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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of the Secretary**

**Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201**

APR 20 1998

MEMORANDUM TO THE SECRETARY**SUBJECT: Review of Scientific Data on Needle Exchange Programs**

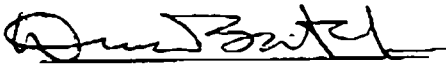
At your request, we have reviewed the scientific studies on the effectiveness of syringe and needle exchange programs. Attached is our review. It includes:

- o Appendix A: The Department's February 1997 Report to Congress
- o Appendix B: Recent data analysis completed since February 1997
- o Appendix C: Summary document reviewing the scientific literature by outcome measures of interest
- o Appendix D: Data summary specifically addressing the criteria established by Congress as conditions for federal funding for needle exchange programs

After reviewing all of the research, we have unanimously agreed that there is conclusive scientific evidence that needle exchange programs, as part of a comprehensive HIV prevention strategy, are an effective public health intervention that reduces the transmission of HIV and does not encourage the use of illegal drugs. In addition, when properly structured, needle exchange programs can provide a unique opportunity for communities to reach out to the active drug injecting population and provide for the referral and retention of individuals in local drug treatment and counseling programs and other important health services.

Therefore, based on the scientific data, we strongly recommend that you certify that needle exchange programs are effective in reducing the transmission of HIV and do not encourage the use of illegal drugs.

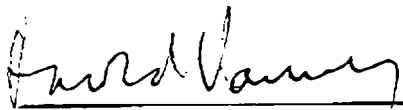
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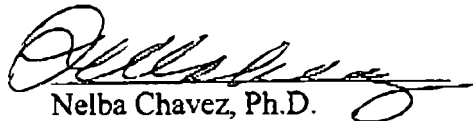
David Satcher, M.D., Ph.D.
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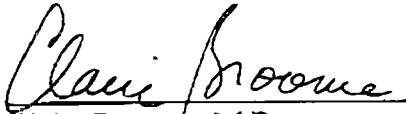
Margaret Hamburg, M.D.
Assistant Secretary for
Planning and Evaluation



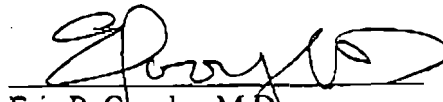
Harold Varmus, M.D.
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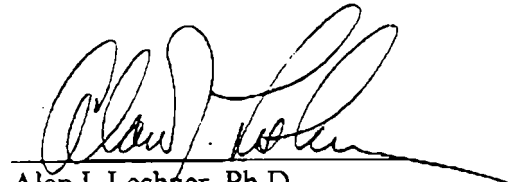
Claire Broome, M.D.
Acting Director
Centers for Disease Control and Prevention



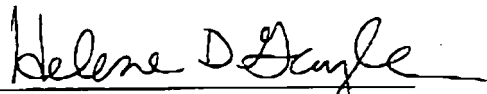
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**Drug Treatment Slots/Drug Treatment Dollars
and the
Presence of Needle Exchange Programs in Three Communities**

The question that we address in this brief memo is whether or not the presence of operating needle exchange programs (NEPs) will, in the long run, erode support for the drug treatment system.

There are two hypotheses: 1) that the presence of needle exchange increases the likelihood that a city/community recognizes the importance of drug treatment dollars and drug treatment slots; and, 2) that with the expansion of needle exchange programs, there is a decrease in the support and the availability of drug treatment.

To address this issue, data is provided from several cities with existing NEPs since 1994. Specifically, data is reported on Baltimore City, San Francisco, and Philadelphia. This is not an uncomplicated question and there are a number of factors that could affect increases and/or decreases in capacity in treatment slots and people served. The data provided below were accessed quickly and are illustrative of the relationship between drug treatment slots, drug treatment dollars, and the presence of needle exchange. We should, but time does not permit, accruing data from cities without needle exchange programs. Data was obtained by calling the appropriate authorities in each of the cities.

FINDINGS:

Baltimore

Baltimore City needle exchange began operating legally in 1994. In 1994, there were 5,100 treatment slots. In 1997, there were 5,700 treatment slots. In Fiscal Year 1998, there will be between 9 -10,000 treatment slots available.

In 1997, Baltimore City spent \$14.7 million for drug treatment. In Fiscal Year 1998, the city will have spent \$31.3 million for treatment. Baltimore City is establishing a drug treatment policy which will take some time to implement. The Baltimore data has been confirmed by two sources.

San Francisco

Since 1992, the total treatment funds have increased from approximately \$20 million to \$42 million (Federal Block Grant funds and State allocations -- the bulk from the local tax base.) The number of treatment slots have increased commensurate with budget increases. In the last 3 years, treatment funding has increased by 50%. The number of slots have also increased by 50%.

In November 1996, the Board of Supervisors approved Resolution No. 1055-96, introduced by Supervisor Leal. This resolution endorsed the goal of substance use treatment on demand for indigent San Franciscans, and urged the Mayor, the Health Commission and the Director of Public Health to provide full funding for substance use treatment on demand. Subsequently, the Health Commission and the Director of Public Health charged CSAS with developing a plan for

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a treatment on demand system.

Philadelphia

NEP started in 1992. As have NEPs been introduced, so has managed care. (More recovery houses and opportunity for treatment). Budget increases: NEPs have increased the demand for treatment. NOTE: Philadelphia data will arrive by fax in the morning.

Conclusion

These conclusions are based on quickly obtained data from a select number of sites that have had needle exchange programs for more than 4 years, and have immediate access to data on drug treatment slots/persons served, and drug treatment dollars. It can be suggested that the presence of needle exchange stimulates communities to increase their support for drug treatment.

Non-concur

1. Mixed message to youth around drug use
2. NEP a substitute for drug treatment
3. Claim that NEP's are already up and running without Federal support
4. Sick Brain concept of drug dependence creating a web of destructive behaviors
5. NEP link to an increase in drug use

Concur

1. Treatment slots needed (810,000 addicts with 115,000 slots)
2. Concerns in community must be addressed
3. Drug addicts in treatment reduce heroin use by 70%, arrests by 64%, drug selling by 78%, and survival sex by 56%
4. Methadone Treatment is effective in reducing drug use

Outline of Response

1. Agree that substance abuse is of paramount importance but is confounded by the dual epidemic of HIV. The majority of new HIV seroconversions are occurring in patients who have been exposed to contaminated needles, or are having sexual relations with someone actively or remotely using injection drugs. Injection drug use is driving the expansion of the epidemic into minority populations, women, and children .

2. The literature shows that patients using injection drugs are exceptionally high risk for HIV from multiple independent risk factors. These include patients who are in need of housing, have multiple sex partners, contracted STD's within the last 18 months, engaged in survival sex, use cocaine/crack or methamphetamine, inject multiple times each day, and share needles. Due to the constellation of multiple risk factors for HIV seroconversion, these patients are at significantly increased risk for seroconversion compared to non-NEP users. Within the cohort of NEP users, cocaine/methamphetamine users are at higher risk for HIV seropositivity and transmission.

In that we do not have readily available drug treatment slots and acknowledging that this population serves as the principal conduit for movement of HIV into minority populations, women and children; it is in keeping with the best practice of public health to develop strategies that will decrease HIV transmission in the IVDU population. For

those IVDU's not interested in drug treatment, and because of a high rate of recidivism for those in drug treatment, it is imperative that we develop strategies that address the active user.

3. There is no known scientific evidence showing an association between Needle Exchange Program use and iv drug use in any age group whatsoever. Indeed, to the contrary, we see NEP users decreasing drug use and sharing of needles. NEP participants afford a repetitive opportunity to engage the individual in drug treatment, medical treatment for HIV and other diseases, and introduce prevention interventions.

4. NEP's have never been presented as a replacement for drug treatment. The effectiveness of drug treatment for opiate addicted populations is well established. Methadone effectively decreases drug use and associated criminal behaviors. NEP's realize their full potential when they serve in concert with drug treatment programs and act as a conduit to both drug and medical treatments.

5. The preponderance of evidence, as concluded by the National Academy of Science review and virtually all researchers in the field, NEP's do not increase drug use they decrease drug use. The data reporting on the experience in Zurich showing increased drug use, was confounded by selection bias and has been discounted when viewed in the totality of the available data.

6. Support has been forthcoming from a variety of different professional organizations including;

AMA, CSTE, NAS, US Conference of Mayors, American Public Health Association, American Bar Association, and the Black Police Officer Association.

7. Due to the controversial nature of this issue, the needed cooperation from political and law enforcement interests in any given city and the community in which the NEP resides, the decision to implement a NEP in any given community must remain a local decision.

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Jeff thought you'd
like to see a copy
of this. He also
has a copy.

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Ban on Funding For Needle Swap Expected to End White House decision is imminent, sources say

Louis Freedberg, Chronicle Washington Bureau

Saturday, April 11, 1998

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URL: <http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/1998/04/11/MN89399.DTL>

Under intense pressure from scientists, public health experts, activists and its own AIDS advisers, the Clinton administration is moving to lift a 10-year-old ban on using federal funds for needle exchange programs, according to key individuals close to the issue.

Although the administration's official stand is that it is still studying the matter, a range of AIDS organizations and key individuals say they have been assured a decision is imminent -- and they are anticipating that the ban will be lifted.

"We have reason to be optimistic that the administration will lift the ban, because it will fit comfortably within their perspective of research, prevention and care of people with AIDS," said Representative Nancy Pelosi, D-San Francisco. "I know they are committed to stop the spread of AIDS, and I am confident they won't let politics stand in the way of that."

Dr. Scott Hitt, a Los Angeles physician and the chairman of President Clinton's advisory council on AIDS, said he believes an announcement could be made within a week.

About 100 communities -- approximately 30 of them in California -- run needle exchange programs without federal funds. The San Francisco AIDS Foundation runs the largest in the nation, using a combination of city and private funds to hand out 2.2 million needles a year.

State and federal laws require a public health emergency to operate a needle exchange program, forcing the Board of Supervisors to make such a declaration every two weeks since the program started in 1993.

Lifting the ban would allow San Francisco to spend federal AIDS prevention funds on needle exchanges and free up funds for other programs. It would also allow many other communities that do not have a needle exchange program to initiate one.

"There could certainly be a financial benefit to San Francisco, and it would certainly benefit hundreds of other programs around the country that do not have the kind of support that San Francisco has," said Regina Aragon, policy director of the San Francisco AIDS Foundation.

According to authoritative estimates, more than half of new cases of HIV infection are related to drug use. Some experts argue that at least 14,000 new cases of HIV could be prevented each year if needle exchange programs were widely in place across the nation.

The congressional ban imposed in 1988 gives the secretary of health and human services the authority to lift the ban if there is sufficient scientific evidence to meet two criteria: needle exchange programs reduce the spread of HIV, and they do not encourage drug use.

As late as this week, a spokesman for Health and Human Services Secretary Donna Shalala said the administration is not yet convinced that needle exchange programs do not promote drug use.

PRESSURE ON SHALALA

As frustration at the administration's inaction mounted, the president's advisory council

approved a resolution of "no confidence" last month in the administration, marking an embarrassing rebuke to a president who has prided himself on his efforts to fight the AIDS epidemic. Hitt sent a sharply worded letter to Shalala saying that her failure to lift the ban represented an "abdication" of her responsibilities.

On Thursday, council members held a conference call to decide whether to approve an even tougher resolution calling on Shalala to resign. But they decided to hold off after administration officials said a decision on the ban was imminent -- although they didn't provide details about what the decision would be.

But those close to the controversy believe the administration will lift the ban in light of the mountain of scientific evidence demonstrating the efficacy of needle exchange programs. Scientific panels and reports commissioned by the National Institutes of Health, the Centers for Disease Control and Prevention, the National Academy of Sciences, as well as the American Medical Association and the American Public Health Association have come to similar conclusions.

Within the administration, the emotional debate among Clinton's top advisers on AIDS and drug policy has led some officials to wryly refer to the conflict as "czar wars."

On the one side is Clinton's "drug czar," retired General Barry McCaffrey, who insists that handing out clean needles to drug users would send the message that the government is condoning drug use. He has been supported in that view by a combination of conservative Republicans and some Democratic representatives of cities with large African American populations.

THE 'AIDS CZAR'

On the other side is "AIDS czar" Sandra Thurman, head of Clinton's Office of National AIDS Policy, although she downplayed her differences with McCaffrey.

"We are not warring," said Thurman. "General McCaffrey is every bit as committed to stopping the AIDS epidemic as I am."

At the same time, she said "We have convincing evidence that the criteria (needed to lift the ban) have been met."

On Wednesday, a major obstacle appeared to be removed when the authors of the only major study suggesting that needle exchange programs lead to increased drug use contended that their research in Montreal and Vancouver had been misinterpreted by McCaffrey and others.

Some AIDS advocates say they are skeptical of administration assurances that it is moving on the issue, saying they have heard the same thing too many times before.

"Until the decision is made, it is premature to say we have a victory here," said San Francisco's Aragon. "This is not an easy thing for the administration to do, and I would caution my colleagues not to be overly optimistic."

But others believe the administration is finally ready to act. "I don't think it will be much longer now," said Daniel Zingale, executive director of AIDS Action in Washington, D.C. "They understand where the science comes down on this issue."

Written Testimony of Dr. Peter Beilenson
Baltimore City Health Commissioner
to the Subcommittee on National Security, International
Affairs and Criminal Justice
of the Congress of the United States
September 18, 1997

Description of the Program

The Needle Exchange Program (NEP) operates out of two 26 foot mobile health recreation vehicles. The program operates at six sites; two in East Baltimore, one in West Baltimore, two in Park Heights and one in Cherry Hill, and is open four days a week. Enrolled clients are able to exchange used needles for sterile needles on a "one-for-one" exchange basis. Clients receive counseling about drug treatment programs, harm reduction in the use of needles, and education regarding HIV, tuberculosis, and sexually transmitted diseases. Blood tests and counseling for HIV, syphilis and skin tests for tuberculosis are also available.

Client placement in drug treatment programs is an important aspect of the NEP. Various drug treatment options are available on demand for interested participants. NEP participants who request treatment are enrolled in a comprehensive drug treatment program at Bon Secours' New Hope Treatment Center, Johns Hopkins Bayview Medical Center or the University of Maryland on demand within 24 hours, depending on the availability of NEP-designated treatment slots.

Funding Sources

FY 96: State/City Targeted Funds:
\$250,000 for drug treatment
\$310,000 for operation of the needle exchange

Potential Cost-Savings

The average cost of caring for an adult AIDS patient, from the time of diagnosis with AIDS (not HIV infection) to death, is approximately \$102,000. Since the vast majority of our clients are either Medicaid eligible or uninsured (and thus, the cost of their care is passed on as uncompensated care), virtually all of AIDS care for this population is borne by state taxpayers. Since the actual program operation will cost about \$300,000 to serve an

estimated 6,000 clients, if even three cases of AIDS are prevented, the program will be cost-effective.

Clients Served

Although we estimated during our initial testimony in 1994 that our NEP would serve between 500 and 750 clients in the first year of operation, the program has been far more popular than we anticipated. After the first 36 months of operation, approximately 6,000 clients had registered at one of the six program locations, making over 50,000 visits to exchange over 1.1 million needles. We are currently serving between 325 and 550 new and return clients per week.

Community Acceptance and Police Cooperation

The NEP has been well-accepted by the community, and we have had excellent cooperation from the Baltimore Police Department. There has been only one call for police assistance during the entire period of operation. It is important to note that despite the fact that virtually all of our clients have been in trouble with the law at one time or another, the program is basically self-policed by clients, who have "bought into" the program and have become very supportive of it.

Success in Providing Drug Treatment

Through City funds provided by the Mayor, approximately 90 treatment slots (which will be able to treat about 200 clients per year) have been earmarked for NEP participants. We have discovered some interesting facts about our NEP participants seeking treatment. First, our NEP clients in general, as well as those who seek treatment, tend to be "harder core" addicts than those in the typical Baltimore addict population which has been studied previously. The NEP clients going into treatment are significantly less likely to have been in treatment and have significantly more medical problems than those who enter treatment who are not NEP clients. Despite these facts, NEP clients in treatment are doing as well as non-NEP clients in terms of successful retention in treatment.

The average delay before a client of the NEP can obtain a slot in one of our two dedicated treatment programs is 7-10 days, a significant improvement over the city-wide average delay for non-dedicated treatment slots which is 2-4 weeks for drug-free programs and 2-4 months for methadone maintenance.

Major Preliminary Findings from the Evaluation Study

1. Discarded Needles Do Not Increase After the Opening of Needle Exchange. There was some concern during initial legislative hearings that used needles would be discarded in the areas surrounding the NEP, despite the fact that the program is a one-for-one exchange (i.e. bring in a dirty needle in exchange for a clean, sterile one). In fact, a well-designed study looked at discarded needles around the two program sites compared to other high drug-use areas in the city and found no increase in the number of discarded needles in the areas surrounding the exchange.
2. The Average Age of Needle Exchange Clients is 39 Years Old. Another concern raised by a few of the legislators in hearings was that the program would make it easy for youngsters to get needles. The average age of our clients is 39 years old; and our records show that only two of our 6,000 clients are under 18. Other demographic characteristics of our clients: a) they are predominantly unemployed (92%), African-American (87%), and are very frequent injectors; b) 90% inject at least daily (compared to 40% from a community sample of users); c) heroin and cocaine are the drugs of choice, with over 90% of clients reporting use of both drugs; d) about half of enrollees become active exchangers, returning on average every two weeks for on average 14 needles and syringes.
3. Needle Sharing Is Reduced. Obviously, the major goal of our NEP is to prevent the spread of HIV/AIDS in the injection drug use community. To do that, we need to change our clients' drug use behavior. The preliminary results of our study look promising in this regard. Our clients reported significant drops in the following unsafe drug behaviors after starting the NEP: a) using needles after someone else; b) using cookers after someone else; c) using cotton after someone else; and d) letting a friend use your needle and syringe.

In addition, prior to the initiation of the NEP, 63% of clients reported their source of needles as the "street", compared to only 39% two weeks after starting the program. The program has also been successful at getting some addicts to stop injecting in "drug houses" or on the street, with 25% more of our clients reporting that they inject in their home two weeks after starting the NEP than prior to joining the program. Also, very importantly, we have found that the average circulation time of our clients' needles has dropped by 33%.

Finally, although some legislators expressed concerns that the program would make it more likely that injection drug users would use more frequently, that has not been the case-our clients report a 22% decrease in their frequency of drug use since joining the NEP.

4. 65% of Baltimore City Residents Favor Needle Exchange. In a survey conducted in Baltimore City in October 1995, 65% of the respondents were supportive of needle exchange. Respondents were supportive based on their perception that needle exchange reduces the number of discarded needles on the street, that needle exchange does not increase drug use, and that needle exchange programs decrease the incidence of HIV.
5. Injection Drug Users Care About HIV Prevention. Needle exchange clients were asked about their attitudes and behaviors regarding the desirability and safety of existing needle sources. The findings indicate that the clients clearly have a good understanding of health risks associated with existing needle sources (off the street, shooting galleries) and prefer to use sources that they know to be medically safe.

HIV Seroconversion

The bottom-line goal of this program is to decrease the transmission of HIV. Currently, in Baltimore, the HIV seroconversion rate among injection drug users (IDUs) is about 4% per year. In other words, 4% of IDUs who are HIV-convert to HIV+ each year. If our program is working, we would hope to be able to demonstrate that the seroconversion rate among our NEP clients will be lower than 4%. We are showing a 39.7% decrease in HIV seroconversion among the injection drug using population that we are serving.

SUMMARY

After more than three years of operation, we are very pleased with how the NEP is going. The program is attracting much larger numbers of clients than we expected. The program is well-accepted by these clients as evidenced by the numbers making repeat visits to the NEP and by the way in which our clients self-police the program. The NEP is also well-accepted by the communities in which it operates and by the police, who have been extremely cooperative. Finally, the program is accomplishing its mission of reducing the transmission of HIV among injection drug users, their sexual partners and their offspring. It serves as a much-needed point of access to care for hard-core addicts who otherwise have had virtually no access to drug treatment or other health care.

Peter Beilenson, M.D., M.P.H.
Commissioner of Health
September 1997

I. EXECUTIVE SUMMARY

HIV infection among injecting drug users (IDUs) is a major public health problem among IDUs in many countries throughout the world. In particular, it is a problem in the United States, where approximately half of all new HIV infections are occurring among injecting drug users (Holmberg, 1996).

Syringe exchange programs (SEPs) to prevent HIV infection among IDUs have been implemented in almost all industrialized countries and in several developing countries. Research evaluations have shown SEPs to be an effective method of reducing risk behavior and HIV transmission among IDUs (Normand et al., 1995). A pilot syringe exchange was implemented in Hawaii in 1990. In 1992, the Hawaii State Department of Health assumed responsibility for the SEP in the state, with the Community Health Outreach Worker (CHOW) Project designated as the lead agency for SEP work. The legislation governing SEPs in the state requires an annual evaluation report to the Syringe Exchange Oversight Committee (SEOC). This current report covers the year from October 1, 1996 to September 30, 1997.

A variety of data sources have been used in the preparation of this report, including: operational records of the SEPs; the "SEP database," consisting of the brief interviews conducted at each visit by a client to the SEP; the "survey database," consisting of formal baseline and follow-up research interviews conducted with a randomly selected sample of SEP clients; the "referral database," records of referrals of SEP clients to drug abuse treatment programs; and the "surveillance database," consisting of AIDS cases, HIV testing and hepatitis B testing conducted throughout the state. These data sources do not provide complete information about HIV infection among IDUs in Hawaii. The use of multiple data sources and the consistency of the data across the different sources, however, do permit drawing relatively firm conclusions regarding the low levels of risk behavior and HIV infection among IDUs in Hawaii.

The SEP in Hawaii operates out of two fixed sites (both on Oahu) and through five mobile van routes, one on Oahu, one on Maui, one on Kauai, and two on the Big Island of Hawaii. During the early 1990s, the SEP system was

expanding and the number of syringes exchanged increased each year, reaching a peak of 173,671 in 1995. In 1996, the number of syringes exchanged fell to 133,958, due to a combination of loss of high volume clients to death and incarceration and staff turnover at some of the neighbor island sites. In 1997, the number of syringes exchanged increased to 143,715. While the number of syringes exchanged still needs careful monitoring, the change from cocaine to heroin as the predominant drug injected and the decrease in injection frequency among syringe exchange clients (discussed below) also indicate a need for a smaller number of syringes among the clients.

As at most other SEPs throughout the world, many SEP clients exchange not only for themselves, but also for other IDUs. This creates opportunities to use clients as "extended staff" of the SEP, who provide risk reduction education to their peers. During 1997, a formal Peer Educator program was initiated in Maui. Follow-up work with the trained peer educators is currently in process, and the program will be expanded to the Big Island.

The SEP also provides referrals to drug abuse treatment, including direct contracting of treatment services. During 1997, 96 clients were placed in various forms of drug abuse treatment.

The SEP serves a diverse group of IDUs. The clients are 76% male and 24% female. Caucasians comprise the largest ethnic group among SEP clients at 61%, with 12% Asian, 8% Hispanic, 6% Hawaiian/part Hawaiian, 5% Native American, and 4% African-American. Most of the clients have been injecting drugs for long time periods; the mean age is 41.6 years old, and the clients report a mean of 20.3 years since their first drug injection. Housing is a problem for many of the clients, only 51% live in places that they own or rent, and 21% report living "on the streets" or in shelters.

Over the last several years, heroin has replaced cocaine as the drug used by the great majority of SEP clients. Ninety-two per cent of clients report injecting heroin (in the month prior to a research interview), 28% report injecting cocaine, 26% report injecting "speedballs" (a mixture of heroin and cocaine), and 9% report injecting amphetamines. (The sum of the percentages exceeds 100% as many clients report injecting more than one drug in the

previous month.) Non-injecting drug use is also common among SEP clients, with 63% reporting heavy alcohol use, 49% reporting crack cocaine use, and 43% reporting marijuana use in the previous month. The frequency of drug injection has declined over the last several years among SEP clients. Among clients who participated in multiple research interviews (linked by code numbers), 47% had decreased their frequency of injection over time, 40% had maintained the same frequency of injection, and 19% had increased their frequency of injection.

The extent of drug injection and non-injected drug use among SEP clients clearly indicates a great potential for injection and sexual risk behaviors. The amount of injection risk behavior, however, was relatively low. In the 1997 research interviews, 76% of participants reported no unsafe injections in the month prior to the interview, and of the 24% who reported some injections with syringes that had been used by others, 43% reported always using bleach to disinfect the "shared" syringes. Thus, only 13% of the participants should be considered at relatively high risk for syringe-borne HIV infection. A modest percent of SEP clients persist in unsafe injection practices. Of the participants with both baseline and follow-up research interviews, 9% reported injecting with syringes that had been used by others in the one month periods prior to both baseline and follow-up interviews. Among the participants in the research interviews in 1997, 59% reported sexual intercourse in the month prior to the interview. Six per cent of the participants should be considered as at relatively high risk for sexually transmitted HIV (and particularly for other sexually transmitted diseases), in that they reported multiple sexual partners and no use of condoms in the previous month. In a sub-study of male drug injectors who also reported engaging in male-with-male sexual activity (MSM-IDUs), it was found that risk behaviors among this subgroup were substantially higher.

The available HIV data support the conclusions from the risk behavior data that HIV transmission is an uncommon event among injection drug users in Hawaii. The State Health Department operates a system of HIV counseling and testing centers. Among the persons who sought testing at these centers and reported drug injection as a risk behavior, 1.2% were HIV seropositive in 1997. HIV counseling and testing is also conducted at the SEP fixed site at 710 North King Street in Honolulu. Of the 120 HIV tests conducted at this site over the past four years, only one new HIV infection was reported.

The SEP and the CHOW projects are fully integrated, so the budgets for both projects were combined in a benefit/cost analysis. The benefit/cost analysis was undertaken from the perspective of a State government that must either pay for HIV prevention or must pay for the medical costs of treating HIV infection. Data for other possible costs, such as lost productivity or human suffering, were not available, and therefore not included in the analysis. The cost of treating a single HIV infection was estimated to have a present value of \$102,000. Given current developments in combination antiviral treatments, this must be considered a conservative estimate. Prevention of a total of seven HIV infections per year would produce a benefit/cost ratio greater than 1.0, and would represent a cost saving for the State. Since many IDUs who become infected with HIV transmit the virus to non-injecting sexual partners, prevention of HIV infection among drug injectors also serves to prevent heterosexual transmission of HIV. Based on current estimates of heterosexual transmission from IDUs, prevention of a total of five infections per year among IDUs would also lead to prevention of an additional two HIV infections among non-injecting heterosexual partners. Thus, if the combined SEP and CHOW projects lead to prevention of five HIV infections per year among drug injectors this would represent a cost saving for the State. Given the low levels of risk behavior among SEP clients, one may have great confidence that the combined SEP and CHOW programs are cost beneficial.

The program is to be commended for supporting a rigorous evaluation effort and for addressing problematic issues noted in previous evaluation reports. The formal evaluation process, including the reports to the SEOC, appears to be an important factor in the continued positive development of the SEP in Hawaii.

Recommendations:

(1) The SEP in Hawaii should be continued. HIV infection and injection risk behavior are relatively low among IDUs in the state. The program provides a number of needed services to drug injectors at risk for HIV infection. Maintaining a skilled and dedicated staff is critical for effective delivery of these services.

(2) National and international studies of hepatitis B and hepatitis C show these infections to be exceedingly high among IDUs. The SEP mission statement should be revised to include a statement concerning hepatitis B and C prevention. Furthermore, the SEP should incorporate information concerning hepatitis B and hepatitis C prevention into all of its standardized educational messages. The SEP is an excellent medium for hepatitis education because a high proportion of hepatitis B and C infections in the United States occur among IDUs and studies have shown that the use of SEPs can reduce hepatitis B and C infections among drug injectors (Normand et al., 1995). Additional data on hepatitis B and C among IDUs in Hawaii should be collected.

(3) Many SEP clients are at risk for sexually transmitted diseases other than HIV. The safe sex education and encouragement of condom use should include specific information about other sexually transmitted diseases.

(4) Future research and program service development should concentrate on hepatitis B and C prevention as well as HIV prevention. The "persistent" unsafe injectors and the MSM-IDUs appear to be particularly important groups for additional research and risk reduction services.



235-4453

1413 K Street, NW, Suite 700
Washington, D.C. 20005
(202) 789-3565 Fax (202) 789-4277

FACSIMILE COVER SHEET

TO:	Sandy Thurman
FAX#:	(202) 632-1096
FROM:	Tony Teano
TELEPHONE#:	(202) 789-3565
DATE:	January 28, 1998

 3 Pages (including this cover).

Note:

Alexander Robinson wanted you to have a copy of this letter from the Honorable Wellington E. Webb, Mayor of the City and County of Denver, Colorado.

Wellington E. Webb
MAYOR



City and County of Denver

CITY AND COUNTY BUILDING - DENVER, COLORADO - 80202

AREA CODE 303 640-2721

640-2720 (V/TDD)

January 27, 1998

Honorable William Jefferson Clinton
President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington DC 20500

Dear Mr. President:

I am writing to seek your support for a \$105 million increase for Title I Ryan White CARE Act funding in your FY 1999 Budget.

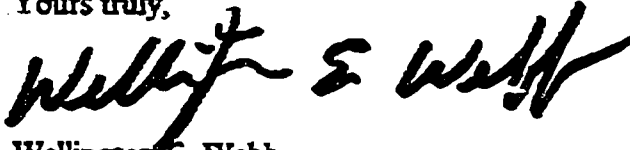
Denver has been a recipient of Title I funding since 1994. We currently have over 5700 people reported living with HIV disease in the Eligible Metropolitan Area which includes Denver, Arapahoe, Douglas, Adams and Jefferson counties. With Title I funds we have developed and maintain an excellent continuum of specialized health care and support services for the uninsured. Our system of care accomplishes exactly what the Ryan White CARE Act intends - a reduction in the high cost of emergency room and inpatient hospital care for people living with HIV-AIDS.

Your recent proposed Title II increase of \$100 million for drug therapies is highly appreciated. The increase in Title I is just as critical because it will fund the level of primary care necessary to support successful drug therapy. The new National Institute of Health Treatment Guidelines suggest drug therapy treatment for early stage HIV disease. Early treatment is leveling enormous stress on care systems across the United States as cities strive to get more infected people into care and provide them with specialized medical and social service support. The increased need for viral load testing alone will require an additional \$67 million for the number of people nation-wide who received service in 1995. The additional \$38 million is needed to fund primary care services for current and new patients.

We strive to coordinate HIV-AIDS service across all titles of Ryan White through joint planning and collaborative service provision. The funding across titles needs to support efficient service delivery as well. The \$105 million increase will allow cities nation-wide to provide the primary care essential for successful drug treatment.

Thank you for your consideration of this essential budget request.

Yours truly,

A handwritten signature in black ink, appearing to read "Wellington E. Webb", written in a cursive style.

Wellington E. Webb
Mayor

cc: Franklin Raines
Office of Management and Budget

**NEWS RELEASE****2-page FAX to:Federal Government Reporters****FOR IMMEDIATE RELEASE**

Media Contact: Derek Gordon (415) 487-3031

Pager: (415) 998-2871

PRESIDENT CLINTON PROPOSES SUBSTANTIAL FUNDING INCREASE FOR AIDS DRUGS, OTHER VITAL HIV/AIDS SERVICES

VICE PRESIDENT GORE URGED TO REINVIGORATE MEDICAID EXPANSION PLANS

ADVOCATES EXPRESS CONCERN ABOUT PROPOSED FLAT FUNDING FOR PREVENTION PROGRAMS

San Francisco, CA, February 2, 1998 — President Bill Clinton's proposed budget for Fiscal Year 1999 recommends strong and critical funding increases for the Ryan White CARE Act—including the AIDS Drug Assistance Program (ADAP)—and the Housing Opportunities for People With AIDS (HOPWA) program.

"President Clinton has sent a strong message to Congress that AIDS funding is once again a top priority for the Administration," said Ernest Hopkins, Director of Federal Affairs at the San Francisco AIDS Foundation. "A recommitment to AIDS is essential if we are to focus both political attention and public opinion back on the AIDS crisis."

In his budget released today, President Clinton is recommending a \$165 million overall increase for the Ryan White CARE Act, which represents a 14% increase over the current FY 1998 budget of \$1.15 billion. The proposed \$100 million increase for the ADAP portion of the CARE Act represents a 35% increase over current fiscal year funding, and is welcome news to many state-administered programs that are desperately trying to keep up with growing demand for promising new HIV treatments. New client enrollments in ADAP have topped 1,000 per month nationwide.

"The combination of increased dollars for AIDS drugs and the commitment to medical care and support services through other CARE Act programs will give thousands of new clients with HIV the chance at longer, healthier lives," said Hopkins. "The Foundation will aggressively advocate with its national partners for the \$267 million shortfall between the increased funding needs for the CARE Act identified by national AIDS advocacy organizations and the \$165 million increase proposed by the Administration today."

Housing Opportunities for People With AIDS, or HOPWA, will see a request for \$225 million in the President's budget, although advocates have indicated that \$250 million is necessary to assure adequate funding nationally. In San Francisco, where HIV and AIDS has had an enormously disproportionate impact, HOPWA provides a \$600 per month housing subsidy in a market where the average one-bedroom apartments rents for \$1,400 per month.

"Without this support," said Hopkins, "thousands of people housed today would be homeless."

President's HIV/AIDS Budget—page 2

While the President's proposals are a good first step, Hopkins notes, they should not be considered a substitute for Vice President Al Gore's 10 month-old commitment to expand the Medicaid program to include people living with HIV disease who are not diagnosed with AIDS.

"Medicaid expansion efforts must be reinvigorated if we are serious about providing long-term access to medical care, treatment and critical support services," said Hopkins.

The significant commitment in the President's budget to biomedical research at the NIH would provide the critical resources to enhance the knowledge of HIV, and development of new therapies, while moving forward aggressively with HIV vaccine research, Hopkins said.

Federal support of programs to prevent HIV infection is more important today than ever before. While the AIDS Foundation applauds the President's \$5 million earmark for HIV prevention programs, targeted to racial and ethnic minorities, within the Race Initiative Budget, the AIDS Foundation is troubled by the unacceptable decision to flat fund community-based HIV prevention programs at the Centers for Disease Control and Prevention, Hopkins said. "Congress and the Administration should support a \$120 million *increase* in HIV prevention efforts at the CDC, not flat funding—lives literally depend on it," he said.

In addition to recommending flat funding for overall prevention efforts, the Clinton Administration still has not indicated whether or not Secretary of Health & Human Services Donna Shalala will exercise her authority to eliminate federal restrictions on funding for needle exchanges. San Francisco AIDS Foundation HIV Prevention Project operates the nation's largest needle exchange program.

"Numerous scientific studies have shown that needle exchange reduces HIV transmission and does not increase drug use," says Hopkins. "The Clinton Administration must put public health before politics and act now to fund needle exchange."

* * *

The San Francisco AIDS Foundation is a non-profit, community-based AIDS service organization that has been at the forefront of the battle against HIV disease for sixteen years. This past year SFAF provided a range of vital services to 130,000 individuals, and reached nearly 1 million others through community outreach, advocacy efforts, prevention campaigns, treatment publications and the World Wide Web (www.sfaf.org).

#

Author: Richard Needle <RNEEDLE@ngmsmtp.nida.nih.gov> at INTERNET
 Date: 8/1/97 10:54 AM
 Priority: Normal
 TO: Eric Goosby at -ONAPC, Deborah Von Zinkernagel at -ONAPC
 Subject: FW: Demonstrate for Syringe Exchange -Forwarded
 FYI

I'm sure you know about this, but if not, an announcement about plans for an NEP demonstration.
 rich

Received: from [128.231.2.3] by ngmsmtp.nida.nih.gov
 (SMTPD32-3.02) id A5B4CBC021A; Thu, 31 Jul 1997 22:11:00 -0400
 Received: from itchy.dcert.nih.gov (itchy.dcert.nih.gov [128.231.2.54])
 by helix.nih.gov (8.8.5/8.8.5) with ESMTMP id KAA22856;
 Fri, 1 Aug 1997 10:03:08 -0400 (EDT)

Received: (from daemon@localhost)
 by itchy.dcert.nih.gov (8.8.5/8.8.5) id KAA17332;
 Fri, 1 Aug 1997 10:03:07 -0400 (EDT)

Received: from imc.nih.gov (imc.nih.gov [128.231.90.85])
 by itchy.dcert.nih.gov (8.8.5/8.8.5) with ESMTMP id KAA17327;
 Fri, 1 Aug 1997 10:03:05 -0400 (EDT)

Message-Id: <199708011403.KAA17327@itchy.dcert.nih.gov>
 Received: by imc.nih.gov with Internet Mail Service (5.0.1458.49)
 id <QAC9VRR>; Fri, 1 Aug 1997 10:03:02 -0400

X-PM: V3.18@itchy.dcert.nih.gov
 From: "Auerbach, Judith" <AUERBACJ@od3leml.od.nih.gov>
 To: "Gust, Steve" <sg84q@nih.gov>,
 "Needle, Richard" <rn28e@nih.gov>

Subject: FW: Demonstrate for Syringe Exchange
 Date: Fri, 1 Aug 1997 10:32:59 -0400
 X-Priority: 3
 X-Mailer: Internet Mail Service (5.0.1458.49)

Have you seen this yet?

 From: Julie[SMTP:jdauids@CritPath.Org]
 Sent: Thursday, July 31, 1997 11:10 AM
 Subject: Demonstrate for Syringe Exchange

Please spread the word and get involved. We need everyone's
 help to finally win federal funding for syringe exchange, before
 it is too late!!!

DEMONSTRATE

STUNNED BY THE CALLOUS DISREGARD FOR HUMAN LIFE SHOWN BY H.H.S.
 SECRETARY SHALALA, WHO KNOWS SYRINGE EXCHANGE STOPS AIDS AND SAVES LIVES

... FRUSTRATED BY CLINTON ADMINISTRATION'S REFUSAL TO END THE BAN ON
 FEDERAL SUPPORT FOR NEEDLE EXCHANGE, IN SPITE OF YEARS OF PROVEN
 EFFECTIVENESS ...

... NCSLN MEMBERS JOIN ACTIVISTS NATIONWIDE IN CALLING FOR MAJOR
 DEMONSTRATION IN WASHINGTON TO DEMAND AIDS PREVENTION THAT WORKS.

THE DATE: WEDNESDAY, SEPTEMBER 17TH, 12:30PM.
 THE PLACE: THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

THE CLINTON ADMINISTRATION HAS THE POWER TO STOP TENS OF THOUSANDS OF
 NEW CASES OF AIDS WITHIN THE NEXT SEVERAL YEARS, SIMPLY BY ENDING THE
 BAN ON NEEDLE EXCHANGE FUNDING.

The initial sponsors of this demonstration include (list in formation):
 ACT UP Philadelphia, Atlanta Harm Reduction Coalition, Exponents,
 Inc./ARRIVE, Harm Reduction Care Network of New York, Housing Works,
 Mobilization Against AIDS, New Orleans Syringe Exchange Network, The Harm
 Reduction Coalition, The National Coalition to Save Lives Now!, The
 Latino Commission on AIDS, The North American Syringe Exchange Network.

```

++++ stop the execution of Mumia Abu-Jamal ++++
++++ if you agree copy these 3 sentences in your own sig ++++
++++ sec: http://www.xs4all.nl/~tank/spg-1/sigaction.htm ++++

```

Author: "Vaux; Lenore" <lmw1@cdc.gov> at INTERNET

Date: 8/1/97 10:01 AM

Priority: Normal

TO: Deborah Von Zinkernagel at -ONAPC, "Gbaie; Babette Irie" <big0@cdc.gov> at INTERNET,
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TO: "Respass; Richard" <rfr5@cdc.gov> at INTERNET, "Golub; Joshua"
<jug9@cdc.gov> at INTERNET

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CDC Wonder Customer Support <cwus@cdc.gov> at INTERNET, "Gaiter; Juarlyn"
<IMCEAMS-CORP_CIDHIV2_jlg3@cdc.gov> at INTERNET

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"Davenport; Joan F." <jfd2@cdc.gov> at INTERNET,
"Shepherd; Melissa" <mhs3@cdc.gov> at INTERNET,
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"Bunnell; Rebecca" <rrb7@cdc.gov> at INTERNET, "Beck; Vicki" <vcb6@cdc.gov> at INTERNET,
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"Secura; Gina M." <gis7@cdc.gov> at INTERNET, "Posid; Joe" <jmp2@cdc.gov> at INTERNET,
"McCullough; Kristin" <kgm9@cdc.gov> at INTERNET, "Smart; S. Rene" <shl3@cdc.gov> at INTERNET,
"Wenderoth; Suzanne"

<IMCEAMS-EXPK_CIDHIV1_snw3@cdc.gov> at INTERNET

TO: "Becker; Carolyn G." <cgb3@cdc.gov> at INTERNET, "Purcell; David" <dhp8@cdc.gov> at INTERNET,
"Heitgerd; Janet" <jbh0@cdc.gov> at INTERNET, "Sacco; James L." <jds5@cdc.gov> at INTERNET,
"Carey; James W." <jfc9@cdc.gov> at INTERNET, "Lifshay; Julie" <jjl6@cdc.gov> at INTERNET,
"O'Connor; Kevin" <kpol@cdc.gov> at INTERNET, "Kay; Linda" <lsk0@cdc.gov> at INTERNET,
"Renaud; Michelle L." <mer9@cdc.gov> at INTERNET, "Davis; Steven" <sjd1@cdc.gov> at INTERNET,
"Barry Silberg"

<Bill_Silberg@ama-assn.org> at INTERNET

TO: ESchulman

<eschulman@porternovelli.com> at INTERNET

TO: Marty Suter <marty_suter@ama-assn.org> at INTERNET

Subject: CDC AIDS Daily Summary, 8/1/97

AIDS Daily Summary
August 1, 1997

The CDC National Center for HIV, STD, and TB Prevention makes available the following information as a public service only. Providing this information does not constitute endorsement by the CDC. 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 1997, Information, Inc., Bethesda, MD

"TB Cases Drop to Record Low"

"Agouron Says Sales of New AIDS Drug Tops Projections"

"TB Prophylaxis Not Necessary for All High-Risk HIV-Positive Individuals"

"Brazil Sees Increase in New AIDS Cases"

"Three More AIDS Cases Identified in Cyprus"

"French AIDS Group Rejects Far-Right Mayor's Funds"

"AIDS: Best Hospitals 1997: AIDS"

"TB Cases Drop to Record Low"

Washington Times (08/01/97) P. A7

The number of tuberculosis cases in the United States is the lowest since national reporting on the disease began in 1953, according to the Centers for Disease Control and Prevention. Last year, 21,337 cases of TB were reported in the 50 states and the District of Columbia, down 6.7 percent from 1995. The District had the highest TB rate in the country, with 25.6 cases per 100,000 people, for a total of 139 infections.

"Agouron Says Sales of New AIDS Drug Tops Projections"

Wall Street Journal (08/01/97) P. B2; Rundle, Rhonda

Agouron Pharmaceutical's new AIDS drug Viracept produced \$43.6 million in sales in its first full quarter on the market, exceeding analysts' expectations. Moreover, based on current

*Sand -
Companies are moving
news very fast!*

nds, sales of the drug in fiscal 1998 are expected to surpass \$10 million, said Peter Johnson, president and CEO of the pharmaceutical firm. Johnson adds that recent prescription information reveals that Viracept has already claimed nearly 25 percent of the market for protease inhibitors. The company estimates that 35,000 patients were using the drug by the end of the year.

B Prophylaxis Not Necessary for All High-Risk HIV-Positive Individuals"

Reuters (07/31/97)

New research published in Thursday's issue of the New England Journal of Medicine suggests that HIV-infected patients with energy who have risk factors for tuberculosis do not benefit from isoniazid prophylaxis unless they have been exposed to active TB. Researchers from the Veteran Affairs Medical Center in Washington D.C., examined more than 500 such patients. They found "no significant differences" between the group that received isoniazid therapy and the group that received a placebo with regard to death, the progression of HIV disease, or adverse events." National Institute of Allergy and Infectious Diseases head Dr. Anthony Fauci noted, "This study suggests that we can make more efficient use of TB prevention resources by focusing on HIV-infected persons with known TB infection or who have close contact with another individual with active TB."

"Brazil Sees Increase in New AIDS Cases"

Xinhua News Agency (07/31/97)

Between April and June of this year, 7,552 new cases of AIDS were reported in Brazil, bringing the country's total number of registered cases since 1980 to 110,000. According to the Brazilian Health Ministry, Sao Paulo had the highest number of cases with 56,605. Illiterate persons represented 5 percent of the cases, while 59 percent had only primary education and 23 percent had secondary education.

"Three More AIDS Cases Identified in Cyprus"

Xinhua News Agency (07/31/97)

The Cypriot Health Ministry reports three new cases of HIV infection for the month of July, raising the total number of infections diagnosed on the island to 271. Of that total, Cypriots account for 158 of the cases, 134 of whom are male. Some 80 percent of the infections are reportedly in persons between the ages of 20 and 40.

"French AIDS Group Rejects Far-Right Mayor's Funds"

Reuters (07/31/97)

Sida Info Service, a hotline for AIDS patients in Vitrolles, France, has rejected funding from mayor Catherine Megret's municipality because it claims her views are "fundamentally different" than those of the group. "When there is social exclusion, health problems, especially those linked to HIV-infection, become even more serious, relegating the vulnerable people concerned to the state of touchables," Sida Info Service explained. The group noted that Megret's municipality deposited about \$160 directly into its account even though the group never requested a subsidy. The French government announced earlier this week that \$81,000 will be donated to non-profit organizations in Vitrolles to make up for the \$810,000 worth of subsidies that Megret has withdrawn. Vitrolles is one of four towns run by the extreme-right National Front, which advocates sending home 3 million immigrants to free up jobs and welfare for French-born citizens.

"AIDS: Best Hospitals 1997: AIDS"

U.S. News & World Report (07/28/97) Vol. 123, No. 4, P. 77

In the July 28 issue of U.S. News & World Report, several hospitals were evaluated and ranked for their AIDS treatment facilities. Coming in at No. 1 was San Francisco General Hospital Medical Center. The top five rankings were rounded out by Johns Hopkins Hospital in Baltimore, Md.; Boston, Massachusetts' General Hospital; the University of California's San Francisco Medical Center; and UCLA Medical Center in Los Angeles, respectively.

The AIDSNews Mailing List is maintained by the CDC National AIDS Clearinghouse for the dissemination of AIDS-related information. Regular postings include the CDC AIDS Daily Summary, conference announcements, clinical trials information, current funding opportunities, and AIDS-related MMWR articles. To SUBSCRIBE, send the command "subscribe aidsnews firstname lastname" to the address listproc@aspensys.com. To UNSUBSCRIBE, send the command "unsubscribe aidsnews" to the address listproc@aspensys.com. If you need assistance, please contact aidsinfo@cdcnao.org.

MEMORANDUM TO BRUCE REED

FROM: Sandy Thurman, Office of National AIDS Policy

SUBJECT: Needle Exchange Programs

This memorandum is to give you an update on the Hill and community politics around the needle exchange, as this issue is going to heat up in the next two weeks.

House L/HHS Appropriations The House L/HHS Subcommittee is likely to mark up the FY 1998 appropriations bill the week of July 15. At Subcommittee, there's every reason to believe Chairman Porter (R-IL) has included identical language to last year giving the Secretary of HHS authority to waive the ban on federal funding of needle exchange programs. We've been told 6 Republicans sent a letter to Porter indicating they intend to submit an amendment to strip the Secretary of this authority. Mr. Porter probably has the votes to win this at Subcommittee, but at full committee it is much dicier, much less a full House vote. It's unclear if Rep. Livingston will stick by his standard of keeping riders off Approps. bills when it comes to conservative social agenda issues.

Dept. of Health and Human Services It's my understanding that a fair level of consensus has been reached at staff level around a limited lifting of the needle exchange ban -- with a clear set of conditions to be met before funds are used. A final discussion with the Secretary is still pending.

Public Health/Community Politics As you know, the U.S. Conference of Mayors passed a resolution favoring local flexibility and opposing a federal ban on needle funding. The American Medical Association passed a resolution calling for the lifting of the ban last week. The issue is getting more mainstream political cover with AMA, and the public health arguments have been put out front.

The AIDS community is nearly united in believing that the House action will come out unfavorably, with a loss of the Secretary's authority. They are pushing for early action, lifting the ban before the House Appropriations process begins. Rep. Stokes (D- OH) who sits on Approps and is a leader in the Congressional Black Caucus has been sending signals that he is willing to be vocal in support of lifting the ban -- and the CBC will likely follow his lead when the time comes. They are waiting for the Administration.

Timing Issues There are pros and cons to moving ahead to lift the ban on needle exchange. Briefly -

Page 2 - Needle Exchange

Pros

- o There is some clear momentum to ride on after USCM and the AMA.
- o If the Secretary lifts the ban before House action, respected public health/scientific voices like Harold Varmus are freed up to meet with Reps. Porter, Obey and a few key members to walk through the scientific data underlying the decision. Porter may need the scientific credibility and public health arguments at Subcommittee to help hold Members and stem the slide to a partisan vote.
- o By acting early, the Administration could get credit for having taken the right public health stance on needle exchange as a component of HIV prevention with the public health community and the advocacy groups. The onus for keeping the ban would shift to the Congress -- where the accusations of playing politics with public health can be roundly debated.
- o If the House acts before the Administration to strip the Secretary of her authority to waive the ban, the Administration is subject to criticism that it never intended to act and seeks only to blame Congress -- as it did nothing between February and July on the issue.

Cons

- o There will clearly be media critical of any federal funding of needle exchange
- o There will be action to strip the Secretary's authority -- with or without the Administration's action on lifting the ban. Action to lift the ban is unlikely to provoke conservative amendments alone -- these already appear to be in the works.
- o Some anti-drug groups will try to portray the Administration as starting down the slippery slope of drug legalization by lifting the ban. This will call for vigorous public health arguments and raising the banner of NGA, USCM, ASTHO, AMA, and other state/local public health groups.

Next Steps

I think our best course is to go ahead and get this issue off our plate and onto the lap of Congress by lifting the ban. This is where the groups are at. We continue to take a battering from all sides by sitting on it much longer. I think HHS needs to hear White House support for moving ahead expeditiously. I have had several meetings with General McCaffrey's staff, and am setting up a briefing for him with Dr. Varmus of NIH at the General's request. Your support with ONDCP to keep a simple and consistent message from the Administration remains important.

Office of HIV/AIDS Housing



Office of Community Planning and Development
U. S. Department of Housing and Development
451 Seventh Street SW, Room 7154
Washington, DC 20410-7000

From: David Vos, Acting Director
PHONE: (202) 708-1934 x4620
FAX: (202) 708-1744

Date: July 21, 1997

Material sent to: HIV/AIDS Housing Providers, Residents, Advocates

Comments: As you may know, some HOPWA grantees have inquired about using program funds to pay for pharmaceuticals and other health care items and services in cases where they anticipate shortfalls in funding available under their Ryan White CARE Act or AIDS Drugs Assistance Program (ADAP) resources. Other persons have expressed concerns that using HOPWA for any shortfalls could result in significantly less housing for persons with HIV/AIDS. I have been part of discussions with HHS on how we might better coordinate the use of these related programs. As we consider the policy issues involved, I would appreciate your review of the issues and your thoughts about how serving clients through HOPWA can be done in connection with assistance offered under ADAP and other HHS programs.

The enclosed paper was drafted by this office to help focus our discussion. It covers ideas and some options on what HUD might do to provide guidance to HOPWA grantees on the collaborative use of these programs. The current regulation restricts the use of HOPWA funds to circumstances when that payment is a payment of last resort. Additional guidance could clarify how any use should also conform to policies established by HHS guidance on this type of activity. As you consider this matter, please feel free to offer comments, ideas and other options that should be considered in continuing to make available, or restricting in some manner, or banning altogether the use of HOPWA funds for ADAP related activities.

In addition, I thought you would be interested in the attached legislation, the Homelessness Assistance and Management Reform Act of 1997," which was submitted by the Department earlier this month.

I hope that you find this information useful and I look forward to our future endeavors.

Discussion Topics on the Use of HOPWA Funds for AIDS Drug Assistance

7/18/97 edit.

There are a number of possible options and issues to be considered regarding the use of HOPWA funds for AIDS drug assistance, including payments for pharmaceuticals, such as the protease inhibitors or other prescription drugs. These health care products and services may also be provided to clients through federal funds for AIDS Drug Assistance Programs (ADAP) and under other Ryan White CARE Act components, other federal programs and private sources. A number of persons have expressed concerns that current HUD regulations could be interpreted to allow for this type of health payment and that excessive use of this allowance could result in reducing funding available for HIV/AIDS housing.

Current HOPWA regulations allow for payments for health services as payments of last resort under 24 CFR 574.310(a):

"(2) Payments. The grantee shall ensure that grant funds will not be used to make payments for health services for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service: (1) Under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or (2) By an entity that provides health services on a prepaid basis."

HOPWA grantees may not fully understand the payments of last resort provision of these regulations and may inappropriately attempt to use HOPWA for these activities while other sources of funds remain available for their client.

Some current ideas on resolving these concerns include:

1. Further Guidance on Restricted Use.

HUD guidance could clarify the limited application of the Department's current regulations to specify the limited circumstances and other requirements that would make this an appropriate use of federal housing funds. HUD could clarify to grantees that payments for health costs, including costs of pharmaceuticals, must be made on an individual basis, documented in files that are available for HUD inspection, and that the activities must be consistent with and specifically addressed in any supportive services component of their HUD approved consolidated plan. HUD could issue instructions to area offices to review requests for this activity for such consistency and require grantees to document how they determine individual eligibility.

The guidance could further clarify that payments could only be made in the case that no ADAP funds remain available in that jurisdiction, since that client would otherwise be eligible for assistance from that source. A state ADAP program could not segregate clients into payment groups or otherwise specify that the HOPWA eligible clients be covered under HOPWA for ADAP eligible costs while other ADAP funds remain available to benefit other clients. The statutory authority that allows for such payments may prove beneficial to some

or for which funds are made available by..." If adapted for HOPWA, these agencies listed might include HHS, the Department of Veterans Affairs, the Social Security Administration and under payments authorized under State medicaid waivers as well as the compensation programs referenced in current regulations. Draft requirements also provided that grantees must have a verifiable means of assuring that communities eligible for grants or individuals eligible for assistance comply with this requirement. Grantees will need to have a process in place to ensure that no duplication of benefits occurs and grantees may use a certification process to accomplish this task.

6. Place a Cap on Services.

In addition to the new guidance above, or in lieu of that guidance, HUD could issue a rule to limit the proportion of HOPWA funds that may be used for supportive services by placing a cap of 25 percent (or some other reasonable amount) on this activity to limit the potential scope of any continued allowance. A cap might not directly address the issue and the use of funds up to the cap amount would still be authorized.

7. No Immediate Action.

The lack of some reasonable action is not advisable. The lack of action might expose the program to criticism, in some communities, in appearing to make housing a lower priority or in creating program uses that may run counter to HHS policies that limit the use of ADAP funds.

Other Issues to be Considered in Implementing HUD Policy.

(a) **Timing of Actions.** HUD should also determine if it is appropriate to impose some or all of the proposed actions on current grant funds or if some or all of the provisions should only be imposed on grants issued in the future under fiscal year 1998 funding.

(b) **Monitoring.** If payments continue to be allowed, HUD should consider how area offices or grantees would monitor the use of funds for this purpose in programs established under the consolidated plan or in a competitively-selected grant.

(c) **Further Consultation with Grantees.** In lieu of an immediate action, HUD could ask any HOPWA grantee that may be planning to use funds for this activity to justify their planned use and to consider further the issues raised by this topic.

(d) **Rulemaking.** HUD could amend the HOPWA regulations to clarify or require any of the above, through expedited final rulemaking or through a proposed rule, in order to solicit public comment, through proposed rule.

Comments or recommendations should be directed to David Vos, Acting Director, Office of HIV/AIDS Housing at (202)708-1934 x 4620 or Paul Yandura at x 4619.

Attachments:

ADAP Guidance Letter of 10-17-96 from Anita Eichler, Director, HRSA
Draft HRSA Fact Sheet on ADAP, June 1997



OCT 17 1995

Dear Colleagues:

This letter communicates the Division of HIV Services' (DHS) expectations and recommendations about administration of State AIDS Drug Assistance Programs (ADAPs) supported with Ryan White Comprehensive AIDS Resources Emergency (CARE) Act funds. To assure that all critical constituents in the pharmaceutical assistance arena are consistently informed, this correspondence is being sent to Title II grantees, ADAP directors, Title I grantees and planning council chairs, people living with HIV/AIDS (PLWH) contacts, national organizations, and other Health Resources and Services Administration (HRSA) AIDS programs.

This communication is being sent in response to issues raised during the DHS review of State applications for funding under the fiscal year (FY) 1996 ADAP supplemental appropriation. It also addresses issues identified through our continuing discussions with States, PLWH constituency groups, Federal officials, and others.

These recommendations are based on close consultation with the Office of the General Counsel (OGC) of the Department of Health and Human Services (HHS), the HRSA AIDS Program Office, the Office of HIV/AIDS Policy of HHS, the Office of Management and Budget, and the White House Office of National AIDS Policy. The recommendations fall into four broad categories: administration, eligibility, formulary, and cost-savings.

Administration

The statutory reference to a "State" ADAP carries with it the expectation that both eligibility criteria and covered treatments for anyone enrolled in the program must be equally and consistently applied across the State. Parity must exist regardless of how a State administers its ADAP or delegates administration of it. If a State chooses to operate its program through subcontracts to consortia or other entities, it is obliged to develop and monitor the consistent application of eligibility standards and a common formulary. The Department intends to pursue rule making to assure this consistency in State ADAPs. If a consortium or other entity elects to use other resources (including Title II funds not designated by Congress for ADAPs) to liberalize eligibility standards or to enrich a State-specified formulary it may do so by establishing a complementary program. It may not do so as part of the State ADAP.

States which elect to establish complementary medication assistance programs (or to permit or instruct consortia/other entities to do so), as well as Title I drug reimbursement programs, will be required to file ADAP Annual Administrative Reports for these separate programs.

It is the observation of DHS that centrally-administered ADAPs are better able to achieve the accountability, parity, consistency and cost-savings described in this letter than those which are decentralized. For this reason, DHS strongly recommends that every State consider establishing a centrally-administered ADAP.

HHS, in requesting the supplemental funds for ADAP, and the Congress, in appropriating them, clearly expected that Title II grantees would use these funds to *expand* current efforts to improve access to pharmaceuticals for low income individuals with HIV disease. Inherent in that position is the expectation that States should not use these new funds to supplant Title II resources that had been committed to ADAPs without compelling reasons. Grantees (including *Title I* grantees) electing to controvert this expectation are advised to be prepared to provide explicit and convincing justifications in the case of Congressional or other governmental inquiries. Grantees are also reminded that States subject to the matching requirement for Title II must match these supplemental ADAP resources as well.

Eligibility

The CARE Act indicates that ADAPs are to serve "low income individuals," as defined by the States. DHS strongly believes that a determination of low income should focus ADAP resources on individuals with demonstrated severe need based on poverty. Standards should be anchored to Federal poverty guidelines. States may authorize consortia, or use other mechanisms, to provide pharmaceutical coverage for the occasional client who has the unique combination of relatively higher income and documented severe need for pharmaceutical assistance.

As I pointed out in my remarks at the National Meeting in August, it is vitally important that States prioritize use of these funds and take rigorous steps to assure that Medicaid-eligible individuals are transferred to that program at the earliest possible date. It is equally important in defining ADAP eligibility standards that financial need have at least equal weight with clinical indicators of need. DHS pledges to continue working with States on this critical issue, and to identify and share models for assuring careful and complete response to the legislative mandate that ADAPs serve only low income individuals.

DHS expects that all States will devise, implement, and rigorously monitor the use of consistent eligibility standards across all entities involved in certifying ADAP eligibility. Such certification is expected to include review and *documentation* of an applicant's income from all sources, and any pharmaceutical benefits through private health insurance or other sources. DHS further expects that every State will establish and implement procedures for re-certification on a periodic basis, and for de-certifying individuals who qualify but do not make use of the program over an extended period of time (e.g., one year or longer). Re-certification procedures should include mechanisms to assure that individuals who have become eligible for Medicaid are transferred to that program in a timely fashion.

- **Formulary**

It is the express opinion of DHS, which it intends to enforce through rule making, that the formularies for State ADAPs supported with Title II funds should be limited to *FD-A-approved pharmaceuticals* (as indicated in the appropriations language for the FY 1996 \$52 million supplement) which *treat HIV disease or prevent the serious deterioration of health arising from HIV disease* (as indicated in the CARE Act, as amended). This definition of "pharmaceuticals" includes ancillary devices (e.g., IV tubing, nebulizers, etc.) needed to administer approved medications.

This formulary restriction does not preclude States from using other Title II funds for nutritional supplements, over-the-counter medications, and other items which are of benefit to individuals with HIV disease. Nor does it preclude States (or Title I grantees) from using other CARE Act funds for diagnostic tests associated with monitoring patients' responses/reactions to the approved medications. The restriction simply limits ADAP programs to approved effective pharmaceuticals and, to the extent possible, assures that the appropriate primary health care payment source covers the cost of essential diagnostic tests.

The Senate version of the reauthorized CARE Act required that the Secretary develop a "minimum drug formulary for suggested use by the States." This requirement was not included in the final amendments which reauthorized the Act. However, the Manager's Statement which summarizes the deliberations between the House and Senate includes the following language:

The conferees emphasize that the Secretary is encouraged to advise states on classes of drugs that have been found to be effective in preventing and treating HIV disease...

DHS commits to work in close collaboration with the HRSA AIDS Program Office, grantees, consumers, and constituent groups in responding to this direction provided by Congress.

Cost-savings

Both HHS and the Congress expect that States will use every means at their disposal to secure the best price available for all products on their ADAP formularies in order to achieve maximum results with these funds. Known and proven strategies include participating in the Veterans Health Care Act Drug Pricing discount program, directly negotiating discounts or rebates from manufacturers or wholesalers, negotiating price reductions from dispensaries (whether mail order pharmacies, pharmacy chains, or local retail pharmacies), implementing programs to recoup private insurance and other third party payments, encouraging enrollees to take full advantage of compassionate use and patient assistance programs, and assuring timely enrollment of all eligible individuals in the State's Medicaid program.

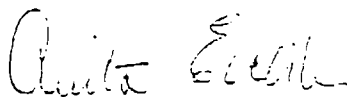
The Division will provide technical assistance to grantees desiring help in understanding and fully utilizing any of these cost saving strategies. We expect that every Title II grantee will adopt

at least one defined cost-saving practice. Grantees who fail to aggressively pursue cost-savings are advised to be prepared to provide convincing justification for Congressional or government inquiries.

The Division acknowledges that this communication is explicitly directive about a specific element of the CARE Act, which might be interpreted by some to diverge from the local autonomy inherent in the legislation. I wish to assure you that we are sharing this information as directly and clearly as possible because we see it as being in the best interests of the program at every level, and essential to our role as administrators of Title II of the CARE Act.

Finally, and most importantly, we are convinced that these steps will assure that the largest number of individuals with HIV and AIDS will have access to medications which show the greatest promise for prolonging and/or increasing the quality of their lives. We are vitally concerned that these promising medications be made available in an appropriate context of primary care and look forward to working with you to identify ways in which the systems of care we support can most effectively promote the patient adherence that is essential to the success of many HIV/AIDS pharmaceuticals.

Sincerely,



Anita Eichler, M.P.H.
Director

cc: William Aspden, Acting Director, Bureau of Health Resources Development
Joseph F. O'Neill, M.D., M.P.H., Associate Administrator for AIDS, HRSA
Don Young, Chief, HRSA Branch, Office of the General Counsel, HHS
Eric Goosby, M.D., Director, Office of HIV/AIDS Policy, HHS
Nancy Ann Min, Associate Director for Health and Personnel,
Office of Management and Budget
Patsy Fleming, National AIDS Policy Director, Executive Office of the President

HRSA Fact Sheet

June 1997

The Ryan White CARE ACT

AIDS Drug Assistance Programs

Introduction

AIDS Drug Assistance Programs, or ADAPs, are Federally-supported programs that are administered by all States, the District of Columbia, Puerto Rico, the Virgin Islands, and Guam. ADAPs are one of several important sources of pharmaceuticals for individuals with HIV disease. In 1996, ADAPs nationwide served almost 83,000 low-income persons with HIV disease who had limited or no coverage from private insurance or Medicaid.

ADAPs are authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, enacted in 1990 and reauthorized in May 1996. ADAP is one of five program uses outlined in Title II, which requires that:

"A State shall use a portion of the amounts provided to establish a program ...to provide therapeutics to treat HIV disease or prevent serious deterioration of health arising from HIV disease in eligible individuals, including measures for the prevention and treatment of opportunistic infection."

While ADAPs have been serving clients since 1987 (see box), recent treatment advances have focused increasing attention on the program. The newest class of HIV drugs, protease inhibitors (PIs), have been shown to be very effective when used in combination with two or three other antiretrovirals. As a result, demand for the promising new combination therapy has grown rapidly -- not only among those already in care, but also among individuals who up to now had not sought treatment. Because the cost of combination therapy with PIs is very high -- between \$10,000 and \$12,000 a year per person -- ADAPs are being severely challenged in responding to the increased client demand.

Even before the expensive new drugs became available, many ADAPs were experiencing strains. In part, this was due to the rapid growth of the HIV

epidemic among poor and historically underserved populations, including women. In addition, the number of people seeking and receiving treatment for HIV and AIDS continues to increase on a monthly basis.

ADAPs have increased dramatically in recent years. In fiscal year 1996, \$52 million in supplemental funds were appropriated for ADAPs. \$100 million was added to the \$53 million which States had already committed from their Title III awards. In fiscal year 1997, \$167 million in Title II CARE Act funds were earmarked for ADAPs.

The story of ADAPs begins ten years ago. In March 1987, zidovudine -- better known as AZT -- became the first drug approved to treat HIV disease. However, when it first became available, AZT cost about \$10,000 a year per patient, placing it out of reach for many people. Congress responded a month later by approving \$30 million in funding under a public health emergency provision, and later enacted Public Law 100-71 authorizing the establishment of an ADAP program nationwide.

As HIV treatment advances occurred and as resources permitted, the program was expanded by States to cover more than AZT. In 1990 when ADAP was folded into Title II, States had the option to cover any FDA-approved drug which could prolong life or prevent deterioration of health.

ADAPs and other CARE Act programs are administered by

HRSA Fact Sheet

(Side Two)

The Ryan White CARE Act AIDS Drug Assistance Programs

States' Role in Managing ADAPs

Since the creation of ADAPs, States have had the authority to establish income and medical eligibility criteria and to determine how drugs will be purchased and distributed to clients. States also determine which drugs to include on their formularies. As the number of HIV treatments approved by the Food and Drug Administration (FDA) increased, most States added some or all of the newer drugs. The faster pace of approval and greatly increased cost of new medications have impacted formulary expansion. Today, there is considerable variation in the number of drugs on ADAP formularies, ranging from 5 to over 100, with half of the States covering 25 or more drugs.

Purchase and Distribution of Pharmaceuticals

Most ADAPs were established to operate under a pharmacy reimbursement model similar to Medicaid. This allows a patient to go to a participating pharmacy, show their ADAP card, and have their prescription filled. The pharmacy then bills the ADAP.

A few States with a system of pharmacies attached to a network of public health clinics have opted to use that system to purchase and distribute drugs for ADAP clients. Only a few ADAPs directly purchase drugs and mail them to clients.

Cost-Containment Measures

With the significant growth in clients seeking treatment and the increases in the cost of new treatments, and changing standards of care, ADAPs are challenged to contain costs at the same time they are asked to expand access. As a result, ADAPs have taken a number of steps to stretch dollars. These include changing the system used to purchase/distribute drugs; seeking larger price discounts (e.g., by participating in the Office of Drug Pricing Program administered by HRSA, or negotiating voluntary manufacturers' rebates); tightening

income eligibility criteria; deleting some drugs from State formularies; setting caps on ADAP benefits;

and/or establishing guidelines for prescribing drugs.

Income Eligibility

Because Title II gives States the authority to set income and medical eligibility criteria for ADAP, there is a great deal of variety among States. (See Table for an overview of income eligibility criteria.)

Table 1: Income Eligibility for ADAPs, 1997

Up to 150% Federal Poverty Level (FPL)	6 ADAPs
150% to 200% FPL	18 ADAPs
200% to 500% FPL	17 ADAPs
Over 500% FPL	11 ADAPs

1997 Federal Poverty Limit is \$7,400/year per individual

The variation in eligibility reflects the type and availability of other health care resources for low-income individuals with HIV disease. Among the most important are differences in State Medicaid programs. For example, income eligibility criteria differ among the States for some Medicaid covered populations, and the extent of drug benefits and other optional health services varies among States.

States also differ in terms of the availability of private health insurance options for low income families and individuals with pre-existing conditions. For example, some States have created high-risk health insurance pools and/or health insurance continuation programs, and some have enacted regulations regarding the extent to which private insurers can cap drug benefits.

Medical Eligibility

Most (40) ADAPs require individuals who meet their income threshold simply to provide proof of their HIV diagnosis. However, fourteen ADAPs also require a laboratory test showing a CD₄ count of 500 or less, and seventeen have specific criteria for access to protease inhibitors and/or antiretrovirals.

HRSA Fact Sheet The Ryan White CARE Act

AIDS Drug Assistance Program

Funding Overview -- June 1997

Increased Demand for ADAP Services

For the last ten years, federal funds have played a major role in providing access to drug therapies for people with HIV and AIDS. Over the last several years, ADAPs have experienced an unprecedented rate of growth in client demand and program costs, due to:

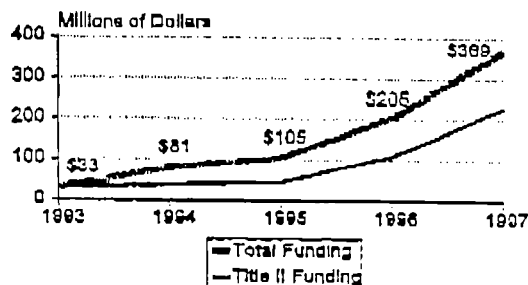
- ◆ the rapid expansion of the HIV epidemic in recent years among low-income and uninsured populations,
- ◆ the high cost of newly approved drugs that must be used in multiple-drug regimens, and,
- ◆ the increasing numbers of people with HIV/AIDS who are now seeking triple combination therapy due to the widely publicized research results that show the promise of these new therapies for improving the health status and quality of life of individuals with HIV disease.

In response, the amount of Federal and State funding allocated to ADAPs has grown significantly since 1995 (see chart at right). Future demand on ADAP resources is expected to escalate as the standard of care shifts toward earlier treatment for people with HIV and as patients continue to respond positively to the new drug therapies.

Overview of Funding

ADAPs receive funding from a variety of sources, including the Federal government, some States, Title I Eligible Metropolitan Areas (EMAs), and cost-recovery strategies. Title II monies are allocated to States based on a formula. In the past two years, additional Federal funds have been appropriated and earmarked specifically for ADAP. Some States have also allocated State resources to ADAP.

AIDS Drug Assistance Program (ADAP)
Total Funding - 1993 to 1997



What is ADAP?

AIDS Drug Assistance Programs (ADAPs) are Federally-supported programs that are administered by all States, the District of Columbia, Puerto Rico, the Virgin Islands, and Guam. ADAPs are one of several important sources of pharmaceuticals for individuals with HIV disease. In 1996, ADAPs nationwide served almost 83,000 low-income persons with HIV disease who had limited or no coverage from private insurance or Medicaid.

ADAPs are authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, enacted in 1990 and reauthorized in May, 1996. ADAP is one of five program uses for Title II, which requires that:

"A State shall use a portion of the amounts provided to establish a program... to provide therapeutics to treat HIV disease in eligible individuals, including measures for the prevention and treatment of opportunistic infections."

Federal Support

Over the past five years, ADAPs have received a 567 percent increase in Title II funding -- rising from \$33 million in FY 1993 to a projected \$220 million for FY 1997. For two years, the President

and Congress have targeted Title II funds specifically to ADAPs to respond to increases in client demand and costs of pharmaceuticals. Last year (FY 1996), a \$52 million supplemental appropriation was approved for ADAP, which together with the \$58 million in Title II funds allocated to ADAP by States, accounted for a little more than half of the \$205 million in total funds available for ADAPs during that year.

For FY 1997, \$167 million in Title II funds were earmarked for ADAPs by the Congress, a 221 percent increase over FY 1996. In addition, States have allocated \$63 million of their "base" Title II funds for ADAPs for FY 1997. These two sources of funding represent 64% of the projected total budget of \$359 million.¹

State Support

During FY 1996, 35 States contributed a total of \$53 million dollars to ADAP, representing 25% of the ADAP budget nationwide. For FY 1997, 30 States to date have allocated \$90 million dollars to ADAP, a 70% increase over last year. For States appropriating general revenue dollars in FY 1997, the contributions range from a low of \$40,000 to a high of \$27,259,000.

Title I EMA Support

Along with support from the States, some ADAPs rely on allocations from Title I EMAs to help fill service-gaps and insure a continuum of care. In FY 1996, 13 of the 23 States with Title I EMAs received Title I funds totaling \$26 million. It should be noted that more than 80% of the \$26 million came from a single EMA -- New York City. In FY 1997, 12 States project receiving \$23 million from their Title I EMAs, but revenue from Title I EMAs is expected to increase as additional ADAPs and EMAs negotiate final FY 1997 allocations.

Cost Recovery Strategies

Most States (41) are engaged in multiple cost recovery strategies designed to maximize available funds and assist the greatest number of people living with HIV and AIDS. Generally, these strategies result in savings secured by the State ADAP which come directly back into its ADAP budget. Examples of such cost-cutting methods include voluntary manufacturers' rebates, purchasing discounts with wholesalers or pharmacies, and insurance recovery mechanisms for clients with partial drug benefit coverage through Medicaid or private insurer.

During FY 1996, 22 States received \$16 million dollars from these cost-saving mechanisms. In FY 1997, 10 States estimate they will receive \$25 million from these methods. For those 10 States, the projected funds to be received range from \$25,000 to \$1,740,000. Complete reports from remaining States are expected to yield significantly increased savings by the end of FY 1997.

Current and Emerging Issues

As new and rapidly changing treatment methods enhance individuals' overall health status and improve their quality of life, ADAPs will continue to face fiscal challenges. Most ADAPs are projecting program growth with increased enrollment and increased utilization of multi-drug combinations. As the goal of managing HIV infection as a chronic disease progresses, program policies will need to change to reflect these advances. ADAPs will also need to re-examine their roles as more State Medicaid programs evolve into managed care. Finally, the impact of Congress and the Administration having agreed to achieve a balanced budget by the year 2002 needs to be anticipated by ADAPs.

¹ Due to the projected shortfalls in two States, \$10 million of those earmarked funds were advanced as emergency funds for use in the last quarter of FY 1996.

ADAPs and other CARE Act programs are administered by the Health Resources and Services Administration, Bureau of Health Resources Development, Division of HIV Services.

June 4, 1997

MEMORANDUM FOR SANDRA THURMAN

From: Daniel C. Montoya and Michael Diz

Re: American Bar Association Standing Committee on Substance Abuse discussion on needle exchange policy.

Attached is a list of the members of the Standing Committee on Substance Abuse.

Speakers included:

Bob Stein, Co-Chair, AIDS Coordinating Committee:

- Needle exchange does not increase drug use.
NIH, CDC and others, including Secretary Shalala, agree.
- The need is greater than ever.
One half of all new infections result from ID use.
- There is popular support for needle exchange.
Polls conducted by both political parties repeatedly show a vast majority are in support of needle exchange when linked with slowing the spread of HIV.
New Mexico and other states have approved legislation in favor of needle exchange.
- Legal Issues:
Counseling should be included in all programs.
Needle Exchange is only an interim measure, not the final word.
Local authorities should determine what type of program will best serve their area.
It may be the case that a needle exchange program best fits one community, but another may be better served by removing the need for a prescription to obtain needles.

Ed Jurith, General Counsel, ONDCP

- The ultimate goal is to decrease **both** HIV transmission and drug use.
- The data on the effect of needle exchange on drug use is inconclusive.
The jury is still out as to whether or not needle exchange leads to a decrease in drug use.
- Needle exchange does not lead to a decrease in drug use.
If needle exchange programs are adopted, the power to do so should be put in the hands of local officials.
It should be recognized that needle exchange is not drug treatment.

Memorandum for Sandra Thurman

June 4, 1997

Page two

Pedro Pierluisi, Committee Member

- It is very important to be careful about the message sent out with regard to this policy.
Be sure not to give the impression that this is making it easier for heroine addicts to continue their use.

Discussion:

There was overall agreement that needle exchange is only an interim measure, and that effective drug treatment is the core issue.

Bill Ide, Chair of Committee asked Ed Jurith what ONDCP's position was on ABA's recommendation:

Answer: Ed Jurith - ONDCP was neutral on the recommendation, because the recommendation is cohesive with federal policies now.

Follow Up:

I suggested to Cliff Cortez that he construct talking points and Qs & As for the ABA House of Delegates in San Francisco regarding their message on Needle Exchange. In addition, I told him to get with Seth Kilbourn and the NORA Needle Exchange Working Group and look at building some coalitions, especially in the San Francisco Bay area to further help him with his message and delivery. Furthermore, I suggested that he speak with Terje Anderson as a possible resource.

American Bar Association
STANDING COMMITTEE ON SUBSTANCE ABUSE
Confirmation List for Wednesday, June 4th

R. William Ide III (Chair)
St. Louis, MO

The Honorable Arthur L. Burnett, Sr.
Washington, DC

Mathea Falco
Washington, DC

The Honorable Sheila Murphy
Markham, IL

Pedro R. Pierluisi
San Juan, PR

LIAISONS

Board of Governors

Steven T. Walther
Reno, NV

Government & Public Sector Law

Cynthia Rapp
Washington, DC

International Law and Practice

Lane Porter
Washington, DC

Judicial Administration Division

Hon. James Rogers
Minnetonka, MN

Labor and Employment Law

Chris Barreca
Stamford, CT

Bernard T. King
Syracuse, NY

Litigation

Bob Saylor
Washington, DC

Unmet Legal Needs of Children

Doris Clanton
Atlanta, GA

ADVISORY COMMITTEE

Jeff Kuhn

Trenton, NJ

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New York, NY

Reginald Robinson
Washington, DC

Dr. Michael Walsh
Bethesda, MD

Harvey Weiss
Austin, TX

STAFF

Gloria Danziger
Staff Director

Stephen Cribari
Project Manager

Michelle Darter Dobles
Program Coordinator

SPEAKERS

Nancy Anderson
Staff Director, Steering Committee on the Unmet Legal
Needs of Children

David H. Bralove
President, National Treatment Consortium

Jenny Collier
Counsel, Legal Action Center

Cliff Cortez
Staff Director, ABA AIDS Project

John Gregrich
Senior Policy Analyst, ONDCP

Ed Jurith
General Counsel, ONDCP

Bob Stein
Co-Chair, AIDS Coordinating Committee

Sandy Thurman
Director, White House Office of
National AIDS Policy



NATIONAL
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440 FIRST STREET, N.W., SUITE 500
WASHINGTON, D.C. 20001
(202) 783-5550 (202) 783-1583 FAX

Post-it [®] Fax Note 7671		Date 6-16-97	# of pages 2
To <i>Ted Summers</i>		From <i>Debbie Mitchell</i>	
Co./Dept.		Co.	
Phone #		Phone #	
Fax # <i>202-632-1096</i>		Fax #	

NACCHO RESOLUTION TO CURB TRANSMISSION OF HIV AND OTHER BLOODBORNE DISEASE INFECTIONS RELATED TO INJECTION DRUG USE

WHEREAS, the practice of sharing needles among drug users (IDUs) is an efficient mode of transmitting bloodborne pathogens including HIV, Hepatitis B and C, and other diseases; and

WHEREAS the Centers for Disease Control and Prevention (CDC) estimates that the majority of new HIV infections in the United States are occurring among IDUs or their sexual partners; and

WHEREAS, the increases in HIV infection among women and infants is inextricably linked to the prevalence of HIV infections among IDUs and the subsequent spread of the virus to their sexual partners and their offspring; and

WHEREAS, several states have repealed statutes restricting access to sterile injection equipment and some have established needle exchange programs (NEPs) in an effort to reduce the spread of bloodborne infections through needle sharing; and

WHEREAS, the experience of existing NEPs has demonstrated the efficacy of this intervention in terms of reducing the risk of HIV and other bloodborne disease transmission; and

WHEREAS, a comprehensive study commissioned by the CDC in 1993 concluded that needle exchange and the repeal of restrictive statutes on the sale and possession of needles/syringes should be embraced at the local, state and federal level, as part of a comprehensive public health approach to curb the spread of HIV.

THEREFORE, BE IT RESOLVED that NACCHO supports and local health officials will advance the following multifaceted strategy:

- the repeal of state statutes that restrict the sale, purchase and possession of sterile needle equipment - without repeal or restriction of existing federal, state, and/ or local drug paraphernalia laws
- initiatives at the local level to promote clean needle access and to cultivate support for this intervention within the context of a multifaceted public health approach to stem bloodborne disease transmission among IDUs, their sexual partners, and their offspring

- aggressive education and outreach to active injection users with explicit instructions on safe needle use and the avoidance of HIV transmission through risky sexual behaviors, based on the most current body of knowledge on effective risk reduction techniques
- the establishment of needle exchange programs in more communities
- education for police officers and pharmacists and other critical groups, about the imperative to provide drug users with access to sterile needles/syringes.

BE IT FURTHER RESOLVED that NACCHO calls upon the federal government to abolish the current prohibition on the use of federal funds for needle exchange programs and for evaluation research to continue to assess the impact of NEPs.

BE IT FURTHER RESOLVED that NACCHO urges state and federal legislators to take swift action to remove legal and social barriers to clean needle access increase the availability of drug treatment services and support continuing study of NEPS.

Resolution 95-3

Adopted by the NACCHO Board of Directors

October 29, 1995

AmFAR

AIDS RESEARCH

PUBLIC POLICY OFFICE

1828 L Street, N.W., Suite 802

Washington, D.C. 20036

(202) 331-8600

FAX: (202) 331-8606

FACSIMILE COVER SHEET

DATE:

6/17

TO:

Sandy Thurman

FROM:

X

Jane Silver

Scott Sanders

Jim Oleson

TOTAL # OF PAGES:
(INCLUDES COVER)

MESSAGE:

Here is FACT SHEET, MMWR coming
out this week, and Resolutions Passed by organizations.
Call me ANY TIME (H) 202 398-5271 (W) 202 331-
8600

AND THANK YOU FOR HAVING THE PHONE CALL

Facts About AIDS and Syringe Exchange in the United States

AIDS in the United States

- One in 250 people in the United States is infected with HIV
- One-third of AIDS cases in the US. are directly or indirectly associated with injecting drug use
- 50% of new HIV infections are occurring among injecting drug users
- HIV infection is almost always fatal

AIDS Prevention

- No preventive vaccine is likely to become available soon
- Syringe exchange programs (SEPs), which are a major component of HIV prevention strategies in most developed and many developing countries, have been shown to reduce the rate of transmission of HIV
- Early implementation of SEPs and legal status influences the spread of HIV. In the United Kingdom, where SEPs were implemented early in the epidemic and have always been legal, only 614 cumulative injection-related AIDS cases had been reported through March of 1995, compared with 48,450 cases in New York City alone or 146,359 in the United States.

The Controversy Surrounding Syringe Exchange

- Syringe exchange has been met with controversy in the United States, resulting in a ban on federal funding of syringe exchange programs
- Opponents argue that syringe exchange will increase the number of injecting drug users
- Scientific studies, including 7 government sponsored studies, show that SEPs do not lead to any detectable increase in the number of drug users on a community level
- An evaluation of SEPs in New York City showed a reduction in the frequency of HIV risk behaviors and the rate of new HIV infections among participants
 - ◆ frequency of risky injection among participants was reduced by 63%
 - ◆ frequency of injection among participants decreased by 7%
 - ◆ the rate of new HIV infections among participants decreased by two-thirds

Facts About AIDS and Syringe Exchange in the United States

"More than Just Clean Needles"

- SEPs are complex organizations which provide a multitude of services both on-site and through referral
- A survey of the approximately 100 SEPs operating in 71 cities in 29 states found that:
 - ◆ 97% make referrals to drug treatment
 - ◆ The 3% that do not offer drug treatment referrals are "underground" exchanges which operate in states with prescription or paraphernalia laws & have not received a formal vote of support or approval from local or elected officials
 - ◆ 97% offered sexual and/or drug risk reduction
 - ◆ More than 40% provided on-site HIV counseling and testing

SEPs are Cost Effective

- ◆ The median annual budget of SEPs in the United States is \$169,000; Since the lifetime cost of treating one person with AIDS is approximately \$120,000, each SEP more than pays for itself by preventing the transmission of HIV/AIDS to less than two people
- ◆ Syringe exchange programs could have prevented 9,700 HIV infection nationwide at a savings of \$538 million

Public Opinion Supports SEPs

- A 1996 Kaiser Survey on Americans and AIDS/HIV found that 66% of respondents favored "having clinics make clean needles available to IV drug users to help stop the spread of AIDS."
- The following professional and government bodies have voiced their support for syringe exchange as an HIV prevention strategy: American Medical Association, American Public Health Association, Association of State and Territorial Health Officials, National Academy of Sciences, National Research Council, U.S. Centers for Disease Control

For further information on this topic contact:

Denise Paone, Ed.D.

Assistant Director of Research

Assistant Professor of Epidemiology and Social Medicine
Beth Israel Medical Center, Chemical Dependency Institute
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Community Levels of Injecting

City	Summary	Reference
San Francisco	An increase was observed in the mean age of IDUs during the years in which the SEPs were in operation. The mean age in 1996 was 36 years, compared with 42 years in 1992. Less than 1% of participants were under 18 years of age.	Watters et al 1994
Portland	Fewer than 2% of program participants had been injecting drugs for less than one year. The average duration of injection drug use among participants was 14 years, & more than 75% of participants had been injecting for 5 years or more.	Oliver et al 1994
Multi-City	The median age of participants ranged from 33 to 41 years, and the mean duration of injection drug use ranged from 7 to 20 years, suggesting that SEPs tend not to attract recent initiates into injecting drug use.	Lurie et al 1993
New Haven	From November 1990 to December 1991, no change was found in the mean age & mean duration of injection over time of SEP participants. Throughout the study period, the average participant was 33 to 34 years old & had been injecting drugs between 5 and 10 years.	Heimer et al 1993
Amsterdam	Despite the initiation of syringe exchange in 1984, the overall number of IDUs remained stable, and the average age of drug users increased over time. The number of IDUs under the age of 22 decreased from 14% in 1983 to 3% in 1988.	Hartgers et al 1989

Frequency of Injection

Injection Frequency Decreased after Introduction of SEPs	Injection Frequency Stable after Introduction of SEPs	Injection Frequency Increased after Introduction of SEPs
Amsterdam ^{a,b} Hartgers et al, 1989)	NYC (Paone et al, 1993)	London/SW England (Dolan et al, 1991; Donoghoe et al, 1991)
Tacoma (Hagan et al, 1991; Hagan et al, 1992)	San Francisco (Watters & Cheng, 1991; Feldman et al, 1989)	
Wales ^a (Stimson et al, 1991)	San Francisco (Grydish et al, 1993)	
NYC (Paone et al, 1994)	Tacoma (Hagan et al, 1993)	
San Francisco (Watters et al, 1994)	NYC (Des Jarlais et al, 1994)	

^aCompared with control group(s)

^bRetrospective component

The available scientific literature provides evidence based on self-reports that needle exchange programs do not increase the frequency of injection among program participants. Most studies show either stable levels of reported drug injection or even declines over time among injection drug users who continue to participate in syringe exchange programs.

HIV Seroincidence and Syringe Exchange

City	HIV Prevalence ^a	Measured HIV Seroconversions ^b	Estimated HIV Seroconversions ^c
Lund, Sweden	Low	0	
Glasgow, Scotland	Low		0-1 (2)
Sydney, Australia	Low		0-1 (2)
Toronto, Canada	Low		1-2 (2)
England and Wales (except London)	Low		0-1 (1)
Kathmandu, Nepal	Low	0	
Tacoma, WA	Low	<1	
Portland, OR	Low	<1	
Montreal, Canada	Moderate	13	
London, England	Moderate		1-2 (4)
Vancouver, Canada	Moderate	18	
Chicago, IL	High	0	
Amsterdam, the Netherlands	High	4	
New York, NY	Very high	2	
New Haven, CT	Very high		0 (3)

^aLow = 0 to 5 percent; moderate = 6 to 20 percent; high = 21 to 40 percent; very high = 41+ percent

^bCohort study and/or repeated testing of participants in per 100 person years at risk

^cEstimated from: (1) stable, very low <2 percent seroprevalence in area; (2) self-reports of previous seronegative test and a current HIV blood/saliva test; (3) HIV testing of syringes collected at exchange per 100 person years at risk; and (4) stable or declining seroprevalence.

*Seroincidence is defined as the rate of new HIV infections observed

Cost Effectiveness

- ◆ From 1987-1995, an estimated 4394-9666 HIV infections could have been prevented by SEPs in the United States¹
- ◆ The cost to the US health care system of treating these potentially preventable HIV infections during this period was between \$244-\$538 million¹
- ◆ The average annual SEP budget is about \$168,650¹
- ◆ In New York City:
 - SEPs avert approximately 788 new HIV infections per year
 - The cost to care for 788 HIV-infected persons per year is approximately \$62,840,000
 - This amount is approximately 40 times more than the cost of implementing syringe exchange

¹Lurie & Drucker 1997

Statements/Resolutions/Policies on Increased Access to Clean Needles and Syringes

American Medical Association

H95.958 Syringe and Needle Exchange Programs
The AMA encourages needle exchange programs

American Medical Association A Physician Guide to HIV Prevention
Primary care physicians can help their patients reduce HIV risk from injecting drugs by encouraging their patients to...

- Abstain from using drugs and to seek treatment.
- Use a new needle and syringe each time drugs are injected.
- Have their own personal injection equipment that is never shared.
- Share only needles and syringes that have been correctly cleaned.
- Use condoms with sex partners who share injection equipment.

American Foundation for AIDS Research

February 1997 Letter to President Clinton

The ethical imperative to provide sterile injection equipment to intravenous drug users is strongly supported by the nation's foremost bioethicists : Consensus Statement "On the Ethics of Denying Injection Drug Users Access to Sterile Injection Equipment"

...These principles inform our conclusion that the failure to fund needle exchange efforts, with the predictable loss of life that can be traced to HIV infections that might have been averted, is ethically unacceptable.

...We believe that a failure to lift the federal ban on funding of needle exchange programs represents a policy that will consign thousands of men, women and children to early deaths. By every principle of medical ethics this situation calls out for a change.

American Public Health Association

9515: Syringe and Needle Exchange and HIV Disease
therefore

1. Urges both Congress and the executive branch take positive steps to support syringe and needle exchange programs;
2. Urges state and local governments to take steps to improve drug users' access to clean injection equipment (e.g. through decriminalizing possession of injection equipment and institution of needle and syringe exchange programs) and to ensure that such programs complement the drug abuse treatment system; and
3. Urges further evaluation of programs to provide sterile injection equipment.

Association of State and Territorial Health Officials

Policy Statement: Needle Exchange

ASTHO promotes the following policy:

- ... Therefore ASTHO recommends that drug users who continue to inject should be advised of the following guidelines for reducing their risk of infection with injection-related blood-borne infections: Use a new sterile syringe to prepare drugs for injection; Only use clean or never-before-used “cookers and “cotton” in preparing drugs; Use clean water from a reliable source (tap water) and, if possible, sterile water for preparing drugs; Clean the injection site prior to injection with a new alcohol swab; Use a new sterile syringe to inject drugs; Use only syringes obtained from a safe, reliable source (e.g.. pharmacy or syringe exchange); Never re-use or share syringes or drug preparation equipment; Safely dispose of syringes after one use.)

- As this nation’s lead public health authority, the U.S. Public Health Service should provide in writing clear policy statements regarding the importance of sterile needles and syringes for injection drug users who continue to inject and clear advice to interested states on 1) how to increase access to sterile needles and syringes and 2) to deregulate possession of needles and syringes.

- The federal government should not restrict the use of federal funds for needle exchange services to also interested states and localities the financial flexibility to support successful prevention and treatment initiatives within their jurisdiction.

- As a possible public health strategy to reduce the transmission of injection-related blood-borne infections, states should explore the removal of legal barriers such as drug paraphernalia and prescription laws, which criminalize the distribution and/or possession of needles and syringes.

- States with needle exchange programs should continue development of state and local syringe exchange programs incorporating a strong evaluation component and disseminating the results of the evaluation research to the public health community. Interested states should develop and implement procedures to identify process, outcome and cost-effectiveness evaluation measures to assess the effectiveness of increased needle access.

- State health departments should explore conducting educational programs with pharmacists, police and members of the legal system about the public health importance of sterile syringes for drug users who continue to inject.

- States should provide leadership strategies to increase access to sterile needles and syringes in communities where such strategies are deemed an important component of the public health approach to reducing injection related blood borne infections. Such leadership could include community/provider education and outreach, as well as financial support for successful community based programs.

- Any strategy, whether developed at the federal, state, or local level, should make a good faith effort to include in the planning and implementation processes members of those communities affected/infected by injection related blood borne infections.

National Alliance of State and Territorial AIDS Directors

NASTAD Resolution

Action to Reduce the Transmission of HIV and Other Diseases Through Increased Access to clean Needles and Syringes

Therefore, be it resolved that:

NASTAD calls upon legislative bodies in the US to increase access to sterile needles and syringes and deregulate possession of needles and syringes and other drug paraphernalia as well as increase access to drug treatment for those individuals ready for such treatment.

NASTAD calls upon federal, state and local agencies carrying out HIV prevention programs to encourage injection drug users who continue to inject: to always use sterile needles and syringes obtained from a reliable source (i.e. pharmacy or syringe exchange program) to prepare and inject drugs; to use new cookers, cotton and water each time; and to safely dispose of injection equipment and other materials after one use.

NASTAD encourages each state health department to work with pharmacy boards and police organizations to convince them of the public health importance of sterile injection equipment for injection drug users who continue to inject, and to work together to increase access to sterile injection equipment and for deregulation of possession of needles and syringes.

NASTAD calls on the Department of Health and Human Services to provide in writing clear policy statements regarding the importance of sterile needles and syringes for injection drug users who continue to inject, and clear advice to states to change laws to increase access to sterile needles and syringes and to deregulate possession of needles and syringes. The Department is encouraged to expand resources for drug treatment and to facilitate linkages between syringe exchanges and treatment, health, and social service agencies.

National Black Caucus of State Legislators

Resolution 97-09 Support for Needle Exchange Programs to Limit the Rate of HIV Infection

Be it Further Resolved, that in the face of mounting positive evidence NBCSL calls on Congress to lift the ban on the use of federal funds for needle exchange programs; and

Be it Finally Resolved, that NBCSL calls upon legislative bodies throughout the country to amend drug paraphernalia and prescription requirements in consultation with their state public health authorities to allow greater access to sterile needle and syringes for those addicted to injection drugs.

New York Academy of Medicine

Report of the Academy Committee on Medicine in Society

Legal barriers to obtaining sterile needles and syringes should be removed. We support the enactment of the New York State legislative proposal to permit the sale by pharmacies of hypodermic needles and syringes without a prescription, and to deregulate the distribution and possession of sterile needles and syringes as a cost-effective approach to preventing HIV transmission.

We support increasing the availability of needle exchange programs to all those who seek such services; these programs should incorporate into their outreach services education on the proper disposal of needles. The State Legislature should substantially increase appropriations for state-sponsored needle exchange programs to \$7 million in order to expand capacity at the state's eleven existing programs, develop new programs, and increase the availability of supplies necessary to implement needle exchange. In addition, we advocate rescinding the present ban on utilizing federal funds for needle exchange programs and research.

→ "as submitted"

For Publication in MMWR
6/20/97

Update: Syringe Exchange Programs --- United States, 1996

as added to

As of December 1996, over one-third (36%) of the 573,000 cases of acquired immunodeficiency syndrome (AIDS) among adults reported to CDC were directly or indirectly associated with injection drug use

new
on
6/19

(ref 1). Syringe exchange programs (SEPs) are one of the strategies for prevention of human immunodeficiency virus (HIV) among injection drug users (IDUs). This report presents data from a recent survey of U.S. SEPs about their activities during calendar years 1995 and 1996 and compares the findings with those of an earlier survey. (ref 2)

In November 1996, the Beth Israel Medical Center (BIMC) in New York City, in collaboration with the North American Syringe Exchange Network (NASEN), mailed questionnaires to the directors of 101 SEPs in the United States that were members of NASEN. Between November 1996 and April 1997, BIMC research staff contacted SEP directors to conduct structured telephone interviews based on the mailed questionnaires. During the interviews, information was obtained about when the SEP began operating, the number of syringes exchanged in 1995, and, for calendar year 1996, legal status, services provided, and the number of syringes exchanged. The survey was funded, in part, by the National Institute on Drug Abuse and the American Foundation for AIDS Research.

Of the 101 SEPs surveyed, 87 (86%) provided data. Of these 87 SEPs, 51 were operating before 1995, 22 began operating in 1995, and

In this report, the term "syringes" refers to both syringes and needles.

14 in 1996. These 87 SEPs reported providing services in 71 cities in 29 states." Forty-four (51%) of the SEPs were located in four states (California (17), New York (10), Washington (11), and Connecticut (6)). In 8 cities, two or more SEPs were reported. The previous survey received reports from 60 SEPs, operating in early 1995 in 46 cities and in 21 states. (ref 2)

In the current survey, the 70 SEPs operating in calendar year 1995 reported exchanging a total of approximately 11 million syringes. In 1996, 84 SEPs reported exchanging a total of almost 14 million syringes (median: 36,017 syringes per SEP; mean: 165,960). (Table 1) The largest volume SEPs were the 10 SEPs that exchanged $\geq 500,000$ syringes in 1996. These high volume SEPs were located in San Francisco, Chicago, Los Angeles, Philadelphia, New York (2 SEPs), Seattle, Tacoma, Oakland, and Bridgeport, Connecticut and exchanged a total of approximately 9.4 million syringes (69% of all syringes exchanged in 1996). The San Francisco SEP reported exchanging the largest number of syringes (1,461,096) in 1996. In contrast, more than half of the SEPs reported exchanging relatively small numbers of syringes in 1996: 50 SEPs (57% of the SEPs participating in the

" The states in which SEPs were reported to be operating in 1996 were California (fourteen SEPs), Washington (nine), New York (seven), Connecticut (four), Illinois and Michigan (three each), Massachusetts, Puerto Rico, Texas and Wisconsin (two each) and one each in Colorado, Florida, Indiana, Louisiana, Maryland, Minnesota, Missouri, North Carolina, New Hampshire, New Jersey, Ohio, Oregon, Pennsylvania, and Rhode Island. Twenty-four SEPs participating in the survey requested that their location be kept confidential.

survey) exchanged $\leq 55,000$ syringes each among which 23 SEPs (26%) exchanged $< 10,000$ syringes each (mean = 2815 syringes exchanged).

In addition to exchanging syringes, all 87 SEPs offered instructions on safer injection techniques and/or use of bleach to disinfect injection equipment. Nearly all, 84 (97%) of the SEPs referred clients to substance abuse treatment programs. Most SEPs offered education and risk reduction services for both sexual and drug risk behaviors. Nearly all, 84 (97%) of the SEPs offered instruction in the use of condoms and dental dams to prevent sexual transmission of HIV and other sexually transmitted diseases (STD) and 70 (81%) offered STD prevention education. SEPs reported providing the following health services on-site; 35 SEPs (40%) reported providing HIV counseling and testing, 15 (17%) primary health care, 23 (26%) tuberculosis skin testing, and 17 (19%) STD screening.

SEPs were defined as legal if they operated in a state that had no law requiring a prescription to purchase a hypodermic syringe (i.e. a prescription law) or had an exemption to the state prescription law allowing the SEP to operate; illegal-but-tolerated if the SEP operated in a state with a prescription law but had received a formal vote of support or approval from a local elected body (e.g., city council); and illegal/underground if the SEP operated in a state with a prescription law and had not received formal support from local elected officials. In 1996, 46 (53%) were legal, 20 (23%) were illegal but tolerated and 21 (24%) were illegal-underground. In this survey, legal SEPs were more likely than illegal ones to offer on-site

HIV counseling and testing (29 of 46 legal [63%] vs. 8 of 40 illegal [40%]) and TB skin testing (19 of 46 [41%] vs. 3 of 40 [8%]) ($p=0.001$ for both). The three SEPs which did not refer clients to substance abuse treatment were illegal-underground programs.

Reported by: D Paone, EdD, D Des Jarlais, PhD, J Clark, BA, Q Shi, MS. Beth Israel Medical Center, New York, NY; D Purchase, North American Syringe Exchange Network, Tacoma, WA; M Krim, PhD, American Foundation for AIDS Research; Div of HIV/AIDS Prevention, National Center for HIV, STD, Tuberculosis Prevention, CDC.

Editorial Note: Among IDUs, multi-person use of syringes ("sharing") is the primary mechanism of transmission of HIV, hepatitis B and C, and other bloodborne infections related to injection of illicit drugs. (ref 3) Multi-person use occurs when a syringe used by one IDU is "borrowed," "rented," and/or "lent" by another IDU and used to prepare or inject drugs. In addition, equipment and water used to prepare drugs for injection can become contaminated with blood remaining in previously used syringes.

The goal of SEPs is to reduce the transmission HIV and other bloodborne infections associated with drug injection by providing sterile syringes in exchange for used, potentially contaminated syringes. Compared with the findings of a similar survey of SEP activities in 1994, carried out by the same investigators, (ref 2) the

data in this report indicate continued expansion of SEPs in the United States. Between 1994 and 1996, the number of SEPs participating in the surveys increased by 58% (from 55 to 87). The numbers of cities and states in which SEPs exist has increased, (compared to the 60 SEPs participating in the April 1995 survey) respectively, by 52% (46 cities to 71) and 38% (21 states to 29). (ref 2) SEPs are geographically concentrated with slightly more than half of the programs operating in only four states.

From 1994 to 1996, the number of syringes exchanged increased by 75% (from 8 to 14 million). However, in 1996, as in the previous survey, two thirds of the syringes were exchanged by a small number (ten) of high volume SEPs. Most SEPs exchanged relatively small numbers of syringes in 1996 (57% of SEPs exchanging $\leq 55,000$ syringes each) and the mean number of syringes exchanged by the 23 lowest volume SEPs was only 2815. Low volume SEPs can increase the availability of sterile syringes and provide access to other services for the individual IDUs who use the programs. However, if the low volume SEPs are located in communities with substantial numbers of IDUs, their impact on the overall availability of sterile syringes to IDUs in those communities is likely to be limited.

This study found that, in addition to syringe exchange, most SEPs provide important public health services. Those services include: facilitating IDUs' entry into substance abuse treatment programs, HIV counseling and testing, prevention and screening for STDs,

tuberculosis screening, and primary health care. Data from this survey suggest that SEPs which operate legally are more likely than illegal ones to offer HIV counseling and testing, tuberculosis skin testing, and referral to substance abuse treatment.

The data reported in this article are subject to several limitations. The SEP activity is probably underestimated because of incomplete participation in this survey of U.S. SEPs and the possible existence of SEPs that are not members of NASEN. In addition, legal barriers to SEP operations may be underestimated by not including the status of drug paraphernalia laws in the jurisdictions where the SEP exist. (ref 4)

In February 1997, a National Institutes of Health Consensus Development Conference concluded that needle exchange programs, drug abuse treatment, and outreach were particularly effective HIV preventive interventions for drug abuse risk behaviors. (ref 5) Recent publications have reported differing patterns of HIV prevalence and incidence associated with SEPs. In New York City, HIV incidence was substantially lower among IDUs who used SEPs compared to those who did not. (ref 6) In Vancouver, British Columbia, Canada, a city with a high volume SEP, among IDUs, HIV-1 prevalence was 27%. In addition, during the 6 months prior to interview, 40% of HIV-infected IDU participants reported lending used syringes and 60% of HIV-uninfected IDUs reported borrowing used syringes. (ref 7) Research is continuing on the determinants of these high risk behaviors.

In May 1997, four U.S. Public Health Service units⁻⁻⁻ released provisional recommendations for persons who continue to inject drugs. (ref 8) These recommendations include advice that drug users who cannot stop injecting drugs should use only sterile syringes to prepare and inject drugs and other steps to prevent blood-borne infection transmission.

If IDUs use a sterile syringe for every injection, the number of syringes required would be many times greater than that currently provided through SEPs. Because of the substantial additional costs of large scale expansion of SEPs, it is unlikely that SEPs alone can be expanded sufficiently to provide IDUs with access to enough sterile syringes to allow for the one-time use of sterile syringes. (ref 9) Existing laws and regulations in many U.S. communities substantially limit the sale of sterile syringes and needles and establish criminal penalties for possession of syringes for persons who inject illicit drugs. (ref 4) These laws and regulations can interfere with legal SEP operations (ref 10) and, also, reduce the possibility that IDUs will be able to obtain syringes from legal sources such as pharmacies. In May 1997, in efforts to prevent HIV transmission among IDUs, the states of Maine and Minnesota removed or substantially reduced existing criminal penalties for possession of syringes. Such changes

⁻⁻⁻ Issued jointly on May 9, 1997, by the Centers for Disease Control and Prevention, the Health Services and Resources Administration, the National Institute on Drug Abuse of the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

are likely to assure the legal operation of SEPs and increase IDUs' use of sterile syringes from legal sources such as pharmacies and SEPs.

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Table 1 - Number and Percentage of Syringe Exchange Programs (SEPs) and Number and Percentage of New Syringes Provided by SEPs, by Size of Program - United States, January--December 1996.

Size of SEP*	SEPs No. -- %	Total Syringes Exchanged - No.	Total Syringes Exchanged - %
<10,000	23 (27%)	64,737	<1%
10,000 - 55,000	27 (32%)	810,247	6%
55,001 - 499,999	24 (29%)	3,658,060	26%
>500,000	10 (12%)	9,407,628	68%
Total	84	13,940,672	100%

* Based on the number of syringes exchanged in 1996.

MEMORANDUM TO THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: U.S. Conference of Mayors Needle Exchange Resolution

This memorandum will provide you a quick overview of the U.S. Conference of Mayors resolution on needle exchange programs, and the politics of this issue in Congress, public health community and AIDS advocacy groups.

USCM Resolution The FY 1997 Appropriations bill maintains the prohibition on federal funding of needle exchange unless the Secretary of HHS determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs. Mayor Willie Brown of San Francisco is sponsoring a resolution at the USCM meeting (see attached) calling on Secretary Shalala to exercise her waiver authority and permit state and local public health officials to use federal funds for needle exchange as one component of a comprehensive HIV prevention strategy. The resolution will be considered in Subcommittee on June 21, and put forward to the full membership on June 24. There has been no visible opposition to the resolution to date.

Other mainstream public health and state government groups (Nation Governor's Association, Association of State and Territorial Health Officers, National Black Caucus of State Legislatures) support removing the federal funding restrictions in favor of state/local flexibility to design HIV prevention strategies that respond to the characteristics of the HIV epidemic in their jurisdiction.

Department of Health and Human Services HHS sent a report to Congress in February 1997 which included the statement that "Overall these studies indicate that needle exchange programs can have an impact on bringing difficult to reach populations into systems of care that offer drug dependency services, mental health, medical and support services. These studies also indicate that needle exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other blood borne infectious diseases in communities that choose to include them." The Department has not acted on the funding restrictions, but is internally moving towards a position that would allow grantees to use federal funds if certain conditions are met. The Department has not yet sent clear signals on its intentions, or the best timing for possible action.

Congress Six Republican members of the House L/HHS Appropriations Subcommittee have indicated their intent to offer an amendment repealing the authority of Secretary Shalala to waive the prohibition on federal funding for needle exchange. The House mark-up is scheduled for the week of July 7. Subcommittee Chair Porter (R-IL) has high regard for NIH's scientific position, but clearly would need tangible support from HHS and the public health community to defeat such an amendment. On the Senate side, Sen. Specter chairs the L/HHS Subcommittee and he has come to generally support needle exchange programs-- Philadelphia has one of the largest.

Both he and Sen. Harkin (ranking Member) would be inclined to leave the waiver language as is and avoid difficult votes on this issue. If HHS were to lift the ban, staff are not sure how the votes would fall.

Community The AIDS advocacy community is pushing to have the federal ban on needle exchange funding lifted. The community has recognized that a lot of political work needs to be done in Congress prior to removing the funding restrictions, so that a worse outcome is not realized with a flat ban on funding in lieu of the Secretary's waiver authority. Now that there's a clear sign that the House Subcommittee will consider an amendment for a flat ban, there is heightened interest in having HHS remove the funding restrictions and aggressively defend the science behind its action on the Hill.

To that end, some groups are trying to place press questions on needle exchange to you in conjunction with the USCM resolution on needle exchange.....

Recommendation:

- * Indicate support for local flexibility in these matters (in keeping with the NGA, ASTHO, AMA positions)
 - * Demonstrate an understanding of ^{these (already changed on disk)} the issues:
 - * Acknowledge HHS is engaged in an internal discussion around developing strategies that would counter the dominant role intravenous drug use is playing in the transmission of HIV.
- *The Federal role must always be in deference to local control.

8] From: Doug Case <Doug.Case@sdsu.edu> at INTERNET 8/13/97 12:59PM (3728 bytes
81 ln)

o: queerpolitics@abacus.oxy.edu at Internet

c: rwockner@netcom.com at Internet

cc: Paul Yandura at CPDPOST2

subject: FRC Press Release on Needle Exchange Programs

----- Message Contents -----

FAMILY RESEARCH COUNCIL

PRESS RELEASE

Received From: Family_Research_Council@townhall.com

Reply-To: corrdept@frc.org

Subject: Press Release - Needle Exchange Programs

If you have any questions or comments about this press release
or about the Family Research Council, please visit our web
site at:

<http://www.frc.org>

FOR IMMEDIATE RELEASE: August 13, 1997
CONTACT: Kristin Hansen, (202) 393-2100

Media Advisory

ARE TAXPAYERS READY TO SUBSIDIZE HEROIN ADDICTS?

FRC TO INTRODUCE NATIONAL POLL ON
NEEDLE EXCHANGE PROGRAMS

WASHINGTON, D.C. -- Donna Shalala is feeling the heat. The American Medical Association, the National Institutes of Health, the U.S. Conference on Mayors, and others are "strongly urging" her to lift the ban on federally funded needle exchange programs (NEPs). Last month, the Washington Post said that "study after study shows that the exchanges do not promote greater use of illegal drugs" (July 14). On July 6, the Los Angeles Times reported that "several major studies have shown that the programs that give addicts clean needles in exchange for used ones decrease HIV infection in injected-drug users by 30%." And Rep. Elijah Cummings told USA Today that NEPs have "cut the spread of the virus while not increasing drug use" (August 5). But is this the whole truth? Are NEPs stopping the spread of AIDS?

In 1986, Switzerland began implementing NEPs. Chaos resulted. Syringes were made available in every pharmacy, and then in public vending machines. Zurich's Platzpitz Park was opened as a "safe haven" for Zurich's own drug addicts and needles were distributed freely. The city was soon flooded with foreign addicts and the number of exchanged needles skyrocketed to 12,000 per day! In 1992, the city closed the distribution center and thousands of addicts relocated to a nearby abandoned railway station called Letten. There, it evolved into a war zone among gangs dealing drugs, while the number of exchanged needles reached 15,000 per day. By February

PHOTOCOPY
PRESERVATION

1995, Letten was closed. Addicts were moved to government-sponsored centers and "shooting galleries."

The result -- Switzerland now claims the highest number of heroin addicts and the second highest HIV infection rate in Europe. It also experiences Europe's highest heroin drug overdose death rate each year.

Now, the United States may be on the verge of federally funding NEPs, but the Family Research Council will fight to keep this from happening.

On August 20, FRC will release an unprecedented national poll declaring what the American people really think about needle exchanges. Anti-drug leaders will join FRC's president Gary Bauer and senior policy adviser Robert Maginnis to brief the press on this urgent matter. The meeting will be held in the National Press Club's Conference Room at 10 a.m.

This message has been forwarded as a free informational service. Please do not publish, or post in a public place on the Internet, copyrighted material without permission and attribution. Forwarding of this material should not necessarily be construed as an endorsement of the content. In fact, sometimes messages from anti-gay organizations are forwarded as "opposition research."

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facsimile
TRANSMITTAL

to: Sandy Thurman
fax #: (404) 249-7349
re: vaccines
date: August 14, 1997
pages: 12, including this cover sheet.

Dear Sandy,

I am FAXing not only the conversation with Bill Paul, but also the information about Ho's comments - keep the faith - we shall do this!!!!

Love,
helen

From the desk of...

Helen M. Miramontes, MSN, RN, FAAN
Associate Clinical Professor & Deputy Director
University of California, School of Nursing &
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alexandra levine, j, 10:05 AM 8/8/97, conversation with Bill Paul

To: alexandra levine, jerry cade, Daniel Montoya, bruce, Sandy
Thurman, scott hitt, Phyllis Greenberger, Bob Hattoy
From: Helen Miramontes <helenmm@itsa.ucsf.edu>
Subject: conversation with Bill Paul
Cc:
Bcc:
X-Attachments:

I had a telephone conversation with Bill Paul, Director of OAR, NIH, this morning about the status of the AIDS Vaccine Center at NIH. This was just a preliminary exploration about what's going on and I asked him if he would be willing to speak later with the research committee. He suggested that the conversation take place after Congress returns and is back in session. That way we would have a better idea about the budget and also they (NIH) would be further along in the process of identifying a director for the vaccine center.

I'm going to briefly summarize our conversation.

BUDGET: The total NIH budget for an AIDS vaccine is 150 million - but most of that is distributed extramurally. The proposed 1997-98 budget has an overall increase for NIH and Congress may actually increase the % more than is in the Pres. budget (will know more later) so there would be an increase for vaccines. NIH does have the resources (\$) for building the building for the Center. In the 1998 budget there will be up to 10 million to run the Center. Baltimore's group is the "over arching" group for the Center and will oversee use of those \$.

The innovation grants (Fauci & Baltimore mentioned during April panel) - had 130 applications - expect that approx. 30 will be funded - will add resources if necessary.

Working on getting funds for FY99 in case they (NIH) decide to move ahead on the prime boost.

STRUCTURE: The vaccine center is the joint activity of NCI and NIAID. The Director of the vaccine center will report to Harold Varmus and the 2 Directors of NCI and NIAID. Supposedly the Center Director will have some autonomy. NIH AIDS vaccine efforts lacked coordination and the Center will address that lack. A steering committee of 6 NIH scientists has been established to set the agenda for the Center. The relationship of the Center to OAR is that the OAR will be providing the resources for the Center.

DIRECTOR: There is no list. A call has been put out. A search committee has been established and will meet next week to begin to identify potential candidates with appropriate expertise. Looking for a candidate with both vaccine research expertise and basic science expertise.

CONCEPTUAL: Center will take certain products and run through (push forward) (whatever that means). The simple paradigm of vaccine research not working well for HIV. That simple paradigm is that

inject something into the arm and something happens. Dr. Paul mentioned that this works for some diseases but not all. Considers this an old immunological idea. We have ignored advances in immunology.

STUDY SECTION; Issue not fully resolved as yet. Looking at whether to reflect all vaccine research or just AIDS vaccine research.

I believe that my summary reflects accurately the focus of our conversation.

I'll be around if anyone has any questions or comments. Also I don't have email addresses for Debra or Ron Johnson, so I will FAX these comments to them.

take care,

helen

**PHOTOCOPY
PRESERVATION**

PHOTOCOPY PRESERVATION

✓

Weniger, Bruce, 06:03 PM 5/20/97, RE: David Ho's statements in B

From: "Weniger, Bruce" <bgw2@NIP1.EM.CDC.GOV>
 To: "Heyward, William" <wlh1@CIDHIV1.EM.CDC.GOV>,
 "Kitayaporn, Dwip" <ddk7@BANGKOK.EM.CDC.GOV>,
 "Kaewkungwal, JARANIT" <jzk7@BANGKOK.EM.CDC.GOV>,
 "Limpakarnjanarat, Khanchit" <kx18@BANGKOK.EM.CDC.GOV>,
 "Chuachoowong, Rutt" <rfe3@BANGKOK.EM.CDC.GOV>,
 "Vanichseni, SUPHAK" <sav9@BANGKOK.EM.CDC.GOV>,
 "Mastro, Timothy" <tdm3@BANGKOK.EM.CDC.GOV>
 To: "Naiwatanakul, THANANDA" <tdm6@BANGKOK.EM.CDC.GOV>,
 "Johnston, Peggy (IAVI)" <103645.1720@compuserve.com>,
 "Chaiyos Kunanusont (MOPH/AIDS)" <chaiyos@health.moph.go.th>,
 "Cohen, Jon (Science)" <cohenj@ix.netcom.com>,
 "Don C Des Jarlais (Beth Israel)" <dodesjarla@aol.com>,
 "'Jose Esparza (UNAIDS)'" <esparzaj@who.ch>,
 "'Donald P. Francis (VaxGen)'" <francis.don@gene.com>
 To: "Gregory, Timothy (Genentech)" <gregory.tim@algw.gene.com>,
 "Chantapong Wasi (Siriraj)" <headsimi@mucc.mahidol.ac.th>,
 "'Miramontes, Helen (PACHA)'" <helenmm@itsa.ucsf.edu>,
 "Kennedy, Donald (Stanford)" <hk.dxx@forsythe.stanford.edu>,
 "Tina Ippolito (VaxGen)" <ippolito.tina@gene.com>,
 "John McNeil (HMJF)" <jmoneil@pasteur.hjf.org>
 To: "'De Cock, Kevin (LSHTM)'" <K.de-Cock@lshtm.ac.uk>,
 "Kenrad E. Nelson (JHU)" <knelson@share.sph.jhu.edu>,
 "Altman, Larry (NYT)" <laltman@nytimes.com>,
 "Clements, Mary Lou (Harvard)" <mclement@hsph.harvard.edu>,
 "Essex, Max (Harvard SPH)" <messex@hsph.harvard.edu>,
 "Russell, Philip (@aol.com)" <PKRussell@aol.com>,
 "Rodney A. Michael" <rod michael@msn.com>
 To: "Berkley, Seth (Rock.Fdn.)" <sberkley@rockfound.org>,
 "Punnee Pitisutthitham (VTC)" <tmppt@mucc.mahidol.ac.th>,
 "Pravan Sutharasamai (TROPMED)" <tmpst@mucc.mahidol.ac.th>,
 "Sricharoen Migasena (VTC)" <tmsmg@mucc.mahidol.ac.th>
 Subject: RE: David Ho's statements in Bangkok
 Date: Tue, 20 May 97 18:03:00 EST
 Encoding: 111 TEXT

Dear Dwip,

Thanks for letting me know what the Time Magazine
 Cover Laureate is saying in Thailand.

Reminds me of Albert Sabin's campaign in the early
 1950s to undermine the Salk polio trials. Apparently no one is
 asking him to defend the US decision of 1994 not to continue
 trials in the U.S. of vaccines which protected animals and were
 found safe in phase I and II studies, which should really be the
 issue on trial. The press ought to be informed of the fact that
 many accomplished vaccine scientists (of which Dr. Ho is not
 one) feel it was a bad decision, reflective more of the politics of
 money for science research, and the ignorance of many basic
 science researchers of how vaccines are developed.

**PHOTOCOPY
PRESERVATION**

The remarkably rapid rate of growth in knowledge of retrovirus pathogenesis and the corresponding human immune response seems paradoxically to condemn us forever to chase our tails in developing an AIDS vaccine, given the long time it takes to move specific vaccine designs through the R&D "pipeline".

In the mid-1980s, the hypothesis was that antibody alone might confer some protection, and eight years later products were ready for a definitive test of that hypothesis, having demonstrated protection in an animal model. But by that time, theory had changed -- without any definitive data disproving the earlier hypothesis -- and it was believed that a T-cell response would be necessary for a successful vaccine.

So a second generation of vectored poxvirus vaccines that hopefully would stimulate a T-cell response became the favored design. But by the time such products are ready for phase III trials in two or three years, knowledge will have advanced to reveal the key role of chemokines and new receptors in the immune response. So one wonders whether the poxvirus vector vaccines will then be abandoned after years of development if they do not stimulate certain chemokines or somehow involve these new receptors, which will soon become the fashionable theory for what a successful vaccine must do.

So we jump from hypothesis to hypothesis without the discipline to obtain definitive answers to earlier ones. The lesson I have learned from many conversations with accomplished vaccine scientists is that the only standard (gold, silver, or otherwise) in vaccine development for validation of hypotheses is protection in humans. And for HIV-1, the most likely way correlates of human immunity are likely to be learned will be by comparing the "breakthroughs" in properly-sized and -controlled human efficacy trials to those vaccinees who remain protected.

Regards,
Bruce

From: Kitayaporn, Dwip
To: Weniger, Bruce; Heyward, William; Kaewkungwal, JARANIT;
Limpakarnjanarat, Khanchit; Chuachoowong, Rutt; Vanichseni, SUPHAK;
Mastro,
Timothy; Naiwatanakul, THANANDA; Chaiyos Kuananusont (MOPH/AIDS); Don C
Dee
Jarlais (Beth Israel); 'Jose Esparza (UNAIDS)'; 'Donald P. Francis
(VaxGen)';
Gregory, Timothy (Genentech); Chantapong Wasi (Siriraj); Tina Ippolito
(VaxGen); John McNeil (HMJF); Kenrad E. Nelson (JHU); Rodney A.

**PHOTOCOPY
PRESERVATION**

Michael;
Punnee Pitisutthitham (VTC); Pravan Sutharasamai (TROPMED); Sricharoen Migasena (VTC)
Cc: Kitayaporn, Dwi
Subject: David Ho's statements in Bangkok
Date: Sunday, May 18, 1997 9:35AM
Priority: High

FYI. Source: Bangkok Post 05/17/97--- Aphaluck Bhatiasavi

RESEARCHERS WARNS OVER VACCINE TRIAL : THAILAND URGED TO BE AWARE OF EXPLOITATION.

World renowned AIDS researcher Dr. David Ho has warned Thailand not to accept foreign AIDS vaccine trials which would not be allowed abroad.

Speaking in Bangkok, the director of New York's Aaron Diamond AIDS Research Center said there were US scientists viewing Thailand as a place in which to conduct medical trials, particularly of vaccines.

He said: "For me as part of the Asian minority in the US, I feel it's important for the Thai people to be aware of the possibility of exploitation. If a product is rejected elsewhere, why should you take it?

The doctor said Thailand was attractive to foreign researchers because of its high rate of infection, even though this had been declining recently; the prominence of HIV subtype E, and a well developed medical infrastructure.

"I feel very strong about it," said Dr. Ho when asked what he thought about certain foreign researchers exploiting weaker laws and regulations to conduct controversial trials in developing countries.

"It's wrong for some US, European and other researchers to look at this only as an opportunity to develop a product," he said.

Dr. Ho is known for his research into what the HIV virus does after infecting a host, and for his experiments on aggressively combating, with a combination of drugs, the infection in the early stages.

He said Thailand should carefully consider approving trials of a vaccine made synthetically from the outer cover of the AIDS virus, known as gp120, because trials on hundreds of US volunteers had shown a very low

Source: Bangkok Post 05/17/97--- Aphaluck Bhatlasevi

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He said Thailand should carefully consider approving trials of a vaccine made synthetically from the outer cover of the AIDS virus, known as gp120, because trials on hundreds of US volunteers had shown a very low impact.

"More Effective Therapies Needed to Cure AIDS"
Xinhua News Agency (05/23/97)

Dr. David Ho, director of the Aaron Diamond AIDS Research Center in New York, said recently that it will be difficult to eliminate HIV. "The therapies can kill 99 percent of the HIV virus in the patients' blood during the first two weeks, but it is very difficult to get rid of the rest of it," he noted. Ho added that more effective therapies are still needed. "I will do my best to invent a vaccine for HIV and develop cheaper drugs to treat the disease," he said.

**PHOTOCOPY
PRESERVATION**

English translation of letter

Programme on AIDS - Thai Red Cross Society

No: 02164/2540

18 April 2540 (1997)

Subject: Information on trial of recombinant gp-120 vaccines

To: Dr. Kachit Choopanya
Deputy Governor of Bangkok

Enclosure: Letter from Dr. Steven Wolinsky and Dr. David Ho

I have received information from Dr. Steven Wolinsky and Dr. David Ho who are the Principal Investigator and Coordinator, respectively, of a study of HIV-infected recipients of recombinant gp120 (rgp120) AIDS vaccines in the U.S. There was evidence that those who had received the vaccine did not have neutralizing antibody or cytotoxic T lymphocytes (CTL) before they got HIV infection, and that the levels of the virus in the blood in this group was not decreased compared to those who did not receive vaccine and got HIV infection. This is to say that those who received vaccines had no differences from those who did not receive vaccine (placebo). This means that rgp120 is not useful in preventing HIV infection. It is not appropriate for Thailand to allow (approve) an efficacy trial of the mentioned vaccine, as stated in the enclosed copied letter.

I believe that the information mentioned will be useful for many parties involved, so I am distributing this for your information as Dr. Wolinsky and Dr. Ho wish.

Sincerely,

Prof. Dr. Praphan Phanuphak
Director, Programme on AIDS

No.BK-0100/xxx/336

To: Dr. Suphak Varichseni
copy for your information

From:
(Kachit Choopanya)
Deputy Bangkok Governor
Acting on behalf of the Governor
22 April 2540 (1997)

NOT PRESERVATION
PHOTOCOPY

/02/97 10:11 FAX 1212 929 1335

Northwestern University Medical School

Department of Medicine

Dan F. Sullivan, MD
 201 East Superior Street
 Chicago, Illinois 60601-3098
 (312) 938-3818/3178
 (fax (312) 938-4722)

Steven M. Whitlock, MD
 Associate Professor of Medicine
 Division of Infectious Diseases

04 April 1997

Prephan Phanuphak, M.D., Ph.D.
 Professor of Medicine and Microbiology,
 Faculty of Medicine,
 Chulalongkorn University,
 Rama IV Road,
 Bangkok, Thailand

Dear Professor Phanuphak,

You have requested from us a copy of the paper that we are preparing which describes our analysis of individuals who became infected with HIV-1 despite participating in clinical trials of recombinant gp120 subunit vaccines. These vaccines (or very similar ones) are presently being considered for efficacy trials in Thailand, specifically in a cohort of intravenous drug users centered in Bangkok. The paper, and its companion written by the NIH's AIDS Vaccine Evaluation Group, are nearing completion, and we are advised by the NIH that they could be sent shortly to the Thailand National AIDS Vaccine Committee if copies are requested officially. Since you are a member of that Committee, perhaps you could ask that the Committee makes such a request to Dr. Patricia Felt, Chief of the Vaccine Branch, Division of AIDS, National Institute of Allergy and Infectious Diseases?

not a member of the HIVAC?

We understand that you and your colleagues have a very difficult decision to make in the near future concerning vaccine trials in Thailand. We all believe that it is important that relevant information is shared, so that the decision is made on the basis of the full facts. As the studies we have performed have already been described publicly, we feel it is appropriate for us to provide you with a summary of them, which we attach below. We think it would be best if you shared this letter with your colleagues on the National Vaccine Committee, so that all the Committee members have the same information available to them.

- 1) A total of 19 HIV-1 infected individuals was enrolled in our study. It is our

The McGraw-Hill Medical Center of Northwestern University

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understanding that sixteen of these were derived from Phase II trials involving individuals at relatively high risk for HIV-1 infection, conducted over an approximately 18-month period. In these trials, 8 of 128 individuals receiving MN rgp120 (Vaxgen) became infected, as did 8 of 129 individuals who received SF-2 rgp120 (Chiron/BioMérieux). Two of 38 placebo recipients also became infected. The infection rate in this cohort was approximately 2.5 per 100 person-years, which is not atypical of high-risk, natural-history cohorts in the USA.

Of the total of 18 infected vaccinees, 10 received MN rgp120, 7 received SF-2 rgp120 and 2 received a placebo. Five individuals (2 MN and 3 SF-2 rgp120 recipients) became infected before receiving their full course of immunizations, so should be considered separately from the other infected individuals. Whether or not these 5 individuals are taken into account, the distribution of infected vaccinees among the MN rgp120, SF-2 rgp120 and placebo groups broadly reflects the composition of the trial cohorts. However, the number of infected vaccinees in the Phase III trials was too low for statistically meaningful conclusions to be drawn concerning vaccine efficacy.

2) Analysis of post-infection viral loads (plasma RNA) in the vaccinees and relevant control groups at 8-12 months post infection indicated that the vaccinees had not had a significant impact on viral load in those individuals who became infected despite vaccination. The lowest viral loads were found in one placebo recipient, and in one recipient of MN rgp120.

3) Phylogenetic analysis of viral sequences from the infected vaccinees and control cohorts indicates that the gp120 vaccinees had not exerted overt selection pressure such that only genetically unusual viral variants were transmitted. The gp120 sequences of the vaccinees' isolates were indistinguishable from those of contemporary United States subtype B strains. Furthermore, we believe that the V3 sequences of the vaccinees' isolates were not different from contemporary control sequences in any meaningful sense.

4) The vaccinees' isolates (18) were successfully made to had phenotypes, co-receptor usage patterns and replication rates typical of transmitted viruses from control cohorts. Two vaccinated individuals were infected by synovium-inducing strains, but this is not necessarily related to vaccination, since synovium-inducing strains are also known to be transmitted in a minority of cases among natural history cohorts. The vaccinees' isolates were also neither unusually neutralizing antibody-resistant, or neutralizing antibody-sensitive. Overall, we could find no evidence that the vaccinees had selected for the transmission only of viruses with unusual phenotypic properties.

5) The gp120 vaccinees failed to induce either a meaningful neutralizing antibody response (in that they did not elicit antibodies able to significantly neutralize the breakthrough isolate in the most relevant neutralization assay available), or a significant CTL response, in the vaccinees prior to infection. All but one of the infected vaccinees who had received a full course of immunizations had, however, responded to the

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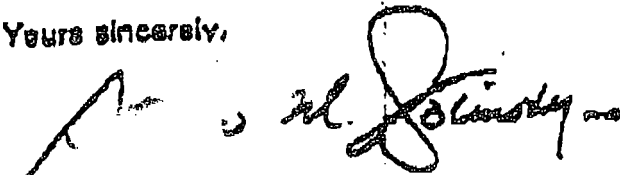
0004

vaccine by developing a significant antibody response to the immunogen itself.

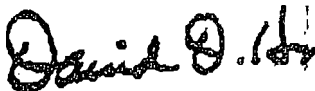
In conclusion, our opinion is that the performance of the rgp120 subunit vaccine has been disappointing in that we could identify no impact that rgp120 vaccination had on any meaningful parameter in the cohort of infected vaccinees. We clearly understand that breakthrough infections should be anticipated in vaccine trials. It is not the fact of the breakthrough infections that particularly concerns us. It is what we have learned from studying these cases in detail.

We hope that you find this information useful when debating with your colleagues in Thailand the difficult decision that you face regarding efficacy trials in your country. For our part, we are committed to the development of an effective HIV vaccine that will be available for use in Thailand and elsewhere in the world, and you have our assurance that we shall continue to devote our efforts to helping create one.

Yours sincerely,



Steven M. Wellnsky, M.D.
Associate Professor,
Northwestern University
(Principal Investigator of the Study on
Infected rgp120 Vaccine Recipients)



David D. Ho, M.D.
Director,
Aaron Diamond AIDS Research Center
(Coordinator of the Study on Infected
rgp120 Vaccine Recipients)

cc: P. Fast, M.D., Chief, Vaccine Branch, Division of AIDS, National Institute of
Allergy and Infectious Diseases
B. Graham, M.D., AIDS Vaccine Evaluation Group

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PRESERVATION

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

808 17th Street, N.W., 8th Floor
Washington, DC 20006

Phone: 202-632-1090
Fax: 202 632-1096

FACSIMILE COVER SHEET

TO: SANDY THURMAN

FAX NUMBER: (404) 249-7359

FROM: TODD

DATE: AUG 14, 1997

PAGES INCLUDING COVER SHEET: 3

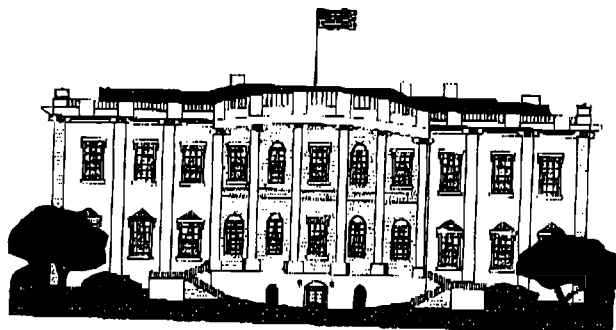
COMMENTS:

Todd
770 579 9876
pay

**PHOTOCOPY
PRESERVATION**

EXECUTIVE OFFICE OF THE PRESIDENT

Office of National Drug Control Policy
Washington, DC 20503



Handwritten signature/initials

FACSIMILE MESSAGE

TO: Sandra Thurman

FAX: 632-1096

DATE: 1/14/98 **TIME:** 2:30 pm **PAGES:** 1 + Cover

FROM: Janet Crist, Chief of Staff

FAX NUMBER: 395-6732

OFFICE NO: 395-6708

COMMENTS: Attached please find ONDCP'S position on needle exchange language that is to be included in the 1999 Budget Appendix.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

January 14, 1998

Jacob J. Lew
Deputy Director
Office of Management and Budget
Old Executive Office Building, Rm. 252
Washington, D.C. 20503

Dear Mr. Lew:

Director McCaffrey has reviewed OMB's recommended changes to the statutory language, which loosen the criteria for the use of Federal funds for needle exchange programs. It is the Director's strong view that these changes could undermine national drug control policy and that such changes in drug control policy are subject to concurrence by the Director of National Drug Control Policy, in consultation with other agency principals.

It is ONDCP's position that sound policy in this area should include the following elements:

- The Ryan White CARE Act retain the complete prohibition on funding;
- The SAMHSA Block Grant retain the two existing criteria
 - Reduce the spread of HIV,
 - Reduce drug use;
- Other HHS programs be subject to the criteria for the SAMHSA Block Grant;
- The Secretary of HHS determine whether criteria are satisfied;
- The Secretary of HHS not establish criteria for the operation of such programs; and
- HHS continue to review the science regarding the satisfaction of both criteria.

To maintain this continuity in policy, ONDCP recommends retention of the following language.

"Notwithstanding any other provisions of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug unless the Secretary of Health and Human Services determines that such programs are effective in preventing the spread of HIV and reduce the use of illegal drugs."

I hope you find this information helpful.

Sincerely,

A handwritten signature in cursive script, reading "Janet Crist".

Janet L. Crist
Chief of Staff



FACSIMILE

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

808 17th Street NW, Suite 820
Washington, DC 20006

Phone: (202) 632-1090
Fax: (202) 632-1096

TO:

Josh Gotbaum

FAX NUMBER:

395-4995

FROM:

Sandy Thurman

DATE:

1/14/98

PAGES:

(including cover sheet)

COMMENTS:

from our friends
at ONDCP
Sandy



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

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A handwritten signature in cursive script that reads "Janet Crist".

Janet L. Crist
Chief of Staff

*** TX REPORT ***

TRANSMISSION OK

TX/RX NO	4523	
CONNECTION TEL		93954995
CONNECTION ID		
ST. TIME	01/14 17:29	
USAGE T	00'55	
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RESULT	OK	



FACSIMILE

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

808 17th Street NW, Suite 820
Washington, DC 20006

Phone: (202) 632-1090
Fax: (202) 632-1096

TO:

Josh Gotbaum

FAX NUMBER:

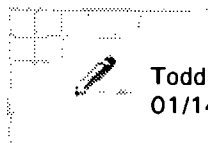
395-4995

FROM:

Sandy Thurman

DATE:

1/14/98



Todd A. Summers
01/14/98 12:48:07 PM

Record Type: Record

To: Sandra Thurman/OPD/EOP

cc:

Subject: needle exchange

----- Forwarded by Todd A. Summers/OPD/EOP on 01/14/98 12:48 PM -----



Thomas Reilly
01/14/98 11:18:29 AM

.....

Record Type: Record

To: Todd A. Summers/OPD/EOP

cc: Richard J. Turman/OMB/EOP, Barbara A. Menard/OMB/EOP

Subject: needle exchange

FYI - ONDCP is challenging the compromise.

----- Forwarded by Thomas Reilly/OMB/EOP on 01/14/98 11:17 AM -----



Janet L. Crist

01/14/98 11:01:23 AM

Record Type: Record

To: Jacob J. Lew/OMB/EOP@EOP, Joshua Gotbaum/OMB/EOP@EOP

cc: Daniel Schecter/ONDCP/EOP@EOP, Thomas Reilly/OMB/EOP@EOP

Subject: needle exchange

per discussion with General McCaffrey this am-- omb's proposed compromise language on needle exchange is unacceptable. Specifically we object to changes that loosen the criteria for the use of federal funds--i.e. omb's language refers to "not encouraging" drug use and ONDCP would retain "reducing the use of illegal drugs." We will have a letter to you shortly, and if need be, are prepared to take this to a principal's level discussion for resolution Janet Crist



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

January 14, 1998

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Deputy Director
Office of Management and Budget
Old Executive Office Building, Rm. 252
Washington, D.C. 20503

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I hope you find this information helpful.

Sincerely,

Janet L. Crist
Chief of Staff

**JOSHUA
GOTBAUM**
01/14/98 01:21:57 PM



Record Type: Non-Record

To: Sandra Thurman/OPD/EOP
cc:
bcc:
Subject: Re: ONDCP Concerns About Needle Exchange 

Don't start firing until we know there's a real problem. Barry appears to have been misinformed by his staff concerning the facts.

Sandra Thurman 01/14/98 01:09:22 PM

Sandra Thurman 01/14/98 01:09:22 PM

Record Type: Record

To: Jacob J. Lew/OMB/EOP@EOP, Joshua Gotbaum/OMB/EOP@EOP
cc:
Subject: ONDCP Concerns About Needle Exchange

ONDCP has objected to the proposed language in the FY99 budget relating to needle exchange (see below). The language proposed by OMB is thoroughly consistent with current Administration policy and public health science. ONDCP's assertion that OMB is proposing to "loosen" the criteria is factually incorrect and misleading; in reality, the criteria have remained the same since originally offered on the floor by Senator Hatch (1990). Making the change proposed by ONDCP would constitute a major shift in Administration policy and severely compromise the current authority of the Secretary.

Any change in Administration policy should be resolved by principals.

Janet L. Crist

01/14/98 11:01:23 AM

Record Type: Record

To: Jacob J. Lew/OMB/EOP@EOP, Joshua Gotbaum/OMB/EOP@EOP
cc: Daniel Schecter/ONDCP/EOP@EOP, Thomas Reilly/OMB/EOP@EOP
Subject: needle exchange

per discussion with General McCaffrey this am-- omb's proposed compromise language on needle exchange is unacceptable. Specifically we object to changes that loosen the criteria for the use of federal funds--i.e. omb's language refers to "not encouraging" drug use and ONDCP would retain "reducing the use of illegal drugs." We will have a letter to you shortly, and if need be, are prepared to take this to a principal's level discussion for resolution Janet Crist

Sandra Thurman 01/14/98 01:06:50 PM

Record Type: Record

To: Jacob J. Lew/OMB/EOP, Joshua Gotbaum/OMB/EOP
cc: Bruce N. Reed/OPD/EOP, Christopher C. Jennings/OPD/EOP
Subject: ONDCP Concerns About Needle Exchange

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2018-0724-P

~~CONFIDENTIAL~~**PRIORITY****Office of HIV/AIDS Policy**

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Deliver to: Ms. S. Thurman
Attention

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PAGE 2/5

~~CONFIDENTIAL~~**DRAFT****DRAFT**

PREVENTING HIV IN WOMEN AND CHILDREN: NEEDLE EXCHANGE AS A COMPONENT OF A COMPREHENSIVE HIV PREVENTION STRATEGY

Changing Dynamics of the HIV Epidemic

AIDS incidence has been increasing more rapidly in women than men, largely because HIV prevalence has disproportionately increased in injection drug users (IDUs) and heterosexual contacts (Wortley and Fleming, 1997).

IDUs alone now account for approximately half of all new infections and "... the HIV epidemic is now clearly driven by infections occurring among injection drug users, their sex partners, and their offspring" ... and, in terms of emerging risk groups "... a consistent profile of the highly at-risk person is a generally young, minority, indigent woman who uses crack cocaine ..." (Holmberg, 1996: 649-650).

As more women of childbearing age become HIV infected, the number of children infected will also rise (HCFA, 1997). Specifically:

- o 92,000 adolescent and adult women have been diagnosed with AIDS -- 13,714 between July 1996 and June 1997 (CDC, 1997).
- o 44% of cumulative AIDS cases are in female IDUs (CDC, 1997).
- o The number of women diagnosed with AIDS increased 63% between 1991 and 1995 (Wortley and Fleming, 1997).
- o Greatest increases in AIDS incidence rates were observed in heterosexual women born between 1970 and 1974, i.e., women who were 14 to 18 years old in 1988 (Wortley and Fleming, 1997).
- o AIDS death rates in women increased by 3% between January to June 1996 compared to the same time period in 1995, and decreased by 15% in men (CDC, 1997).
- o Increasing mortality affects children. It is estimated that between 125,000 and 150,000 children born to the 80,000 women alive with HIV in 1992, will be orphaned in the 1990s (Women's Interagency HIV Study, NIH, 1997).
- o Each year, approximately 7,000 infants are born to HIV infected women in the U.S. (Davis, 1995).
- o Women with HIV are disproportionately minority and poor.
- o Only 10% of the 1.5 million female and male IDUs have access to syringes, risk reduction information, condoms, and referral to other services through Needle Exchange Programs (NEPs).

Preventing HIV Transmission in Women: NEPs and Drug Treatment

HIV transmission can be prevented. Stopping drug use and providing access to the means for behavior change is the priority for all HIV prevention programs. The goal of needle exchange programs is to reduce the transmission of HIV and other blood-borne infections associated with drug injection by providing sterile syringes in exchange for used, potentially contaminated syringes. In addition to dispensing new needles and collecting used ones, most NEPs offer a variety of other materials and services, including the provision of condoms and risk reduction

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information, to help IDUs avoid risks of acquiring or transmitting HIV sexually to their partners. NEPs have also been effective in referring IDUs to drug treatment, and data clearly indicate that if IDUs access and remain in treatment, they will change their drug use, needle use, and to a lesser extent, their sexual risk behaviors, and thereby reduce their risks of acquiring HIV. Research clearly indicates that needle exchange programs can prevent HIV and other blood-borne infectious diseases. Drug treatment can also result in improved birth outcomes, and drug treatment for drug abusing pregnant women has been demonstrated to be cost-effective.

Expanding access for syringe availability through NEPs and pharmacies to more IDUs, in combination with expansion of drug treatment, is essential to slow the spread of HIV and other blood-borne diseases. NEPs and drug treatment are complementary public health strategies. They represent components of a comprehensive HIV prevention strategy that have been demonstrated to effectively reduce risk behaviors and prevent the spread of HIV and other blood-borne diseases.

References:

1. Centers for Disease Control and Prevention. *HIV/AIDS Surveill Rep.* Atlanta, Ga: Centers for Disease Control and Prevention:1997;9.
2. Davis, SF, Byers RH, et al. Prevalence and incidence of vertically acquired HIV infection in the United States. *JAMA.* 1995;274:952-5.
3. Gorsky, RD, Farnham, PG, et al. Preventing perinatal transmission of HIV -- costs and effectiveness of a recommended intervention. *Public Health Reports.* 1996;111:335-41.
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5. Holmberg, SD. The estimated prevalence and incidence of HIV in 96 large U.S. metropolitan areas. *AJPH.* 1996;86(No.5):42-54.
6. Reducing HIV transmission: The maternal AIDS project. *Maternal AIDS Initiative.* HCFA. 1997.
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8. Wortley, PM, Fleming, PL. AIDS in women in the United States. *JAMA.* 1997;278:11:911-16.

DRAFT

Office of National AIDS Policy

Executive Office of the President



Needles

URGENT: "AIDS" "Needles" "Congress"

For Immediate Release
October 31, 1997

Contact: Jeff Kamen
(202) 632-1090

White House AIDS Czar Praises, Challenges Congress on Needle Exchanges; Hails Conference Committee Vote to Retain HHS Secretary's Power To Remove Restriction on Funding of Needle Exchange Programs

**"Let Science Drive this Policy," Urges Sandra Thurman
"New Public Opinion Poll Should Help."**

Programs Underway Show Cut of HIV Infection Rate & No New Drug Users

(Washington, DC) ----Sandra Thurman, the White House AIDS Policy Director, today congratulated and challenged the House and Senate after conferees voted late last night to preserve the power of the Secretary of Human Services to removed current restrictions on federal funding of needle exchange programs. There are more than 100 such programs across the nation. All studies of needle exchange programs have shown that they reduce the spread of HIV/AIDS without encouraging drug abuse.

Thurman, the principal policy advisor to President Clinton on HIV/AIDS said, "It took genuine political courage for members of Congress to let science drive this policy and I challenge them to move forward in that spirit."

A floor vote in both houses is expected soon.

"The results of the new Harris poll, which shows that 71 percent of the American people support removing current restrictions on Federal funding for needle exchange programs should help some members of Congress to remember to keep politics out of public health considerations," Thurman said in a statement released by her office.

"With last night's vote, the debate on this issue has turned a significant corner. In this bill, Congress began the process of defining essential elements of needle exchange programs worthy of federal funding. Bi-partisan support for moving forward is based on a willingness to follow the science, but it took some old fashioned guts for the lawmakers to ignore those who would play politics with this issue. What we are talking about here is simple: if the science says needle exchange programs slash HIV infection rates and don't encourage drug use, then that translates into lives saved.

"We know that there are those who are committed to stopping needle exchange programs and they are expected to try to do so legislatively over the next six months. But when you consider that the American Medical Association, the American Public Health Association, the American Bar Association and the American Academy of Pediatrics all endorse needle exchanges as a proven method for attacking the spread of this deadly disease, few questions should remain about what is good public health policy, and we will continue to explain the facts to anyone who will listen.

"Over the next several months, I will be urging Congress to continue to act based on the scientific facts and not out of ignorance or fear." ###