survey of Inmates in State Correctional Facilities were statistically significant at the 95-percent confidence level. To test the significance of comparisons not mentioned in the report, use percentages in text or tables. The standard errors reported below should be used only for tests on all inmates. Comparisons of male and female inmates require different standard errors.

Appendix table 2. Standard errors of the estimated percentages, State prison inmates, 1991

Base of the estimate	Estimated percentages					
	98 or 2	95 or 5	90 or 10	80 or 20	70 or 30	50
1,000	4.9	7.7	10.6	14.1	16.2	17.7
5,000	2.2	3.4	4.7	6.3	7.2	7.9
10,000	1.6	2.4	3.4	4.5	5.1	5.6
25,000	1.0	1.5	2.1	2.8	3.2	3.5
50,000	0.7	1.1	1.5	2.0	2.3	2.5
100,000	0.5	0.8	1.1	1.4	1.6	1.8
200,000	0.4	0.5	0.8	1.0	1.1	1.2
400,000	0.2	0.4	0.5	0.7	0.8	0.9
600,000	0.2	0.3	0.4	0.6	0.7	0.7
711,843	0.2	0.3	0.4	0.5	0.6	0.7

Bureau of Justice Statistics Special Reports are written principally by BJS staff. Caroline Wolf Harlow wrote this report, under the supervision of Allen Beck. Virginia Baldau and Cheryl Crawford of the National Institute of Justice, Theodore Hammett of Abt Associates Inc. and William Darrow, Steven Jones, and Sandra Kerr of the Centers for Disease Control and Prevention gave expert advice on measurement and presentation of the HIV-related data collected. Louis Jankowski provided statistical assistance. Corrections reports are produced under the general guidance of Lawrence A. Greenfeld. Tom Hester edited the report. Marilyn Marbrook, assisted by Betty Sherman and Jayne Pugh, produced the report.

September 1993, NCJ-143292



MEMORANDUM

*orig. file
xc of all: Debbie*

To: Carol Rasco

From: Kevin Thurm

Re: Status of gp-160 trials *file*

Attached for your information is all of the relevant information and correspondence pertaining to the gp-160 issue.



August 20, 1993

BY MESSENGER

Honorable Jamie S. Gorelick
General Counsel
U.S. Department of Defense
Office of the Secretary of Defense
Washington, D.C. 20301

Dear Jamie:

I have seen today's public announcement that the Department of Defense (DoD) is preparing to start a large scale single vaccine trial of MicroGeneSys gp 160 AIDS vaccine. It seems appropriate, nonetheless, that I write to make clear the continuing readiness of the Department of Health and Human Services (HHS) to direct a multi-vaccine, multi-year clinical trial of potential AIDS vaccines (including MicroGeneSys gp 160). Let me review the events that underpin that proposal.

The October, 1992, appropriation to the Department of Defense contemplated a test of gp 160 to be carried out by DoD unless, within six months of the appropriation, DoD, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) certified in writing that the clinical investigation should not proceed. [Attachment 1]. You will recall that the NIH [Attachment 2] and the FDA [Attachment 3] both so certified. I call your attention to the fact that the NIH certification was based on deliberations of a panel of experts comprised of NIH and FDA scientists and officials, DoD representatives and others. [Attachment 2 at page 1] The NIH submission specifically recommended that "...the large-scale clinical trial of a therapeutic vaccine for HIV should be designed to study several products, including the MicroGeneSys gp 160 candidate vaccine and other vaccine candidates from among those now being developed...". [Attachment 2 at page 2]

In Late March and early April, 1993, the DoD engaged in discussions with HHS regarding a mutual agreement to conduct a large-scale, multi-vaccine (including gp 160) test under the direction of HHS. HHS was to receive, by formal agreement, \$20 million appropriated to DoD for the purpose of carrying out the test. During those discussions, HHS made clear its intention to continue its longstanding practice of requiring that manufacturers donate the vaccine to be tested. It was further

Honorable Jamie S. Gorelick
August 20, 1993
Page Two

understood that \$20 million was adequate to cover the costs of a multi-vaccine trial if, but only if, the vaccine was donated. Though the discussions between DoD and HHS reached an understanding on these points, no memorandum was finalized once it became evident that MicroGeneSys was demanding \$10 million as the purchase price of its vaccine.

I called you soon after you became DoD General Counsel to discuss the foregoing. You asked for some time to discuss with your colleagues the then-current state of events since much of the above-described history pre-dated your arrival at DoD. You then sent me a letter on June 14, 1993 [Attachment 4] which stated in pertinent part,

NIH now does not wish to proceed unless the vaccine to be tested is donated by the manufacturer, which it has resisted. As you may be aware, this is a condition that was not part of the original agreement and we have all been advised that the manufacturer would likely find it unacceptable.

Because the facts about NIH's interest in proceeding with the multi-vaccine trial were not as your letter represented them, I responded on June 21, 1993, [Attachment 5] correcting that misimpression and reporting that HHS had been making efforts to persuade MicroGeneSys to alter its donation decision. I received no response to my letter. Unfortunately, the manufacturer continued to insist on payment.

On July 13, 1993, [Attachment 6], I again wrote to you continuing the HHS offer should the vaccine become available through donation, to commence the multi-vaccine trial. I was prompted to write on July 13, by a news article suggesting that if MicroGeneSys donated its vaccine, DoD would undertake the test. [Attachment 7].

I then received your letter of July 26, 1993 [Attachment 8] stating that HHS had decided not to proceed with the agreement to do a multi-vaccine test. That was precisely the opposite of the point of both my June 21 and July 13 letters.

On August 17, 1993, [Attachment 9], my Deputy General Counsel had a conversation with your colleague, John Casciotti, who informed him that your Department had decided to commence a three year, single vaccine trial of gp 160. Mr. Casciotti stated that the manufacturer will donate the vaccine for the first year of the trial and then will assess whether to continue providing the vaccine at no cost for the remaining two years of the trial.

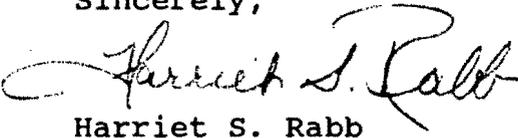
Honorable Jamie S. Gorelick
August 20, 1993
Page Three

Finally, this morning I received a fax from John McNeill, your Acting General Counsel, in which he stated that, the Army was also unsuccessful in obtaining agreement from MicroGeneSys to donate the amount of vaccine needed for the trial. However, MicroGeneSys did obtain investment sponsorship for one-third of the vaccine needed. Accordingly, the Walter Reed Army Institute of Research (WRAIR) has reluctantly agreed to begin the proposed three-year trial without a commitment from the company for donation of all of the vaccine needed for the trial. Continuation of the project beyond the first year remains contingent upon a subsequent agreement of the parties; WRAIR and MicroGeneSys have signed an agreement to this effect.

Let me reiterate the position of HHS now and from the outset. This Department is ready and willing to undertake a multi-vaccine (including MicroGeneSys gp 160), multi-year clinical trial of potential AIDS vaccines. One requirement precedent to going forward with that test now and always has been that the manufacturer donate the vaccine to be tested. If and when gp 160 is available through donation to undertake and complete the full clinical trial, HHS is ready to enter into the agreement that would make \$20 million available from the Department of Defense for this purpose and to commence the trials forthwith.

I apologize for the length of this letter, but I wanted to be certain that you understand the matter from my perspective and see the full documentary history on which my understanding of these events rests. Should you have any questions about the foregoing, please do not hesitate to contact me.

Sincerely,



Harriet S. Rabb

Attachments 1-9



replacement only; and expansion of public and private plants, Government-owned equipment and installation thereof in such plants, erection of structures, and acquisition of land, for the foregoing purposes, and such lands and interests therein, may be acquired, and construction prosecuted thereon, prior to approval of title; reserve plant and Government and contractor-owned equipment layaway; \$7,686,524,000, to remain available for obligation until September 30, 1995.

NATIONAL GUARD AND RESERVE EQUIPMENT

For procurement of aircraft, missiles, tracked combat vehicles, ammunition, other weapons, and other procurement for the reserve components of the Armed Forces; \$1,567,200,000, to remain available for obligation until September 30, 1995.

PROCUREMENT, DEFENSE AGENCIES

For expenses of activities and agencies of the Department of Defense (other than the military departments) necessary for procurement, production, and modification of equipment, supplies, materials, and spare parts thereof, not otherwise provided for; the purchase of not to exceed 1 vehicle required for physical security of personnel, notwithstanding price limitations applicable to passenger vehicles but not to exceed \$10,000 per vehicle; the purchase of not to exceed 565 passenger motor vehicles, of which 554 shall be for replacement only; expansion of public and private plants, equipment, and installation thereof in such plants, erection of structures, and acquisition of land for the foregoing purposes, and such lands and interests therein, may be acquired, and construction prosecuted thereon prior to approval of title; reserve plant and Government and contractor-owned equipment layaway; \$1,962,058,000, to remain available for obligation until September 30, 1995.

TITLE IV

RESEARCH, DEVELOPMENT, TEST AND EVALUATION

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, ARMY

For expenses necessary for basic and applied scientific research, development, test and evaluation, including maintenance, rehabilitation, lease, and operation of facilities and equipment, as authorized by law; \$6,032,860,000, to remain available for obligation until September 30, 1994: *Provided*, That the general reduction of \$180,583,000 taken against the appropriation level provided herein, shall be applied, except for the \$210,000,000 for breast cancer research, on a pro rata basis by subproject within each R-1 program element as modified by this Act: *Provided further*, That \$210,000,000 of the funds appropriated in this paragraph shall be available for a peer reviewed breast cancer research program with the Department of the Army as executive agent: *Provided further*, That the Army shall coordinate with the Armed Services Biomedical Research and Evaluation Management (ASBREM) Committee to involve facilities and medical and research personnel of the Department of the Navy and the Department of the Air Force, or other entities, in addition to facilities, medical and

Reports.

research personnel, and resources of the Department of the Army in the breast cancer research program: *Provided further*, That the Department of the Army, as executive agent, shall provide a report to the congressional defense committees not later than June 1, 1993, setting forth the details of the breast cancer research program, noting inter alia the benefits which may be achieved through such research in the reduction of future costs of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS): *Provided further*, That \$7,500,000 of the funds in this paragraph shall be made available only for establishment of a flexible manufacturing center at the Scranton Army Ammunition Plant and may be transferred to another appropriation in title III of this Act: *Provided further*, That \$2,000,000 shall be made available only for the Center for Prostate Disease Research at the Walter Reed Army Institute of Research: *Provided further*, That \$3,000,000 shall be made available only for synaptic transmission research: *Provided further*, That \$20,000,000 of the funds appropriated in this paragraph may be made available in the Acquired Immune Deficiency Syndrome program element only for a large-scale Phase III clinical investigation of the GP-160 vaccine: *Provided further*, That the funds referred to in the preceding proviso may be obligated unless, within six months after the date of the enactment of this Act, the Secretary of Defense, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs submit to the Committees on Appropriations of the Senate and House of Representatives a written certification containing a determination of such officials that the large-scale Phase III clinical investigation should not proceed, the reasons for that determination, and an assessment of the GP-160 vaccine: *Provided further*, That if such certification is presented, the Secretary of Defense may use these funds only for other AIDS research needs of the Department of Defense: *Provided further*, That of the funds appropriated in this paragraph for medical technology, \$4,000,000 may be used for Assistive Technology Center at the National Rehabilitation Hospital.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, NAVY

For expenses necessary for basic and applied scientific research, development, test and evaluation, including maintenance, rehabilitation, lease, and operation of facilities and equipment, as authorized by law; \$8,930,381,000, to remain available for obligation until September 30, 1994: *Provided* That for continued research and development programs at the National Center for Physical Acoustics, centering on ocean acoustics as it applies to advanced antisubmarine warfare acoustics issues with focus on ocean bottom acoustics, seismic coupling, sea-surface and bottom scattering, oceanic ambient noise, underwater sound propagation, bubble related ambient noise, acoustically active surfaces, machinery noise, propagation physics, solid state acoustics, electrorheological fluids, transducer development, ultrasonic sensors, and other such projects as may be agreed upon, \$1,000,000 shall be made available, as a grant, to the Mississippi Resource Development Corporation, of which not to exceed \$250,000 of such sum may be used to provide such special equipment as may be required for particular projects: *Provided further*, That none of the funds appropriated in this paragraph or in Title IV of Public Law 102-172 may be obligated or expended to develop or purchase equipment for an Aegis



MAR 31 1993

The Honorable William H. Natcher
Chairman
Committee on Appropriations
H 218 - The Capitol
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Natcher:

The 1993 Department of Defense Appropriations Act provided \$20 million "for a large scale Phase III clinical investigation of the gp160 vaccine....." The appropriation language specified that the funds be obligated "unless, within six months after the date of the enactment of this Act, the Secretary of Defense, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs submit to the Committees on Appropriations of the Senate and the House of Representatives a written certification containing a determination of such officials that the large scale Phase III clinical investigation should not proceed, the reasons for that determination, and an assessment of the gp 160 vaccine....."

In response to that directive, the National Institutes of Health convened a panel of experts to assist in providing the scientific advice requested concerning the merit of proceeding with the proposed large scale clinical investigation. The gp160 Panel was comprised of NIH and FDA scientists and officials, DoD representatives, university scientists, representatives from the pharmaceutical industry, members of health advocacy organizations, and experts from nursing, medical ethics, and law. (Attachment 1)

The full Panel met on November 5 and November 23, 1992 to address the following essential questions: (Attachment 2)

- What is the current scientific assessment of the MicroGeneSys gp160 vaccine candidate as a therapeutic agent?
- Based on gp160's scientific merits, should a large-scale efficacy trial be initiated in HIV-seropositive individuals?
- What role should NIH play in reviewing proposals for such a large-scale clinical trial?

- Should other promising vaccine candidate products be included for comparative purposes in a large-scale clinical efficacy trial?

In addition, a gp160 Trial Design Team was established to develop a proposal for the design of an efficacy trial of gp160 and other therapeutic vaccine candidates. The design team developed a protocol to serve as an experimental framework for the proposed study and prepared a paper that addresses the key issues and options concerning the design and conduct of the study. (Attachment 3) These documents were reviewed at a January 28, 1993 meeting of a Subcommittee of the gp160 Panel and revised to incorporate several changes recommended by the Subcommittee to delineate priorities within the plan and to keep the clinical trial within the \$20 million budget designated by Congress. (Attachments 4 & 5)

On the basis of the deliberations of the Panel and its subcommittees--and relying on non-traditional scientific criteria and other considerations that arise from the unique nature of the HIV epidemic--the gp160 Panel recommended that the funds designated in the Department of Defense appropriation should be used to begin a large-scale clinical efficacy trial of therapeutic HIV vaccines. However, the Panel recommended that:

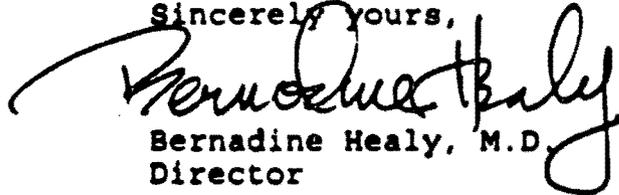
- The large-scale clinical trial of a therapeutic vaccine for HIV should be designed to study several products, including the MicroGeneSys gp160 candidate vaccine and other vaccine candidates from among those now being developed by Genentech, Chiron-Biocrine, ImmunoAG, and Immunization Products Limited.
- The large-scale clinical trial should not be limited to military personnel and veterans, and should include a broad-based civilian population group, extending to underrepresented minorities, injecting drug users, and others among whom the incidence of HIV infection is high.
- The clinical trial should focus on HIV-infected individuals whose CD4+ T cell counts range between 200/mm³ and 500/mm³. Expansion of the trial to include individuals with less than 200/mm³ should be contingent on results from current Phase I studies of the vaccine candidates indicating whether the products are appropriately immunogenic.
- The primary objective of the trial--determining the clinical efficacy of therapeutic vaccines in HIV-infected individuals--should be assessed by measuring progression to marker diseases and mortality. A secondary objective of the trial, evaluating the correlation between CD4+ T cell counts and clinical outcomes, should also be met (with a focus on participants with CD4+ T cell counts between 200/mm³ and 500/mm³).

Page 3 - The Honorable William H. Nacher

- Appropriate samples also should be collected and stored for future analysis of other potential surrogate markers of efficacy, particularly quantitative HIV microculture determinations.

It is against this backdrop that I endorse and forward to you the above recommendations of the gp160 Panel and the protocol and issue paper developed by the gp160 Trial Design Team.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Bernadine Healy". The signature is written in black ink and is positioned above the printed name and title.

Bernadine Healy, M.D.
Director



April 1, 1993

The Honorable William H. Natcher
Chairman
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The 1993 Department of Defense Appropriations Act provided \$20 million "for a large scale Phase III clinical investigation of the GP-160 vaccine...." Furthermore, the appropriation language specified that the funds be obligated "unless, within six months after the date of the enactment of this Act, the Secretary of Defense, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs submit to the Committees on Appropriations of the Senate and the House of Representatives a written certification containing a determination of such officials that the large scale Phase III clinical investigation should not proceed, the reasons for that determination, and an assessment of the GP-160 vaccine."

To address this appropriation, the National Institutes of Health (NIH) convened a panel of experts to provide advice and recommendations concerning the proposed therapeutic HIV vaccine efficacy trial. The panel proposed a design for an efficacy trial that could evaluate the clinical benefit of the candidate vaccines to trial participants. The Food and Drug Administration (FDA) participated in all of these panel meetings and contributed to the work products of these meetings, including the issue paper from the GP-160 Trial Design Team. In addition, the Department of Defense (DoD) held a separate DoD GP-160 Panel meeting with its own group of experts that FDA attended as a nonvoting observer and commentator. At this DoD meeting, issues such as the minimum criteria for vaccine candidate selection were productively discussed.

The recommendations of the NIH GP-160 Panel, the issue paper developed by the NIH GP-160 Trial Design Team, and the list of participating experts have been forwarded to you under a separate letter from the NIH.

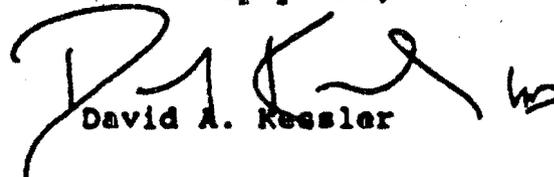
The FDA concurs with the concept of conducting an efficacy trial with several therapeutic HIV vaccines. Specifically, FDA considers the trial design proposal discussed at the NIH GP-160

Panel Subcommittee Meeting of January 28, 1993¹ to be a reasonable approach for this clinical trial. However, the plan to conduct this trial should be considered in the context of the statutory regulatory review and licensure process. FDA will review the product information and the results of animal and human studies on a case-by-case basis to determine if each proposed product is suitable for use in an efficacy trial for the intended patient population. To facilitate the process, the FDA will continue to assist the DoD and the NIH with the further development of the clinical protocol and related issues, and provide other support as requested, such as assistance with candidate vaccine selection. The final trial design should be reviewed by FDA and the trial must be conducted in accordance with FDA regulations.

It should be emphasized that conducting an efficacy trial does not guarantee licensure. FDA will review the trial results for each product and, in consultation with FDA advisory committee members and other experts, determine whether or not the data support licensure for specific patient populations.

We hope that this appropriation will advance the development of effective AIDS therapeutics.

Sincerely yours,



David A. Kessler

cc: The Honorable Joseph P. McDade
Ranking Minority
Committee on Appropriations
House of Representatives

The Honorable Robert Byrd
Chairman
Committee on Appropriations
United States Senate

The Honorable Mark O. Hatfield
Ranking Minority
Committee on Appropriations
United States Senate

¹ Described in the February 16, 1993 Summary Report of the NIH gp160 Panel Subcommittee meeting of January 28, 1993.



GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE

WASHINGTON, D.C. 20301-1600

June 14, 1993

Honorable Harriet Rabb
General Counsel
Department of Health and Human Services
Washington D.C. 20201

Dear Harriet:

This is to follow up on our recent telephone conversations concerning implementation of the gp160 vaccine clinical trial mandated by the Department of Defense Appropriations Act, 1993, Pub. L. 102-396 (Oct. 6, 1992).

As you know, on April 7, the Department of Health and Human Services and the Department of Defense agreed that the \$20 million appropriation for this project should be transferred, under the authority of the Economy Act, from the Department of the Army to the National Institutes of Health in order for the trial to be conducted through established NIH clinical research structures. To consummate the agreement, the Army provided to NIH the necessary funding document, a "Military Interdepartmental Purchase Request" (MIPR), on April 9, with a request that it be signed and returned by April 23. As agreed by HHS and DoD, the MIPR contained only the stipulation that NIH assure compliance with the statute. The funding transfer document has not yet been signed by NIH. In our conversations, you have suggested that NIH now does not wish to proceed unless the vaccine to be tested is donated by the manufacturer, which it has resisted. As you may be aware, this is a condition that was not part of the original agreement and we have all been advised that the manufacturer would likely find it unacceptable.

We are very concerned about the delay in bringing this matter to closure. Without an NIH signature on the MIPR, the project remains DoD's legal responsibility, but relying on the HHS-DoD agreement, the Army stopped all implementation activities. As long as this circumstance persists, the project remains in limbo, with no clear basis to assure interested parties of the Administration's commitment to carrying out the statutory direction.

As we see it, there are three main options at this juncture:

1. NIH could sign the MIPR, as per the HHS-DoD April 7 agreement.
2. If it is the HHS conclusion that there is a legal or

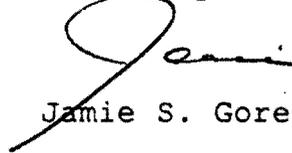
other problem in NIH's planned execution, HHS could propose a legislative solution. Assuming endorsement as Administration policy, DoD would certainly support any such legislative proposal. Under this option, NIH could sign the MIPR, and note the intention to seek a legislative amendment.

3. NIH could return the MIPR unsigned. The Army would then proceed with its original implementation plan (including the invitation to NIH to support expansion of the project to include other vaccines).

DoD will support whichever of these options HHS selects. However, it is necessary that a decision be made promptly. Because DoD continues to be legally responsible for this project, we request a decision within ten days of this date.

If we can do anything to assist you, please advise. Thank you for your attention.

Sincerely,



Jamie S. Gorelick



June 21, 1993

Honorable Jamie S. Gorelick
General Counsel of the Department of Defense
Office of the Secretary of Defense
Washington, D.C. 20301

Dear Jamie,

I just today got your letter of June 14 discussing next steps in the matter of a gp160 clinical trial. The Department of Health and Human Services ("HHS") made clear from the outset that the only way that a multi-vaccine trial could be undertaken for \$20 million was on the expectation that the manufacturer of gp160 (and makers of the other vaccines to be tested simultaneously) would donate the vaccine to be used in the trial. The vaccine donation requirement is long-standing HHS practice and was explicitly referenced in meetings with the Defense Department during the negotiation and discussions of the prospective trial. I know you were not yet at the Department when these events occurred, occasioning, I expect, your not realizing that the discussion of vaccine donation was quite explicit from the outset.

When we spoke on the telephone about this matter during the third week of April, I mentioned that a high-level member of HHS' staff was making one more effort to persuade the manufacturer of gp160, through the intervention of others, to donate the vaccine so that the trial could proceed. That effort has not produced positive results. This Department is not in a position to go forward with the multi-vaccine test unless and until that situation changes and the vaccine is made available, without cost, so that the trial can proceed.

Your letter suggests next steps. We agree that we should not go forward with the Military Interdepartmental Purchase Request and, instead, the Army could proceed with its original plan regarding a gp160 trial.

Please let me know what your decision is.

Sincerely,

Harriet S. Rabb



July 13, 1993

Honorable Jamie S. Gorelick
General Counsel of the Department of Defense
Office of the Secretary of Defense
Washington, D.C. 20301

Dear Jamie,

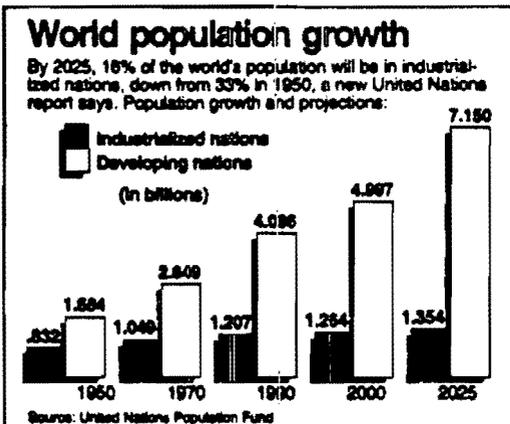
A recent news story (copy attached) reported that if MicroGeneSys donates its gp 160 vaccine, the Department of Defense will proceed with the drug trials about which your Department and mine have been in discussion much of this Spring and early Summer.

I am writing to reiterate the readiness of the Department of Health and Human Services to stand by its commitment to undertake a multi-vaccine test of gp 160 should the vaccine be donated for that purpose by its manufacturer. Indeed, the unavailability of that donation was the sole obstacle to getting the NIH/FDA-recommended multiple vaccine testing underway. Prior efforts to persuade MicroGeneSys to supply its vaccine without cost failed. If you reverse the manufacturer's decision, the Department of Health and Human Services would commence work on the multi-vaccine trials expeditiously.

Please advise me should the Department of Defense succeed in securing gp 160 for a multi-vaccine trial that we have committed to undertaking.

Sincerely,

Harriet S. Rabb



USA Today; 7-6-93 By J.L. Alber, USA TODAY

U.N. report: HIV infections will triple by century's end

By Juan J. Walte
USA TODAY

QA

The number of people infected with the AIDS virus will more than triple to 40 million by the end of the century, says a U.N. population and migration report out today.

The 1993 report by the United Nations Population Fund says that as of January about 13 million men, women and children had been infected with the HIV virus worldwide.

"There were an estimated 1 million new infections in the second half of 1992, the majority in south and southeast Asia and in sub-Saharan Africa," says the 54-page study.

Using figures from the World Health Organization, the reports adds that as many as 1 million people will die of AIDS annually by century's end.

The assessment of world population and migration adds that there are an estimated 100 million refugees worldwide.

Some highlights:

► Women make up almost half of all immigrants or refugees forced to move.

► Money sent by international migrants home amounts to \$68 billion, second only to oil in its value to the global economy.

► Earth's population will reach nearly 5.6 billion by the end of this year, compared with 2.5 billion in 1950.

Wash. Post; 7-6-93

Army May Hold Up AIDS Vaccine Trial

Drug to Be Tested Only If Maker Donates It

By Sally Squires
Washington Post Staff Writer

A13

A \$20 million planned trial of an experimental AIDS vaccine has become a political ping-pong ball since Congress ordered the study last fall. After being bounced from the Department of Defense to the National Institutes of Health, it has landed back at DOD, where Army researchers said they will now conduct the study—maybe.

The Army confirmed Friday that it will test the drug, VaxSyn, provided that its manufacturer, MicroGeneSys, of Meriden, Conn., donates enough vaccine for the study, which would involve about 6,000 HIV-infected people.

"Right now the only thing that stands between us and proceeding with the trial is the availability of the vaccine for free from the company," said Col. Donald S. Burke, director of the Division of Retrovirology at the Walter Reed Army Institute of Research.

But that was the stumbling block that this spring prevented a similar trial of VaxSyn by NIH. Sources said it may kill the Army study as well unless a compromise can be reached.

It is standard policy for drug manufacturers to donate experimental products for testing by federal researchers at NIH or other agencies.

NIH has considerable influence in deciding which AIDS drugs will be tested. But after MicroGeneSys's chief executive officer, Franklin Volvovits, ran into problems getting VaxSyn tested by NIH, he hired former senator Russell B. Long (D-La.) last fall as a lobbyist. In October, in an unusual move, Congress mandated that the Defense Department conduct this particular study and allocated \$20 million to pay for it, including purchase of the vaccine. The money was added to an amendment to the defense appropriations bill.

Because of its large system of medical facilities, the Defense Department plays a major role in AIDS drug research, including trials on civilians. Army researchers were among the first to test therapeutic AIDS vaccines.

The bill specified testing only one product: a therapeutic vaccine made from a tiny piece of outer en-

velope of the AIDS virus. Therapeutic vaccines are not designed to prevent infection but to slow disease progression for people infected with HIV.

Several companies, including Genentech and Chiron-Biocrine, also are developing therapeutic AIDS vaccines. But MicroGeneSys had the only product far enough along in development to enter the clinical trial, and it was the sole beneficiary of the legislation.

The congressional mandate drew sharp criticism from many AIDS researchers and activists. NIH convened an expert panel that met last fall to review the trial and voted unanimously to go ahead. But the panel added the condition that VaxSyn should be tested against other related products and that participants in the study should include a broad representation of HIV-infected individuals, not just military personnel or patients in the Veterans Affairs system.

But the original legislation did not specify multi-drug trials, and after much debate, the project was returned to the Army.

In a meeting Friday, acting secretary of the Army John W. Shannon emphasized the trial would not proceed unless MicroGeneSys donated the vaccine, Burke said.

"We have done some very careful cost analyses of what it will take to do a scientifically certain and significant trial," Burke said, noting that "we would not have enough funds to both purchase the vaccine and do a good trial."

In a letter faxed July 1 to Burke, Robert W. Scherrer, vice president of MicroGeneSys, noted that the company pioneered the use of such vaccines to treat HIV-infected patients and had spent more than \$20 million in the development and testing of VaxSyn, "which includes the cost of providing approximately 18,000 doses of the vaccine free of charge to the Army and to other trial sites."

Because MicroGeneSys has limited assets, Scherrer noted, "we are not able to donate [the vaccine] for a large-scale study. Also, our access to financial resources has been adversely affected by the negative publicity which arose from the legislation concerning this study."



GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE

WASHINGTON, D.C. 20301-1600

July 26, 1993

Honorable Harriet S. Rabb
General Counsel
Department of Health and Human Services
Washington, D.C. 20201

Dear Harriet:

Thank you for your recent letter regarding the gp160 clinical trial called for in the Department of Defense Appropriations Act, 1993.

I certainly understand the position of the Department of Health and Human Services not to proceed with the Economy Act transfer of funds to carry out this project. In view of this, the Department of the Army will proceed with development of plans consistent with the statutory provision.

Thank you for your help in bringing this matter to closure.

Sincerely,

A handwritten signature in cursive script that reads "Jamie".

Jamie S. Gorelick

August 17, 1993

NOTE TO THE FILES

Re: gp 160

This morning I spoke with John Casciotti (703-697-9341) from the Department of Defense's Office of the General Counsel regarding the status of gp 160. He informed me that the Department of the Army had decided to conduct a three year, single vaccine trial of gp 160. The Army has gotten MicroGeneSys' parent company to agree to purchase gp 160 from its subsidiary and to donate it to the Army for the first year of the trial. The parent company will then assess whether it will continue to provide vaccine to the Army at no cost for the remaining two years of the trial.

Beverly Dennis, III
Beverly Dennis, III

THE WHITE HOUSE
WASHINGTON

November 10, 1993

MEMORANDUM

TO: CAROL RASCO, Special Assistant to the President
for Domestic Policy

HOWARD PASTER, Legislative Affairs

FROM: KRISTINE M. GEBBIE, National AIDS Policy Coordinator *M. Stus Lee for*

RE: DRAFT LETTER TO SENATOR KENNEDY

There is some expectation that Senator Helms will introduce an amendment to the pending crime bill restricting further federal funding for needle exchange programs.

I and others have indicated that this Administration endorses the current law, which is to leave a determination of the public health effectiveness of needle exchange with the Surgeon General.

Attached is a draft letter to Senator Kennedy from me supporting the current law while we await CDC's further study of recent reports on needle exchange. I would send the letter if problem amendments were presented.

Please let me know if you have any comments or changes to the letter. I'll keep you posted if there is any legislative action.

Thank you.

*I am fine on this - discussions
have been ongoing with Kennedy
staff on this issue. Please advise.*

C. Rasco

THE WHITE HOUSE

WASHINGTON

Senator Edward M. Kennedy
315 Senate Russell Office Building
Constitution & Delaware Avenues NE
Washington, D.C. 20510

Dear Senator Kennedy:

Public Law 102-321 currently provides that "no funds appropriated under this Act shall be used to carry out any program of distribution of sterile needles for hypodermic injection of any illegal drug, unless the Surgeon General of the United States determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, except that such funds may be used for such purposes in furtherance of demonstrations or studies authorized in the ADAMHA Reorganization Act (Public Law 102-321)." That language for FY 1993 was substantially re-enacted for FY 1994.

As you are aware, a number of studies evaluating needle exchange programs in the United States and abroad have been recently concluded and are currently under evaluation by the Center for Disease Control and other agencies within the Department of Health and Human Services.

Until such evaluations are concluded and recommendations made, I strongly recommend that current law not be altered and would oppose any amendments to alter current law in either house of Congress.

Sincerely yours,

Kristine M. Gebbie, RN MN FAAN
National AIDS Policy Coordinator

File: Gebbie

TM
tell her
OK IF
NECESSARY
O'Donnell
W. Pitt

Leave to
message
Steve Lee 11/15

THE WHITE HOUSE
WASHINGTON

November 10, 1993

MEMORANDUM

TO: CAROL RASCO, Special Assistant to the President
for Domestic Policy
HOWARD PASTER, Legislative Affairs *W. Steve Lee for*
FROM: KRISTINE M. GEBBIE, National AIDS Policy Coordinator
RE: DRAFT LETTER TO SENATOR KENNEDY

P.S. if the
issue hasn't
already come up,
let's wait til
it does.

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THE WHITE HOUSE

WASHINGTON

Senator Edward M. Kennedy
315 Senate Russell Office Building
Constitution & Delaware Avenues NE
Washington, D.C. 20510

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Until such evaluations are concluded and recommendations made, I strongly recommend that current law not be altered and would oppose any amendments to alter current law in either house of Congress.

Sincerely yours,

Kristine M. Gebbie, RN MN FAAN
National AIDS Policy Coordinator