NLWJC - Kagan

DPC - Box 016 - Folder 006

Drugs - Needle Exchange [3]

Drugs - needle exchange

Jose Cerda III 03/16/98 01:01:51 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Christopher C. Jennings/OPD/EOP

cc: Leanne A. Shimabukuro/OPD/EOP, Laura Emmett/WHO/EOP, Sarah A. Bianchi/OPD/EOP
Subject: Aids Council Meeting Press Conference

FYI -- I take it this is not news for those of you working on this. jc3

---------- Forwarded by Jose Cerda III/OPD/EOP on 03/16/98 01:01 PM ----------

Patricia M. McMahon
03/16/98 12:46:25 PM

Record Type: Record

To: Walter L. Holton/ONDCP/EOP, Daniel Schecter/ONDCP/EOP, Kathleen D. Malliarakis/ONDCP/EOP, R J. Gregrich/ONDCP/EOP

cc: See the distribution list at the bottom of this message
Subject: Aids Council Meeting Press Conference

A group of people want to do a press conference in front of the White House tomorrow to ask for Donna Shalala's resignation, possibly to resign themselves from the Council, possibly to engage in civil disobedience that would lead to the arrest of some demonstrators.

Their is also a consideration to ask for Director McCaffrey to resign. (It would not be a long walk from the White House to our office) The belief is that the Director is standing in the way of Shalala lifting the ban. The group wants to put pressure on her to voice her support for federal funding for needle exchange programs/research and to not be "squeezed" by others (BRM).

"Bus loads" will be arriving in DC tomorrow as per the caller.

Message Copied To:

Darlind J. Davis/ONDCP/EOP
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Tilman Dean/ONDCP/EOP

c/o The Harm Reduction Coalition , 22 West 27th Street, 9th Floor ,
New York, NY 10001, 212.213.6376 x17, fax 212.213.6582
email: ncsln@dti.net, website: http://www.harmreduction.org
Tuesday, March 10, 1998

NATIONAL COALITION to SAVE LIVES NOW!

"NO MORE BIZ AS USUAL ON HIV/AIDS WITHOUT NEEDLE EXCHANGE"

Presidential AIDS Advisory Council Will Consider Resolution Asking for Shalala Resignation

Presidential Advisory Council on HIV/AIDS Quarterly Meeting– March 15-18, Madison Hotel, M & North Capitol Streets, Washington, DC
(Public Comment: Tues March 17th, 11:00am)

In November 1997, the Presidential Advisory Council on HIV/AIDS wrote a strongly worded letter to President Clinton requesting that he instruct Secretary Shalala to make a determination on needle exchange *before January 27th*. Since that time, a) the Secretary has not acted; b) the President has released a budget which includes a virtual decrease in AIDS prevention funding. Will the Administration do *anything* to stop HIV/AIDS? What will the Presidential Council do, now that it is obvious that the Administration does not take them seriously? The next Council meeting is on March 15-18th, in Washington DC.

The Council will consider a resolution asking for Secretary Shalala's resignation on the grounds that she has not fulfilled her responsibility to make a public health determination on needle exchange. They may also hold a press conference on Tuesday (17) or Wednesday (18) to criticize the administration for continuing to allow injectors, their sexual partners, and their children to become infected. The Advisory Council meetings are open to the public and we encourage needle exchange advocates to attend, and show community support for the 'dump Shalala' resolution.

It makes no sense for the Council to continue its important work, while the Secretary of HHS refuses to make a determination on such a central element of any strategy to stop AIDS transmission in the United States. **The Council must refuse to conduct business as usual unless the administration takes a stand on needle exchange.**

Call the Council member nearest you, and tell him/her to support the 'dump Shalala' resolution, and to encourage the council to make a public statement demanding federal funding for needle exchange.

Congresspersons take a stand

Members of Congress who support needle exchange are becoming increasingly active. Congressional Black Caucus and Congressional Hispanic Caucus Chairpersons Waters (D-CA) and Becera (D-CA) wrote a joint letter to Shalala in February urging her to fund needle exchange. Minority leader Gephart has also written to the Secretary. The grassroots campaign to urge friendly members to call the Secretary and the White House continues.

Call your Congressperson and ask them to contact the Secretary and urge a determination on needle exchange: Shalala➔ (202) 690-7000; White House Domestic Policy Advisor Bruce Reed➔ (202) 456-2216. *Copies of the Water/Becara and Gephart letters are available from NCSLN (see below).*

You can make requests for info./materials and offer feedback to the National Coalition to Save Lives Now! at 212-213-6376, x17, fax 212-213-6582, or e-mail ncsln@dti.net

Drugs - needle exchange

HUMAN
RIGHTS
CAMPAIGN

March 11, 1998

Via Facsimile

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear Mr. President:

I understand that a decision may be forthcoming from the Administration regarding the scientific efficacy of needle exchange and the use of federal funds to support local programs. As the March 31 date nears, which ends the Congressionally imposed moratorium on the use of federal funds, I cannot emphasize enough the urgency with which the AIDS and public health communities view this issue.

In concert with Administration officials, we were successful in preserving the Secretary's authority on this issue last year, and the Senate confirmed Dr. Satcher as Surgeon General without a significant focus on his views on needle exchange. I strongly feel that the time has come for the Administration to make a determination on this issue and I call on you to do so immediately.

According to the most recent data from the CDC, nearly one-third of all new AIDS cases can be traced, directly or indirectly to injection drug use. It is estimated that nearly two thirds of new HIV cases are related to injection drug use. Further, 74% of all AIDS cases among women are connected directly or indirectly to injection drug use (34% of the cases are those who inject drugs; 40% of the cases are among those who had sexual contact with an injection drug user). More than 50% of the cases of AIDS among children can be traced back to injection drug use.

These statistics clearly demonstrate the direction in which this epidemic is moving; and the history of the HIV epidemic in this country demonstrates the cost of inaction. It took the federal government nearly ten years to implement a comprehensive response to HIV and AIDS, including funding and support for HIV prevention, research and treatment. I sincerely hope that ten years from now, we will not look back on 1998 as the time when we had an intervention that works, but chose not to encourage and support its implementation. Such a delay will gravely impact the most vulnerable populations increasingly affected by this epidemic – people of color, women and children. We cannot afford such a delay and cannot abandon the urgent HIV prevention needs of those populations.

Needle exchange programs are not contradictory to an anti-drug message or to efforts to reduce drug addiction. We at HRC and the entire AIDS community support reducing the use of drugs in this country and getting more people into drug treatment. We believe equally as strongly that needle exchange programs can be an effective component of a strategy to meet those goals.

Let me be clear that needle exchange programs are in no way meant to divert resources away from drug treatment. They cannot be seen as a low cost substitute for such treatment. They can and should be seen as a part of an overall strategy to connect people to systems of care. Needle exchange programs provide a linkage to drug treatment in addition to other health care, counseling, and psychosocial services. Needle exchange programs are a component of a drug treatment and outreach strategy, they are not a substitute.

No one doubts the effectiveness of drug treatment. The long term solution for injection drug users to reduce their HIV risk and put their lives back on track is to get off drugs. No policy or funding decisions should contradict that message. Because drug treatment on demand is not available in this country, it is imperative that we keep people alive until they can get into treatment. Needle exchange programs not only help people stay alive (through avoiding HIV infection), they also help many drug users start their long journey toward a drug free life.

I do not believe that advocacy for drug abstinence, drug treatment programs, and needle exchange are contradictory or send a double message to young people. All of these efforts are directed at keeping people, old and young, alive and healthy. Studies show that the mean age of injection drug users rises over time even in places where needle exchange programs operate.

Drug use absolutely is detrimental to one's ability to maintain complicated treatment regimens and reduce risky behavior. The best long term solution is a life free of drugs. In the meantime, the linkage that needle exchange programs provide to drug treatment and support services helps, not hinders, the ability of people to maintain their health and reduce their risk.

I urge the Administration to act immediately by issuing a scientific determination that needle exchange decreases HIV transmission and does not increase drug use. Federal funds should be made available to local communities which choose to implement needle exchange programs on April 1. Lives are literally hanging in the balance.

Sincerely,

Elizabeth Birch
Executive Director

cc: Erskine Bowles
John Podesta
Bruce Reed
Maria Echaveste
Sandra Thurman
Eric Goosby
Toby Donenfeld
Rahm Emanuel
Sylvia Mathews
Chris Jennings
Richard Socarides
Kevin Thurm
Monica Dixon

HUMAN RIGHTS CAMPAIGN

1101 14th Street NW
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SYRINGE EXCHANGE

Needle Exchange Does Not Divert Resources

- Needle exchange programs are in no way meant to divert resources away from drug treatment. They cannot be seen as a low cost substitute for such treatment. They can and should be seen as a part of an overall strategy to connect people to systems of care. Needle exchange programs provide a linkage to drug treatment in addition to other health care, counseling, and psychosocial services. Needle exchange programs are a component of a drug treatment and outreach strategy, they are not a substitute.

- No one doubts the effectiveness of drug treatment. The long term solution for injection drug users to reduce their HIV risk and put their lives back on track is to get off drugs. No policy or funding decisions should contradict that message. Because drug treatment on demand is not available in this country, it is imperative that we keep people alive until they can get into treatment. Needle exchange programs not only help people stay alive (through avoiding HIV infection), they also help many drug users start their long journey toward a drug free life.

    * In Tacoma, WA the needle exchange program was the source of 43% of new recruits into methadone treatment

    * Seattle's treatment slots have increased by 350 since needle exchange began.

    * The 90 treatment slots reserved for participants in the Baltimore needle exchange program were rapidly filled.

- No one is advocating for the use of drug treatment funds to support needle exchange programs. The money at issue is in the CDC HIV prevention budget. These funds flow through a community planning process which would have to support needle exchange as a component of the community's HIV prevention plan.

Support for Needle Exchange Is Not A Double Message

- It is not a double message to advocate for drug abstinence, drug treatment programs, and needle exchange. All of those efforts are directed at keeping people, old and young, alive and healthy.

    * Studies show that the mean age of injection drug users rises over time even in places where needle exchange programs operate.

Needle Exchange Should Be Continually Monitored

- The language in the FY 1998 Labor/HHS Appropriations bill requires any federally supported needle exchange programs to cooperate with federal efforts to evaluate and monitor the programs.

- Contrary findings to the general scientific consensus that needle exchange programs reduce HIV transmission and do not increase drug use should be examined carefully. One study in Montreal found an increase in seroconversion rates in the study population. Some have questioned whether those increases were related needle sharing as opposed to unsafe sexual behavior on the part of study participants, many of whom were prostitutes.

Alternative Approaches

- Data from Connecticut, which recently relaxed it laws restricting access to syringes, suggest that access to clean needles reduces HIV transmission. Whether that access comes through an exchange program or a pharmacy, the data show that when people can use clean needles, they reduce their risk for HIV. Pharmacy access and other means of obtaining clean needles may not, however, also provide referrals to drug treatment and support services, as do most needle exchange programs.

Impact of Drug Use on Treatment Regimens and Risk Behavior

- Drug use absolutely is detrimental to one's ability to maintain complicated treatment regimens and reduce risky behavior. The best long term solution is to free one's self from drug use. The linkage that needle exchange programs provide to drug treatment and support services helps, not hinders, the ability of people to maintain their health and reduce their risk.

Impact on Women and Children

- 74% of all AIDS cases among women are connected directly or indirectly to injection drug use (34% of the cases are those who inject drugs; 40% of the cases are among those who had sexual contact with an injection drug user).

- More than 50% of the cases of AIDS among children can be traced back to injection drug use.

Americans Support Needle Exchange and Local Control

- A poll commissioned by the Human Rights Campaign found that 55% of the American public favors needle exchange programs. (Source: The Tarrance Group and Lake, Sosin, Snell and Associates, April 1997)

- A Kaiser Family Foundation poll found that 61% of Americans favor changing federal law to allow state and local governments to decide for themselves whether to use their federal funds for needle exchange programs. (Source: Kaiser Family Foundation Omnibus Survey, November 1997)

MEMORANDUM

February 23, 1998

TO: Elena

FR: Chris and Sarah

RE: Needle Exchange

The purpose of this memo is to help frame the Administration's options as they relate to the needle exchange issue and to develop a strategy to lay the groundwork for whatever decision is made. Following the confirmation of Dr. David Satcher as Surgeon General and the expiration of the Congressional prohibition on releasing needle exchange funds (which is coming up on March 31th), there will be great pressure for the Administration to take a formal position on this issue.

Background: Congress has given the Secretary of Health and Human Services the authority to release Federal funding for needle exchange programs if she concludes that needle exchange programs decrease HIV transmission and do not increase drug use. The Secretary has already concluded that these programs do decrease the transmission of HIV, but has yet to make a formal finding regarding their impact on drug use. There has been increasing pressure from scientists, the public health community, and the AIDS community regarding the Administration's position on needle exchange programs. The pressure has become more intense as a great number of people believe that the evidence that needle exchange programs do not increase drug use is quite strong. As a result there is a heightened sense among the advocates that the only reason the Administration has mot made a positive finding is the fear of the political consequences of such an action.

Although there does appear to be credible information that needle exchange programs do not increase drug use, this is not a widely held view among the public and the law enforcement community. This fact helps explain why another critical player in this discussion, General McCaffrey, continues to send strong signals against any movement in this area.

With the General's opposition in mind and with the confirmation of Dr. Satcher for Surgeon General pending, the Administration hesitated to make any dispositive finding regarding needle exchange. This decision was further validated when during the appropriations process, there was a very real chance that any move to make such a finding would have led Congress to eliminate, altogether, the Secretary's current authority to release funds for needle exchange

programs. Instead, at least partially as the result of our decision not to act, the authority was not repealed and the Congress limited its intervention to delaying our authority to release funds until March 31. As a consequence, even if the Administration makes a final determination that needle exchange programs do not, in fact, increase drug use, no dollars can be released until the end of March.

There is little question that Dr. Satcher's confirmation and the pending March deadline places extraordinary pressure on the Administration to release findings on the impact of needle exchange programs on drug use. This means we must quickly move to decide how best to position ourselves on this issue and begin to lay the foundation for whatever position we take.

Options: There are currently three options to contemplate as we move forward.

(1) Maintain Status Quo: Maintain our current position that there is not enough information to make a decision as to whether needle exchange programs increase drug use. The Administration could continue to conclude that there is not sufficient data to make a final determination on the impact of these programs with regard to drug use. Under this option, we would choose to delay the issue until a more appropriate time for a determination (e.g. if ever a more friendly Congress is in place). This position would no doubt anger the AIDS community even though we would, under this resolution, stand a better chance at retaining the Secretary's authority to release funding to needle exchange programs over the long haul. The AIDS community believes that there is more than enough information to conclude that needle exchange programs do not increase drug use and do help reduce HIV transmission. Therefore they would find any efforts by the Administration to further delay this issue to be morally reprehensible. We would also likely be criticized by other elite validators who would find this choice to be a purely political move.

On the other hand, under this option, the Secretary is far more likely to retain her current statutory authority to fund these programs. It would also help us avoid a major confrontation with the Republican Congress on this issue -- a confrontation that many political experts believe we would inevitably lose.

(2) Make and Release a Finding That Needle Exchange Programs Do Not Increase Drug Use. The Secretary could, based on a new study (that could easily be produced by HHS), conclude that needle exchange programs do not increase drug use and release funding for needle exchange programs. With this conclusion, the President would be widely praised by the AIDS community for his moral leadership. The American Bar Association, the American Medical Association, and other influential validators would also, no doubt, praise the Administration. Our position could be described as one of community empowerment and choice rather than the Federal government micromanaging these programs: Federal funds would only be released to those communities that decided themselves to have programs. Having said this, the far right and the law enforcement community could be expected to react extremely negatively to such a move.

Taking this position would, no doubt, create a very visible fight -- a fight which would be difficult to sustain in an election year where the Democrats are trying to win back the House by claiming they are more in touch with the American public. In particular the conservative wing of the party would have no appetite to fight for this position. Republicans would seize upon this issue to illustrate their point that the Democrats are out of touch with the public and in the pocket of certain special interests.

If we choose this option, Congress would inevitably make an effort to remove the Secretary's authority to release funds, and many believe they would be successful. Interestingly, even though it is extremely likely the Secretary could lose all authority to release federal funding, the AIDS community (even acknowledging this) would still likely back this as the only acceptable option.

(3) Make Positive Finding But Do Not Release Funds Unless Local Law Enforcement Community Draws Similar Conclusion. This approach would require the law enforcement community in each particular area applying for funds to draw a similar conclusion to that of the Administration: that needle exchange programs do not increase drug use. This compromise option would help mitigate the inevitable opposition for a positive finding and reduce the chances that the Congress would remove the Secretary's authority. It would also help immunize the Administration from attacks from the right. However, this approach would likely draw a great deal of criticism from the AIDS community, who are likely to approve of nothing less than full victory because they feel it would reduce the number of communities eligible for funding. Also, it is important to note that Republicans would still try and use this issue to their advantage, suggesting that any needle exchange programs will increase drug utilization. As such they would inevitably use option 2 or 3 as a weapon in the upcoming mid-term Congressional elections.

Addendum: Regardless of what decision is made, it is extremely important that we begin to lay the foundation for how we plan to proceed. We will have to think about timing as well as how our decision is rolled out with regard to the AIDS community, the Congress, the law enforcement community. Most important of all, whatever decision we make must be made with a total commitment with all the Administration parties to ensure it is consistently communicated and competently implemented.

ELENA

THE WHITE HOUSE

WASHINGTON

FEB 26 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy

RE: Update on Status of Needle Exchange Programs

There have been a number of recent events involving needle exchange programs. On February 13, a National Institutes of Health Consensus Conference Statement recommended lifting the ban on use of federal funds for needle exchange programs. On February 18, HHS sent a Congressionally requested report to the Senate Appropriations Committee reviewing the scientific data on needle exchange programs to date. This memo provides background to put the issue in context, ~~with a discussion of~~ and discuss these recent events.

Current Statute There are three statutory restrictions on the use of federal funds for needle exchange programs. (1) The Substance Abuse and Mental Health (SAMHSA) block grant prohibits use of federal funds for needle exchange unless the Surgeon General determines that ~~they are~~ effective in reducing the spread of HIV and the use of illegal drugs. The statute does permit federal research and evaluation of existing needle exchange programs. (2) The 1996 Ryan White CARE Act reauthorization places a flat prohibition on the use of Ryan White funds for needle exchange. (3) The Labor/HHS Appropriations bill prohibits funding of needle exchange unless the Secretary determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.

Epidemiology of HIV Infection Thirty six percent of AIDS cases are directly or indirectly caused by IV drug use. Up to fifty percent of new HIV infections may be related to IV drug use. The effects of IV drug use have become a driving force in the HIV epidemic.

Number of Needle Exchange Programs There are over 100 needle exchange programs ~~up and running~~ in the US, with most programs ~~distributing through~~ two or more sites. As of 1995, twenty one States had local needle exchange programs.

Federally Sponsored Research The National Institute on Drug Abuse (NIDA) at NIH has funded 15 demonstration projects to evaluate the impact of needle exchange programs on rates of HIV infection, patterns of drug use, and their effectiveness as a gateway to ~~entering IV drug users into~~ substance abuse treatment. Only two of the 15 studies are completed at this time. There has also been a significant amount of privately funded research on needle exchange programs through foundations and other nonprofit groups.

State and Local Government At ~~their~~ its recent winter meeting, the National Governors Association passed a resolution stating: "Federal restrictions or requirements on the use of available funding interfere with the ability of States to develop comprehensive prevention strategies." The Association of State and Territorial Health Officers passed the following resolution in December 1995: "The federal government should repeal the ban on the use of federal funds for needle exchange services to allow interested States and localities the financial flexibility to support successful prevention and treatment initiatives within their jurisdictions." The US Conference of Mayors also supports lifting the ban on use of federal funds for needle exchange.

HHS Report to Senate Appropriations Report language was included in the September 1996 Senate L/HHS Appropriations bill requesting that HHS provide a report on the status of current research projects, an itemization of previously funded research, and findings-to-date regarding the efficacy of needle exchange programs for reducing HIV transmission and not encouraging illegal drug use. The report prepared by HHS reviewed all published studies of US needle exchange programs, including one by the Institute of Medicine; it did not attempt to determine if the Congressional standard has been met for lifting the ban on federal funding. The summary section of the report contains the following: "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."

NIH Consensus Conference A NIH Consensus Development Conference on Interventions to Prevent HIV Risk Behaviors was held February 11-13, 1997. This conference was developed and directed by a non-Federal panel of experts, predating the Congressional request for an HHS report. The resulting Consensus Conference Statement is an independent report of an expert panel, not a policy statement of the NIH. This Statement released on February 13, concluded that needle exchange programs are effective in reducing both HIV transmission and IV drug use, and recommended lifting the legislative restrictions on needle exchange programs.

IV Drug Use

Coordination of the Administration's Response HHS, ONDCP, and the White House jointly developed Q&A's to respond to questions about the HHS report. In summary, these say that data on reducing HIV seroprevalence is solid but the data on effect on drug use patterns is less clear-cut. HHS will continue research efforts to evaluate new data on needle exchange programs, and work with the Congress on effective HIV prevention strategies.

THE WHITE HOUSE

WASHINGTON

February 28, 1997

NOTE TO BRUCE REED

FROM: Eric P. Goosby, MD, Office of National AIDS Policy

SUBJECT: Additional Information on Needle Exchange Programs

Needle Exchange Programs and IV Drug Use

In studying the effects of needle exchange on drug use behaviors, the preponderance of data suggests a stable or declining level of drug use among needle exchange participants. About half of the studies show a decline in drug use. Two studies show an increase in drug use by self report, ~~this has been~~ discounted by expert panels as outliers. Corroborating evidence found in different studies includes: 1) rising age of participants in needle exchange programs argues against new recruits; 2) SAMHSA data showing no increase in drug users in given geographic areas; and 3) needle exchange programs refer persons to drug treatment where some are retained, no longer needing clean needles.

Most studies have ~~some~~ methodological weaknesses inherent to the population and ~~effect being studied~~ that are nearly impossible to overcome. These include: 1) reliance upon self-reported ~~frequency~~ of drug use that cannot be substantiated; 2) technical, ethical and logistical difficulties in randomizing one group to receive clean needles while denying another group yet expecting their continued participation in a study; and 3) isolating ~~out~~ the effects of needle exchange programs ~~among~~ the ~~many community~~ factors ~~which~~ may influence drug using ~~behaviors~~ in ~~any given~~ population.

Data quality issues received careful scrutiny by the Institute of Medicine in their 1995 report on needle exchange. The IOM panel examined patterns of evidence across all available studies, instead of relying only on the quality of each study design. The likelihood that a finding is real increases through repeated assessments across many different types of studies. In addition to research focused on individuals using needle exchange programs, other studies have examined indicator data for prevalence of drug use in communities such as unintended needle stick injuries to public and law enforcement workers. In MA and Portland OR, police and sanitation workers reported a decrease in needlestick injuries. Measures on selected population groups, such as the Drug Abuse Warning Network or Drug Use Forecasting lack precision to measure the effects of a needle exchange program, given the limited reach of most needle exchange programs and numerous variables affecting drug use patterns in a given community.

In addition, almost

With respect to the President's new initiative to combat drug use among youth, it is important to note that almost all studies indicate that needle exchange program participants tend to be older (median age 33 to 41 years old) and are long-term users (duration of use 7 to 20 years). There is no data to suggest needle exchange programs increase new initiates into drug use, and the age of participants often increases over time.

Ashley Court

Next Steps for HHS in Evaluating Effects on Drug Use

HHS will conduct a scientific review of the data presented at the NIH Consensus Conference in February 1997. Data presented at that conference have not yet been through the peer review process required for publication, and need close examination. A second step will be an analysis of data already collected through the NIDA demonstration projects which has not yet been specifically studied for effect on drug utilization patterns.

Congressional Climate and Community Expectations

The HHS report was released during the Congressional recess, and Hill reaction has been muted to date. This week Harold Varmus, Director of the NIH, received direct questions on needle exchange from Reps. Dickey (R-AR) and Wicker (R-MS) during a NIH Appropriations hearing. Secretary Shalala also received one question on lifting the federal funding ban prior to release of the report. Rep. Rangel once adamantly opposed needle exchange but is reported to be shifting somewhat in his stance.

Both the House and Senate have been uncomfortable with needle exchange programs, ducking the issue by punting to HHS. The exception to this was last year's prohibition on use of Ryan White treatment funds for needle exchange programs, which passed unanimously. While the majority party's views would predict an unfavorable climate for needle exchange options, Senator Specter, Chair of L/HHS Appropriations Subcommittee, has come to support needle exchange programs; Philadelphia has one of the largest. The State flexibility arguments advanced by NGA and ASTHO may also start having an effect.

The AIDS community is united in seeking an end to the ban on federal funding of needle exchange programs. Aside from the most vocal proponents of needle exchange, the national AIDS organizations understand the downside of demanding the ban be lifted before the education and political work is done, and vote counts are taken. What the community wants is a willingness on the part of the Administration to let science guide policy, and to hold HIV prevention as a high priority.

Mainstream public health and state government groups (the Association of State and Territorial Health Officers (ASTHO), US Conference of Mayors, NGA, National Black Caucus of State Legislators, etc.) support lifting the federal ban in favor of local discretion; of these, ASTHO and NASTAD are the most energized and publicly visible. There is strong concern that substance abuse continue to be understood primarily as a public health issue -- a treatable disease -- and not solely through the lens of law enforcement. On the other side, the Family

Research Council has begun gearing up on needle exchange and may try to alter the terms of the debate by claiming the ultimate goal of proponents is drug legalization.

[HHS is also planning a demonstration project specifically addressing the high risk behavior of IVDUs with the goal of reducing the rate of new HIV infections. This effort combines merging outreach and prevention efforts into every service delivery system an active IVDU may access, including emergency rooms, homeless shelters, soup kitchens, health centers, etc.]

Crime
Drugs - needle exchange

JOSHUA
GOTBAUM
02/12/98 11:55:43 PM

Record Type: Non-Record

To: Elena Kagan/OPD/EOP

cc:
Subject: FYI: Heads Up on Possible Bruce Reed Memo on Needle Exchange Programs

A note from Tom Reilly of the OMB staff.
---------- Forwarded by Joshua Gotbaum/OMB/EOP on 02/12/98 11:54 PM ----------

Thomas Reilly
02/12/98 12:56:33 PM

Record Type: Record

To: Joshua Gotbaum/OMB/EOP@EOP, Richard J. Turman/OMB/EOP@EOP, Barry T. Clendenin/OMB/EOP@EOP, Ann Kendrall/OMB/EOP@EOP

cc: Jill M. Pizzuto/OMB/EOP@EOP
Subject: Heads Up on Possible Bruce Reed Memo on Needle Exchange Programs

Todd Summers called me this morning and asked if I would fax him the FY 1998 L/HHS Conference Report language on the needle exchange general provision. When I asked him what he needed it for, he said he's working on a memo for Bruce Reed to send out to EXOP policy officials regarding needle exchange. He said they were under time pressure to get this to Bruce. My sense is the memo will provide background and call for a meeting to strategize on next steps. I asked if Josh would be getting the memo and Todd said Josh is on the distribution list.

Below is the language from the Conference Report (House Report 105-390) that I faxed to Todd:

DISTRIBUTION OF STERILE NEEDLES

Both the House and Senate bills contained restrictions on the use of federal funds for the distribution of sterile needles for the injection of any illegal drug (section 505). The Senate bill repeated language from previous appropriations bills allowing the Secretary to waive the prohibition if she determined that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs. The House bill removed the Secretary's authority over this issue.

The conference agreement includes the House language prohibiting the use of federal funds for carrying out any program for the distribution of sterile needles or syringes for the injection of any illegal drug. This provision is consistent with the goal of discouraging illegal drug use and not increasing the number of needles and syringes in

communities.

The conference agreement also includes bill language limiting the use of federal funds for sterile needle and syringe exchange projects until March 31, 1998. After that date such projects may proceed if (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs. This provision is consistent with the goal of allowing the Secretary maximum authority to protect public health while not increasing the overall number of needles and syringes in communities.

With respect to the first criteria, the conferees expect the Secretary to make a determination based on a review of the relevant science. If the Secretary makes the necessary determination, then the conferees expect the Secretary to require the chief public health officer of the State or political subdivision proposing to use federal funds for exchange projects to notify the Secretary that, at a minimum, all of the following conditions are met: (1) a program for preventing HIV transmission is operating in the community; (2) the State or local health officer has determined that an exchange project is likely to be an effective component of such a prevention program; (3) the exchange project provides referrals for treatment of drug abuse and for other appropriate health and social services; (4) such project provides information on reducing the risk of transmission of HIV; (5) the project complies with established standards for the disposal of hazardous medical waste; and (6) the State or local health officer agrees that, as needs are identified by the Secretary, the officer will collaborate with federally supported programs of research and evaluation that relate to exchange projects.

It is hoped that the delay in implementation of the provision with regard to exchange projects will allow the authorizing committees sufficient time to conduct a complete review and evaluation of the scientific evidence, as well as any conditions proposed by the Secretary, and consider the need for legislation with regard to these programs. It is the intent of the conferees that the Appropriations Committees refrain from further restrictions on the Secretary's authority over exchange after March 31, 1998.

Drugs - Needle exchange

Health Law and Ethics

Prevention of HIV/AIDS and Other Blood-Borne Diseases Among Injection Drug Users

A National Survey on the Regulation of Syringes and Needles

Lawrence O. Gostin, JD; Zita Lazzarini, JD, MPH; T. Stephen Jones, MD, MPH; Kathleen Flaherty, JD

We report the results of a survey of laws and regulations governing the sale and possession of needles and syringes in the United States and its territories and discuss legal and public health proposals to increase the availability of sterile syringes, as a human immunodeficiency virus (HIV) transmission prevention measure, for persons who continue to inject drugs. Every state, the District of Columbia (DC), and the Virgin Islands (VI) have enacted state or local laws or regulations that restrict the sale, distribution, or possession of syringes. Drug paraphernalia laws prohibiting the sale, distribution, and/or possession of syringes known to be used to introduce illicit drugs into the body exist in 47 states, DC, and VI. Syringe prescription laws prohibiting the sale, distribution, and possession of syringes without a valid medical prescription exist in 8 states and VI. Pharmacy regulations or practice guidelines restrict access to syringes in 23 states. We discuss the following legal and public health approaches to improve the availability of sterile syringes to prevent blood-borne disease among injection drug users: (1) clarify the legitimate medical purpose of sterile syringes for the prevention of HIV and other blood-borne infections; (2) modify drug paraphernalia laws to exclude syringes; (3) repeal syringe prescription laws; (4) repeal pharmacy regulations and practice guidelines restricting the sale of sterile syringes; (5) promote professional training of pharmacists, other health professionals, and law enforcement officers about the prevention of blood-borne infections; (6) permit local discretion in establishing syringe exchange programs; and (7) design community programs for safe syringe disposal.

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THE MAGNITUDE OF THE EPIDEMICS OF DRUG USE AND BLOOD-BORNE DISEASES

The dual epidemics of drug use and the human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) are highly destructive of public health and social life in America.[1] The drug-related health problems of the estimated 1.5 million injection drug users (IDUs) in the United States[2,3] range from blood-borne infections such as hepatitis B and C, HIV/AIDS, endocarditis, and malaria[4-7] to physical deterioration and death. Illegal drug use and the drug industry that fuels it are associated with a multitude of crimes against persons and property. Drug use induces family disintegration, child neglect, economic ruin, and social decay. Drug use exacts an estimated annual cost to society of $58.3 billion—in lost productivity, motor vehicle crashes, crime, stolen property, and drug treatment.[8]

Injection drug use is the second most frequently reported risk for AIDS, accounting for 184 359 cases through December 1995.[9] In 1995, 36% of all AIDS cases occurred among IDUs, their heterosexual sex partners, and children whose mothers were IDUs or sex partners of IDUs.[10] In contrast, in 1981, only 12% of all reported AIDS cases were associated with injection drug use.[11] In some areas, seroprevalence among IDUs is as high as 65%; in other areas, the rates are significantly lower.[12-17] Minorities, moreover, bear a disproportionately high burden. The rate of IDU-associated AIDS per 100 000 population is 3.5 for whites, 21.9 for Hispanics, and 50.9 for African Americans.[18]

Transmission of HIV infection through injection drug use has a cascading effect; infections spread from IDUs to their sexual and needle-sharing partners and from HIV-infected mothers to their children. Of the 71 818 AIDS cases among women reported through December 1995, nearly 65% were IDUs or were sexual partners of an IDU. Further, of the 6256 perinatally acquired AIDS cases reported through December 1995, 60% had mothers who were IDUs or had sex with an IDU.[10] These data suggest that drug use and related behaviors[19] are potent catalysts for spreading HIV throughout the population.[11] It has been estimated that approximately half of all new HIV infections in the United States occur among IDUs.[20]

THE ROLE OF SYRINGES IN THE TRANSMISSION OF BLOOD-BORNE DISEASE

Injection drug users transmit HIV infection and other blood-borne diseases to other users primarily through multiperson use (often called "sharing") of syringes.[21] (For the purpose of this article, "syringe" includes both syringes and needles.) Each time an IDU injects drugs, the syringe

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Table 1.—Drug Paraphernalia Laws*

	AL	AK	AZ	AR	CA	CO	CT	DE	DC	FL	GA	HI	ID	IL	IN	IA	KS	KY	LA	ME	MD	MA	MI	MN	MS	MO	MT	NE	NV
DP law†	X		X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X
MDPA-based law	X		X	X	X	X	X	X	X	X	a	X	X	X			X[1]	X	X	b	X	c	X		X	X	X	X	X
Exception for SEPs									X			X									X	X							
Local ordinance(s)		X				i										X					j		k						

*Footnotes after Table 3 provide full explanation of all lowercase letter designations. In all three tables, GU indicates Guam; NMI, Northern Mariana Islands; PR, Puerto Rico; SA, American Samoa; VI, Virgin Islands; DP, drug paraphernalia; MDPA, Model Drug Paraphernalia Act; and SEP, syringe exchange program.
†Drug paraphernalia laws prohibit the sale, distribution, possession, manufacture, and/or advertisement of items known to be used to introduce illicit drugs into the body.
‡The total of 46 includes two states (Oregon and Wisconsin) that specifically exclude syringes and needles from the statutory definition of drug paraphernalia.

becomes contaminated with that person's blood and blood-borne pathogens. If another IDU uses the same syringe, he or she is exposed to the previous user's blood with each injection. Decontamination efforts, such as flushing the syringe with bleach, can reduce the risk of exposure, but they are not as safe as using a new, sterile syringe for each injection.[22] Reducing the circumstances in which IDUs are likely to reuse equipment lowers the probability of spreading disease. Consequently, experts in preventive medicine and public health advise persons who continue to inject drugs to use a new syringe for each injection.[22-25] Reducing the risk of disease transmission among IDUs constitutes a legitimate medical and public health rationale for increasing access to syringes.

Multiperson use of syringes is a complex behavior initially reported as part of the subculture of the drug world; sharing was thought to be a sign of social bonding in the drug use community.[26-31] Increasingly, however, researchers have identified scarcity of syringes—not solely a culturally created norm—as a leading factor in sharing behavior.[32,33] In an effort to control drugs, federal, state, and local governments made a conscious policy choice to limit the supply of sterile syringes. Thus, laws and regulations have made it difficult for IDUs to use a sterile syringe for each injection.[23,25]

To determine the extent of laws and regulations controlling access to syringes, we conducted 2 surveys in the 50 states, the District of Columbia, and five territories concerning three sets of legal rules: drug paraphernalia laws, syringe prescription laws, and pharmacy regulations (Tables 1 through 3). A survey was sent by the Association of State and Territorial Health Officials to state and territorial attorneys general who were asked to consult with their respective health departments. A second survey was sent to state and territorial boards of pharmacy in consultation with the National Association of Boards of Pharmacy. Attorneys general and boards of pharmacy were asked to describe the law in their jurisdictions and to provide copies of relevant statutes, ordinances, and regulations. Attorneys general and boards of pharmacy were subsequently sent summaries of their laws and regulations and asked to confirm the accuracy. This article analyzes the full range of laws and regulations that restrict access to syringes and discusses potential legal and public health approaches for the prevention of HIV/AIDS and other blood-borne pathogens among IDUs, particularly those who will not or cannot stop injecting drugs.

STATE AND LOCAL DRUG PARAPHERNALIA LAWS

Drug paraphernalia statutes ban the manufacture, sale, distribution, possession, or advertising of a broad array of devices known to be used (or reasonably should be known to be used) to introduce illicit substances into the body. In contrast to syringe prescription laws, most drug paraphernalia laws include the element of intent by defining the prohibited activity in terms of objects "intended" or "marketed" for unlawful use. Thus, selling or distributing syringes—without knowledge that they will be used to inject illicit drugs—does not constitute an offense under these statutes. For example, a pharmacist who sells syringes over-the-counter to an IDU, believing that the purchaser is a diabetic who will use the equipment to inject insulin, does not violate drug paraphernalia laws.

Legislative History

Drug paraphernalia laws were enacted as a response to the proliferation of the drug paraphernalia industry. Beginning in the late 1960s, cigarette-rolling papers began to be marketed for use with marijuana.[34] By 1976, drug paraphernalia had spawned a $3 billion industry; between 15 000 and 30 000 "head shops" operated nationwide.[35] The Select Committee on Narcotics Abuse Control observed that "there were head shops no matter where [we] looked." An assortment of drug paraphernalia publications also appeared, ranging from books on the use of marijuana, hashish, and cocaine to magazines. Community groups and law enforcement officials expressed concern that "the drug paraphernalia industry, through its glamorizing of the drug culture, acts to undermine parental authority, as well as educational and community programs designed to prevent drug abuse among our youth."[36]

In response, and with increasing frequency during the 1960s and 1970s, state legislatures promulgated "needle laws" and "pipe laws." Many of these laws were inherently vague and were subsequently found to be unconstitutional.[37,38] To surmount the drafting difficulties of these early laws, the Drug Enforcement Administration in 1979 wrote the Model Drug Paraphernalia Act (MDPA), at the request of President Carter. In 1982, the Supreme Court signaled its approval by upholding a law that included a broad definition of drug paraphernalia.[39] Thereafter, lower courts upheld the constitutionality of statutes based on the MDPA.[40,41]

Given the era in which they emerged—where the young celebrated drug use and entrepreneurs openly flouted drug control efforts—drug paraphernalia laws seem reasonable. The social and legislative history of drug paraphernalia laws reveal that only one group opposed government restrictions: the drug paraphernalia industry. Remarkably absent from the debate was the public health perspective, particularly regarding the health consequences of limiting IDUs' access to syringes.

Survey Results

Forty-seven states, the District of Columbia, and the Virgin Islands have enacted drug paraphernalia laws; only Alaska, Iowa, South Carolina, and four territories have no state- or territory-wide drug paraphernalia statute (Table 1). (Alaska and Iowa have local drug paraphernalia provisions covering some counties and cities.) In 44 states, the District of Columbia, and the Virgin Islands, the drug paraphernalia laws

NH	NJ	NM	NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	GU	NMI	PR	SA	VI	Total
X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X					X	49
X	X	X	X	X	X	d	X	e	X	X		X	X	X	X	X	f	X		g	X					X	48‡
			X							X								h									7
																											5

are at least partially based on the MDPA. The statutes often enumerate the objects deemed to be drug paraphernalia, including, for instance, "hypodermic syringes, needles, and other objects used, intended for use, and designed for use in parenterally injecting controlled substances into the human body."[42] Oregon and Wisconsin specifically exclude syringes from the statutory definition of "drug paraphernalia," but both states include the word "inject" in their general definition of the offense. In contrast, Montana does not expressly include or exclude syringes in its definition of "drug paraphernalia." Maine, Massachusetts, Ohio, and Virginia have enacted legislation in addition to their drug paraphernalia laws that specifically restricts the sale of syringes.

The MDPA permits states to designate the penalty for an offense. Most states classify possession as a misdemeanor and delivery as a felony. Delivery to a minor, when the seller is at least 3 years older than the purchaser, often elicits a more severe penalty. Second and subsequent offenses frequently provoke more serious punishment than a first offense. Drug paraphernalia are often subject to seizure and forfeiture. Three states and one territory assess civil, as well as criminal, penalties for violation of drug paraphernalia laws (California, Louisiana, New Hampshire, and the Virgin Islands). These civil penalties include suspension or revocation of business, liquor, and/or occupational licenses or permits. New Hampshire, for example, levies special civil penalties on pharmacists who violate the drug paraphernalia law, including a fine of up to $5000 for repeated violations.

Five states (Hawaii, Maryland, Massachusetts, New York, and Rhode Island) and the District of Columbia carve out an exception in their drug paraphernalia laws for operators of syringe exchange programs (SEPs) and their participants. In addition, the state of Washington recognizes such an exemption based on case law that interprets the state's public health and criminal statutes.[43] These provisions exempt SEP participants who possess and distribute syringes from prosecution under drug paraphernalia laws. Five states require SEP users to carry a certificate or other evidence of SEP participation (Connecticut, Maryland, Massachusetts, New York, and Rhode Island).

In at least five states (Alaska, Colorado, Iowa, Maryland, and Michigan), local ordinances regulate the possession, sale, or manufacture of drug paraphernalia; of these states, only Alaska and Iowa do not also have a state-wide drug paraphernalia law. New York is the only state that explicitly construes its law to preempt local ordinances.[44,45]

THE FEDERAL MAIL ORDER DRUG PARAPHERNALIA CONTROL ACT

The Federal Mail Order Drug Paraphernalia Control Act (Mail Order Act), passed as part of the Anti-Drug Abuse Act of 1986, was expanded in 1990.[46] At the time the Mail Order Act was enacted, the MDPA was considered a triumph; law enforcement officials had succeeded in closing head shops in 38 states. State-level efforts were so effective that they produced a different problem: the interstate commerce of drug paraphernalia.[47] While the head shop business faltered, the mail order drug paraphernalia business flourished:

> All across America children are receiving catalogs and advertisements for the bongs and drug merchandise which we have worked very hard to eliminate. Some of these ads are finding their way into the family mailbox unsolicited.[47]

The Mail Order Act was originally designed to prohibit the use of the US Postal Service to ship equipment to ingest drugs. The statute was later amended to proscribe "any offer for sale and transportation in interstate or foreign commerce" or import or export of drug paraphernalia. In 1994, the Supreme Court upheld the constitutionality of the Mail Order Act.[48]

The Mail Order Act is significant in that it interjects federal law into an area traditionally reserved for the states.[49] In deference to public health, state and local law enforcement officials may choose to relax their enforcement of drug paraphernalia laws. State and local decisions, however, do not preclude federal authorities from vigorously enforcing the Mail Order Act.

In 1986, the year the Mail Order Act was passed, HIV was known to be a blood-borne disease, and the HIV epidemic was a widely recognized public health problem.[46] Despite the foreseeable health effects of restricting access to injection equipment during this epidemic, public health and HIV prevention were not discussed at congressional hearings. Moreover, federal courts that reviewed the Mail Order Act,[50,51] including the Supreme Court,[48] expressed no reservations about potential health consequences.

SYRINGE PRESCRIPTION STATUTES

Syringe prescription statutes prohibit persons from dispensing or possessing hypodermic syringes without a valid medical prescription. Most prescription laws circumscribe a physician's power to prescribe syringes by requiring a legitimate medical purpose. The "legitimate medical purposes" doctrine strengthens the regulatory effect of syringe prescription laws and is intended to hold a prescription invalid unless issued for a therapeutic purpose. Unlike drug paraphernalia laws, a violation of prescription laws does not require criminal intent. For example, to violate the statute, a pharmacist who dispenses a hypodermic syringe without a prescription need not know that the buyer intends to administer illegal drugs; the very act of dispensing the syringe without a prescription constitutes an offense. The defendant, moreover, carries the burden of proving by a preponderance of the evidence that the hypodermic instrument was legally sold or obtained.[52,53] Lacking the element of intent, prescription statutes potentially encompass many more transactions than paraphernalia laws. Furthermore, syringe prescription laws may restrict syringe displays and require pharmacists to maintain sales records. Courts have upheld the constitutionality of syringe prescription laws.[54,55]

Legislative History

Prescription laws can be traced to the widespread use of opium, morphine, cocaine, and heroin during the late 19th and

Table 2.—Laws Limiting Syringe Sales*

	AL	AK	AZ	AR	CA	CO	CT	DE	DC	FL	GA	HI	ID	IL	IN	IA	KS	KY	LA	ME	MD	MA	MI	MN	MS	MO	MT	NE	NV
SP law†					X		l	X		m				X						n		X							
Other limitations																							p			q			r
Record keeping§				X	X		X		X					X				X				X							
Disposal requirement					X		X	X										X											
Display limitations‖					X		X	X										X											
Pharmacy sales	X				X		y		X											z		aa							X
Exception for SEPs							X							cc								X							
Other exceptions					dd		ee	ff						gg								hh							ii
Local ordinance(s)										pp													qq						

*Footnotes after Table 3 provide full explanation of all lowercase letter designations.
†Syringe prescription (SP) laws prohibit the sale, distribution, and possession of syringes without a valid medical prescription.
‡This total of 9 includes only those states which require a prescription by law for most sales to adults.
§"Record keeping" may include name and address of purchaser, number of syringes sold, intended use, and inspections permitted by law enforcement.
‖"Display limitations" include requirements that syringes and needles be stored in particular areas and not made available to customers on a self-service basis.

early 20th centuries. Physicians and pharmacists dispensed opium to treat a myriad of afflictions. In the 1890s, public concern led to a call for restricting physicians' freedom to dispense these drugs. The medical profession reacted with "fear that the state would dominate the practice of medicine."[56] The ensuing debate produced the 1914 Boylan Act, New York's syringe prescription law. The law's intent was to reduce drug addiction by posing obstacles to obtaining narcotic drugs and the instruments to administer them. The Boylan Act strictly regulated the distribution of syringes by pharmacists and physicians. Other states followed suit, adopting prescription laws primarily as a drug abuse prevention strategy.[57] Not surprisingly, states that have enacted syringe prescription laws are those that have experienced the longest history of, or the deepest problems with, drug abuse.

Survey Results

Eight states and one territory statutorily mandate medical prescriptions for most syringe sales (Table 2).[58] These and other jurisdictions, however, do allow exceptions for certain authorized users (eg, manufacturers, wholesalers, researchers, licensed holders, and persons using syringes for agricultural, medical, and industrial purposes).[59] Ten additional states restrict the purchase of syringes without a prescription by law or local ordinance. These laws may require prescriptions to establish a legitimate purpose for specific classes of purchasers (eg, minors) or for certain types of purchases (eg, bulk). In 1992, Connecticut amended its law to require prescriptions only for sales of more than 10 syringes. Virginia requires prescriptions for sale to individuals under the age of 16 years, and Florida requires them for sale to individuals under the age of 18 years. Maine specifies that only certain people can sell syringes; however, anyone over the age of 18 years may purchase from an authorized seller. Alternatively, states or localities may permit nonprescription sales only to persons with a legitimate medical need (eg, Michigan, Nevada, Ohio, Texas, Virginia, and Washington). For example, in Nevada, hypodermic devices may be sold without a prescription for medical, veterinary, industrial, and hobby purposes, as long as the seller is satisfied that the device will be used lawfully.

In addition to criminal penalties, physicians and pharmacists may face sanctions from professional licensing boards for violating state laws concerning syringes. In 1994, the California Board of Pharmacy, for example, accused a pharmacy of allowing a nonpharmacist employee to sell syringes without asking for identification or recording the sale. The board fined the pharmacy and temporarily suspended the licenses of the pharmacy and the pharmacist.[60]

Only three states specifically exempt SEP operators and participants from syringe prescription laws (Connecticut, Massachusetts, and Rhode Island). These states usually require SEP users to carry a syringe exchange card or other proof of participation. The exemption applies only to possession of equipment obtained from the SEP.

Several localities have promulgated syringe prescription ordinances. Michigan does not require prescriptions for sale of needles and syringes; the cities of Warren, Westland, and Detroit, however, place certain restrictions on the purchase or possession of syringes. Florida state law does not require a prescription for adults purchasing syringes; yet Dade and several other counties have prescription ordinances that regulate the sale of syringes. Local ordinances may exist in other states, but they were not reported in this survey.

PHARMACY REGULATIONS AND PRACTICE GUIDELINES

Pharmacy regulations are established under state law by pharmacy boards or other governmental agencies such as a department of consumer protection, department of health, or department of drug control. Pharmacists are legally required to comply with regulations for the sale of syringes. Practice guidelines are typically established by state pharmacy boards. While these guidelines do not have the force of law and technically are not legally binding, failure to comply could leave the pharmacist susceptible to professional sanction or civil liability under state tort law. Legal and public health scholarship has not previously recognized the importance of pharmacy regulations and practice guidelines in restricting access to sterile syringes. While it was previously assumed that over-the-counter sale of syringes was regulated in only a small minority of states with syringe prescription laws, this survey reveals that restrictive regulations are in force in many of the United States.

Twenty-three jurisdictions have pharmacy regulations or practice guidelines that restrict access to syringes by IDUs and persons who need sterile syringes for medical conditions (Table 3).[61] Seventeen of these states do not have syringe prescription laws.[62] In 11 of these states, regulations or mandatory practice standards significantly impede IDUs' access.[63] These rules require the seller to demand of purchasers identification and a prescription or other proof of medical need and/or impose record-keeping requirements. Pharmacists are

NH	NJ	NM	NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	GU	NMI	PR	SA	VI	Total
X	X		X							X							o									X	9‡
						s		t						u			v	w									8
X	X		X			X				X							X									X	14
						X				X																X	7
						X																					5
X	X									bb							X										11
										X																	3
jj	kk		ll			mm				nn							oo									rr	13
																											2

often expressly authorized to refuse to sell syringes if they believe the intended use is illegal (eg, Georgia, Maryland, South Carolina, and Tennessee). Some states require purchasers to produce valid identification such as a driver's license (eg, Indiana, South Carolina, and Virginia).

Eighteen jurisdictions track the sale of needles and syringes by law or regulations requiring pharmacists to maintain records[64] and to permit their inspection by various state agencies. The information requested often includes the purchaser's name and address and the intended use. Purchasers may also be required to sign a register. Pharmacists must usually retain the records for a period of time set forth in the regulations and ensure their availability for inspection by law enforcement or other government agencies.

Seven states and one territory regulate the traffic in syringes to guard against having lawfully obtained equipment used for nonlegitimate purposes.[65]

Three states require syringe purchasers to carry evidence of lawful possession (Delaware, Illinois, and Rhode Island). Delaware and Illinois laws require some or all persons possessing syringes to have a certificate of medical need authorized by a physician or allied medical practitioner. The Rhode Island health department advises patients to carry the pharmacy's dispensing label when transporting syringes.

At least three states that do not require prescriptions for syringe sales report having "voluntary" syringe prescription requirements or guidelines to determine legitimate users (Missouri, New Mexico, and Wyoming). In these states, pharmacists voluntarily screen syringe purchasers and sell only to persons whom the pharmacists consider to have a legitimate medical need for syringes. Missouri has no law restricting syringe purchases, but individual pharmacies may establish their own policies; some require purchasers to present a written statement of legitimate medical need. Moreover, the Missouri Board of Pharmacy maintains that pharmacists are ethically obligated to ascertain whether syringes will be used lawfully. In New Mexico, pharmacists voluntarily question syringe and needle purchasers about their intended use and may refuse the sale. In other states—including those without specific laws or regulations requiring prescriptions—pharmacist discretion likely plays a key role in syringe sales.[66]

PUBLIC HEALTH EFFECTS OF SYRINGE REGULATION: ANALYSIS OF SURVEY RESULTS

The survey reveals that every state and the District of Columbia have enacted state or local laws that restrict the sale, distribution, or possession of syringes (Table 2). Only four territories did not report any restrictions. Forty-nine states, the District of Columbia, and the Virgin Islands have passed drug paraphernalia statutes or local ordinances. Only South Carolina and four territories do not have drug paraphernalia provisions. Ten states and one territory have statutes, regulations, or local ordinances that require a prescription for the purchase of syringes.[67] Sixteen additional states have statutes, regulations, practice guidelines, or local ordinances that can significantly limit the sale and purchase of syringes.[68] To the extent that these laws, regulations, and ordinances restrict access to sterile syringes, they contribute to the spread of blood-borne diseases among IDUs, their sexual contacts, and their children. In addition, because of criminal and professional sanctions, they deter pharmacists, physicians, and public health professionals from providing important HIV prevention services to persons who continue to inject drugs.

RESTRICTIONS ON ACCESS TO SYRINGES AND THE TRANSMISSION OF BLOOD-BORNE PATHOGENS

Legal restrictions on access to syringes are a contributing factor in the multiperson use of syringes, the primary risk behavior in the blood-borne spread of infection. Researchers from a variety of different vantage points conclude that IDUs will use sterile syringes if given the opportunity and the means.[69] First, IDUs report, and ethnographers confirm, that legal restrictions are a primary reason for sharing syringes.[32,33] Second, IDUs who receive syringes from pharmacists rather than street sellers are less likely to share syringes or to attend shooting galleries.[70] Third, IDUs with a history of diabetes have significantly lower HIV seroprevalence than nondiabetic IDUs. This is attributed to safer injection practices afforded by their legal access to sterile syringes.[71] Finally, a significant increase in pharmacy sales of syringes to IDUs and a substantial reduction in the multiperson use of contaminated syringes were reported after Connecticut partially deregulated the sale and possession of syringes.[72,73]

The principal concern about syringe deregulation or SEPs is that they could result in increased initiation into injection drug use or encourage continued drug use. However, despite careful study, most researchers have found no correlation between greater availability of syringes and increased drug use.[11,74] Moreover, since legal access to syringes, particularly through SEPs, affords greater opportunities for referrals to drug treatment and counseling messages about the harms of drug use, it is possible that SEPs and deregulation of syringes could facilitate, rather than hinder, drug control efforts. The effect of increased access to syringes on drug use is important from a public health perspective and deserves rigorous evaluation.

IMPLEMENTATION OF DISEASE PREVENTION AMONG IDUS

Obtaining and using a sterile syringe to avoid transmission of blood-borne disease can pose acute legal problems for

Table 3.—Regulations Limiting Syringe Sales

	AL	AK	AZ	AR	CA	CO	CT	DE	DC	FL	GA	HI	ID	IL	IN	IA	KS	KY	LA	ME	MD	MA	MI	MN	MS	MO	MT	NE	NV
Prescription required																													
"Medical need"											ss								tt		uu				vv	ww		yy	zz
Pharmacy sales					X		fff				ggg				X				tt		X	hhh							
Display limitations§					X			X			X							X	tt			X		X					X
Disposal requirements					X			X										X											
Record keeping‖					X										X			lll	tt		X	X							
Any restriction(s)¶					X			X	X	X	X			X	X			X			X	X	X		X	X			X

*Totals do not include pharmacy rules from Louisiana, which were never implemented.
†Includes only states that require a prescription by regulation for most sales to adults.
‡Syringe purchaser must present proof of medical need or legitimate purpose.
§"Display limitations" include requirements that syringes and needles be stored in particular areas and not made available to customers on a self-service basis.
‖"Record keeping" may include name and address of purchaser, number of syringes sold, intended use, and inspections permitted by law enforcement.
¶Includes significant restrictions imposed by law or local ordinance (Table 2) as well as regulations, rules, and practice guidelines (Table 3).
a. GA, drug paraphernalia (DP) law is partially based on MDPA.
b. ME, has a drug paraphernalia law based on MDPA but also regulates syringe and needle violations under a separate statute.
c. MA, has a DP law based on MDPA but also regulates needles and syringes under a separate statute.
d. OH, law is based on the MDPA; there is an additional statute regarding the possession of needles/syringes.
e. OR, specifically excludes needles/syringes from the definition of DP.
f. VA, in addition to DP law, there is a specific regulation on syringes and needles.
g. WI, specifically excludes needles/syringes from the definition of DP.
h. WA, *Health District v Brocket*, 839 P2d 324 (Wash 1992): syringe exchange program subject to specific public health statute and not general criminal drug paraphernalia law.
i. CO, Denver, Colorado Springs, and Aurora.
j. MD, Annapolis and Howard County.
k. MI, cities of Dearborn, Detroit, Sterling Heights, Warren, and Westland.
l. CT, only applies to sale of more than 10 syringes.
m. FL, purchasers under 18 years of age must have a prescription for syringes.
n. ME, only persons eighteen years of age or older may purchase syringes without a prescription.
o. VA, purchasers under 16 years of age must have a prescription for syringes.
p. MI, local ordinances restrict access to and possession of syringes.
q. MO, no statutory requirement. Individual pharmacies may set own policies, some require physician's written statement that buyer has legitimate medical need.
r. NV, no state law mandates prescription for syringe purchases. However, the seller must be satisfied that the customer's intended use is legitimate.
s. OH, no prescription is required, but pharmacist must know or reasonably believe user is authorized.
t. OR, minors must be have authorization of physician, parent, or guardian or "other acceptable" party to purchase syringes.
u. TX, pharmacists may sell if in their judgment the sale is "for legitimate purposes."
v. VA, sale requires identification and written evidence of legitimate purpose.
w. WA, seller must be satisfied that use will be for "legal purposes."
y. CT, health professionals may also sell/distribute needles and syringes.
z. ME, licenses authorized sellers (pharmacies and certain others); any person aged 18 years or older may buy from an authorized seller.
aa. MA, specified professionals, persons licensed by Department of Public Health, and manufacturers are also permitted to sell syringes.
bb. RI, sellers must be licensed by RI Department of Public Health.
cc. IL, the Chicago City Attorney has interpreted the research exception to the state syringe prescription law to include syringe exchange programs.
dd. CA, no prescription required for syringes used for insulin or adrenaline, for animals, or by manufacturers, wholesalers, or surgical suppliers.
ee. CT, manufacturers, wholesalers, licensed holders, researchers, agricultural, medical, or industrial users.
ff. DE, agricultural, wholesale, jobbers, manufacturers, and industrial users.

IDUs, including prosecution for possessing drug injection equipment.[75] An IDU is unlikely to present a legally acceptable reason for requiring a syringe and, thus, is likely to violate both syringe prescription and drug paraphernalia laws. Drug users may be arrested for carrying syringes.[76]

Why would the potential legal consequences of carrying injection equipment dissuade a drug user, when he or she is already engaged in far more serious criminal behavior? From the IDU's perspective, laws that penalize the possession of syringes are problematic for a number of reasons. First, drug users who are arrested on a drug paraphernalia charge are subject to fines and possible incarceration.[32] Second, the violation itself marks the person as a drug user and may subject him or her to more intense police surveillance.[77] Third, once an individual is found to possess drug paraphernalia, he or she is more likely to undergo a police search for illicit drugs.[32,77] Discovery of a syringe, or even bleach, may provide probable cause under the Fourth Amendment to conduct a broader search of the drug user and his or her possessions, leading to confiscation of illicit drugs and prosecution for sale or use.

Ethnographic studies vividly illustrate that drug users, fearing detection of syringes under these laws, often fail to carry sterile syringes.[32,77,78] Syringe laws and regulations, therefore, create a marked disincentive for drug users to possess sterile syringes when they purchase or inject drugs. Ironically, this is precisely the time when users most need sterile injection equipment because they will otherwise share blood-contaminated syringes and potentially transmit blood-borne pathogens. The threat of arrest and prosecution for possession of drug injection equipment makes it less likely that active IDUs will use sterile syringes.

OVER-THE-COUNTER SALE OF SYRINGES: THE ROLE OF PHARMACISTS

Pharmacists face substantial legal and professional hurdles in selling syringes to IDUs. By requiring prescriptions or proof of medical need, identification, and record-keeping, states impede pharmacists and customers from instituting safer means for drug injection. Drug users, wary of the legal consequences, may avoid pharmacies out of apprehension of intrusive questioning.[79] Pharmacists, wary of criminal prohibitions and professional sanctions, may decline to sell syringes to suspected IDUs.

Nationwide, pharmacists retain considerable discretion in deciding whether, and to whom, to sell syringes. Some pharmacists sell to all buyers; others refuse to sell to purchasers who demonstrate visible signs of injection drug use or who cannot offer a plausible medical justification; still others refuse sales for apparently discriminatory or capricious reasons.[80,81] Pharmacist discretion yields wide variation in the willingness to sell to IDUs.[82] Biases against, for example, racial minorities, young people, and homeless persons potentially limit opportunities for pharmacy customers to purchase syringes.[83,84]

NH	NJ	NM	NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	GU	NMI	PR	SA	VI	Total*
									X																		1
		aaa									bbb		X			ccc		ddd			eee						12
			X			iii			X		jjj		X						X								12
	X					X							X			kkk	X			X	eee						14
					X																						4
			X			mmm					nnn						X		X								10
X	X		X			X			X	X	X		X	X			X	X	X							X	27

gg. IL, medical professionals, farmers, and researchers may purchase syringes without a prescription. Persons who have lost prescriptions may purchase without a prescription but must sign an affidavit that is given to the state police.
hh. MA, health professionals, persons licensed by the Department of Public Health, manufacturers, and researchers can buy syringes without a prescription.
ii. NV, prescriptions are not required for sale to/for asthmatics, diabetics, injection of medication prescribed by a practitioner, use in ambulances and by firefighters, veterinary uses, commercial or industrial, embalming, licensed medical use, research, and hobbyists "if the seller is satisfied that the device will be used for legitimate purposes."
jj. NH, industrial, medical, and research users can buy syringes without a prescription.
kk. NJ, health professionals, veterinarians, undertakers, clinical laboratories, and medical institutions can buy syringes without a prescription.
ll. NY, persons authorized by the health commissioner to obtain/possess syringes can purchase without a prescription.
mm. OH, manufacturers, medical, lawful, and agricultural users can buy syringes without a prescription.
nn. RI, manufacturers, wholesalers, dealers, embalmers, and medical users may purchase syringes without a prescription.
oo. VA, physicians, dentists, podiatrists, veterinarians, funeral directors, and embalmers may possess or distribute syringes without a prescription.
pp. FL, Dade and other counties require prescriptions, but no statewide requirement.
qq. MI, the cities of Detroit, Warren, and Westland restrict access to and possession of syringes.
rr. VI, health care professionals, veterinarians, undertakers, or registered pharmacies, hospitals, laboratories, or medical institutions may obtain syringes without a prescription.
ss. GA, sales shall not be made if seller has reasonable cause to believe that syringes would be used for unlawful purpose.
tt. LA, pharmacy rule, never implemented, would limit sales to authorized sellers, require identification and proof of medical need, impose display and record-keeping requirements, and provide for inspections.
uu. MD, purchasers must show identification and show good-faith indication of legitimate need.
vv. MS, pharmacists may sell without a prescription; some require proof of medical need or buyer signing a log before purchase.
ww. MO, according to state Board of Pharmacy, pharmacists have an ethical responsibility to decide whether needles/syringes would be used for legal purpose.
yy. NE, pharmacists are expected to exercise their professional judgment at the time of sale.
zz. NV, no state law mandates a prescription for syringe purchases. However, the seller must be satisfied that the customer's intended use is legitimate.
aaa. NM, no state law requires a prescription, but some pharmacists question potential purchasers about intended use and may refuse to sell.
bbb. SC, pharmacists must obtain either oral or written affirmation from purchasers that sale is for legitimate medical use.
ccc. VT, the Board of Pharmacy discourages sales of syringes not grounded in medical necessity.
ddd. WA, seller must determine whether syringe is to be used for a legal purpose.
eee. WY, guidelines, strictly voluntary, suggest syringes be kept in prescription department. Pharmacists may ask for identification or about intended use.
fff. CT, health professionals may also sell syringes.
ggg. GA, only pharmacies and physicians may sell syringes.
hhh. MA, persons licensed by the Department of Public Health (eg, manufacturers, dealers) may also sell syringes.
iii. OH, authorized dealers, hospitals, practitioners, and pharmacies are permitted to sell syringes.
jjj. SC, only pharmacists are permitted to make sales without prescriptions.
kkk. VT, the Board of Pharmacy encourages pharmacists to keep needles and syringes behind the counter.
lll. KY, pharmacists must keep records for nonprescription sales; pharmacists are not required to keep records of sales made with prescriptions.
mmm. OH, pharmacists may sell without prescription but pharmacists must keep records of sale and purchaser must provide identification.
nnn. SC, pharmacists must keep records of nonprescription sales.

'LEGITIMATE MEDICAL PURPOSES': THE ROLE OF PHYSICIANS AND OTHER HEALTH PROFESSIONALS

Physicians and other health professionals face potentially dire legal consequences when they prescribe syringes or otherwise directly assist IDUs in obtaining sterile syringes. Physician prescription practices, in particular, are guided by the "legitimate medical purposes" doctrine. Courts have held that physicians who prescribe controlled substances "for the purpose of maintaining [a patient's] habit" are not acting in the course of their professional duty.[85,86] It is unclear, however, whether physicians would be liable for prescribing syringes to a drug injector if they had a good faith intention to prevent the drug user from contracting or transmitting HIV infection. Many public health experts believe that increasing IDU access to sterile syringes will reduce the needle-borne transmission of disease.[23,25] Indeed, in other contexts, courts have concluded that physicians do not violate prescription laws if they act in good faith in accordance with reasonable medical judgment.[87] The most important characteristic of the physician-patient relationship is "the physician using [his or her] best efforts and expertise to promote the patient's total health."[88] If laws and regulations do not recognize access to sterile syringes as a legitimate means of preventing blood-borne disease, how can physicians and other health care professionals provide comprehensive prevention services to persons who will not or cannot stop injecting drugs?

THE LAWFUL OPERATION OF SYRINGE EXCHANGES

Although the users of one SEP were reported to have higher HIV incidence than nonusers,[89] the preponderance of research suggests that SEPs lower the rates of multiperson use of syringes[90-93]; offer a referral source for social services, health care, and drug abuse treatment; and serve as a conduit to HIV testing and counseling, health education, and condom distribution.[74] The National Research Council's review of the data concludes that SEPs constitute a vital component of a comprehensive strategy to prevent infectious disease. Syringe exchange programs reduce the number of contaminated syringes in circulation, which lowers a major risk factor for infectious disease transmission.[11]

Public health professionals or community advocates who run SEPs understand that distributed syringes will be used to inject illicit drugs; thus, absent some separate legal authority, SEPs appear to operate unlawfully under drug paraphernalia laws. Even where law enforcement agencies choose to ignore intent under drug paraphernalia laws, SEPs may be legally vulnerable. For example, SEP operators, who distribute syringes without prescriptions in states with syringe prescription laws or regulations, do so unlawfully. Consequently, in many jurisdictions, federal, state, or municipal police are authorized to arrest SEP participants, and the attorney general is entitled to seek an injunction against the program. At the very least, their uncertain legal status may

discourage drug users from participating in SEPs and communities from establishing SEPs.[94]

Public health officials and community activists have sought to support the lawfulness of SEPs through judicial declaration,[95,96] assertion of public health emergency,[97-99] and invocation of the necessity defense for prosecution of drug paraphernalia[100,101] and syringe prescription laws.[102,103] The results have been mixed.[104] Clearly, the cooperation of public health and law enforcement are essential for effective prevention of HIV transmission associated with illicit drug use.

PREVENTION OF BLOOD-BORNE DISEASE AMONG IDUS

Many public health,[105] medical,[11,106] and legal[107,108] organizations have supported the deregulation of syringes as a strategy to prevent HIV/AIDS and other blood-borne diseases among IDUs. Most laws, regulations, and practice guidelines that restrict the sale, possession, or distribution of syringes were promulgated (1) before HIV/AIDS among IDUs was recognized as a pressing public health problem and (2) without carefully contemplating the health implications. Since that time, the interconnected epidemics of drug use and HIV/AIDS have produced illness and death, particularly among poor, urban, minority communities.

We present the following legal and public health approaches that could be used to increase access to sterile syringes for persons who continue to inject drugs in order to reduce the transmission of blood-borne disease among IDUs, their sex partners, and children. These approaches would not affect current criminal proscriptions against the importation, sale, or possession of illicit drugs.

1. *Clarify the legitimate medical purposes of sterile syringes.* Possession and use of sterile syringes by IDUs serves the legitimate medical purpose of preventing blood-borne diseases. Distinguishing syringes from other drug paraphernalia would allow IDUs to legally buy and possess syringes, legitimize the professional decisions of physicians and pharmacists, and clarify the laws on which criminal justice authorities rely.

2. *Modify drug paraphernalia laws.* Drug paraphernalia laws could be modified to exempt authorized sellers, distributors, or possessors of syringes (eg, pharmacists, physicians, public health officials, registered SEPs, and their patients/clients). Permitting IDUs to obtain syringes from reliable sources would enable them to comply with public health advice to use a new syringe for each injection. The law could justifiably continue to criminalize the unauthorized sale of drug paraphernalia by drug dealers, shooting galleries, head shops, and mail order firms; but the law should not criminalize simple possesion of syringes by IDUs. Unauthorized sellers are dubious sources of sterile injection equipment; dealers and shooting gallery proprietors, for example, sometimes repackage used syringes and sell them as new.[109]

3. *Repeal syringe prescription laws.* Repeal of syringe prescription laws would legalize over-the-counter sale of syringes in pharmacies and would promote several public health benefits. Repeal would enable IDUs and persons who need sterile syringes for medical conditions such as insulin-dependent diabetes to secure sterile syringes, free physicians and pharmacists from risking criminal liability or professional sanction for prescribing or dispensing syringes to prevent transmission of blood-borne infections, and allow pharmacists to participate in public health efforts by educating and counseling customers about safer sex and drug injection practices. If permitted to perform within the scope of their professional practices, physicians and pharmacists could serve as a link to drug abuse treatment and education. Medical and pharmacy boards would retain the authority to sanction unprofessional behavior (eg, physicians or pharmacists who improperly encourage, or assist in, the illicit sale or use of drugs). Over-the-counter sale of syringes is likely to be a highly cost-effective means of increasing the availability of syringes: the extensive network, diverse locations, and extended hours of operation of pharmacies, together with the expertise of pharmacists, would help ensure wide access to syringes and professional advice. Furthermore, over-the-counter sales of syringes would remain within the private sector.

4. *Repeal restrictive pharmacy regulations and practice guidelines.* Repeal of restrictive pharmacy regulations and practice guidelines would increase the availability of sterile syringes to IDUs. States could achieve this public health objective by repealing regulations and guidelines that require purchasers to present prescriptions or other proof of legitimate medical need, proffer identification, or sign a log book prior to purchasing sterile injection equipment. Although they seem reasonable on their face, these regulations and guidelines impede both pharmacists and their clients in transactions involving sterile syringes. Reasonable practice guidelines could be maintained to ensure high professional standards and to limit sales of syringes to licensed pharmacies.

5. *Promote professional training.* Professional in-service training for pharmacists, other health professionals, and criminal justice personnel would advance public health goals. Education about the transmission of blood-borne infections would equip pharmacists to make well-informed decisions about the sale of syringes, encourage health care professionals to offer the best prevention education to IDUs, and inform criminal justice personnel about public health prevention strategies.

6. *Permit local discretion in establishing SEPs.* Permitting public health officials to establish SEPs would augment public health strategies to prevent blood-borne diseases. Many communities have found SEPs to be an important element of a comprehensive HIV prevention program. Local health officials are best situated to assess the community's response to, and the potential effectiveness of, such a program.

7. *Design programs for safe syringe disposal.* Public health officials, health care professionals, and pharmacists are well situated to collaborate in designing and directing effective programs for safe syringe disposal. Programs to ensure the safe disposal of used drug injection equipment would decrease the number of contaminated syringes in circulation and reduce health risks to the public. Indeed, criminal penalties for possession can thwart initiatives for safe disposal of syringes. Injection drug users may discard their syringes once they have been used rather than returning them to an SEP or taking them to a place for safe disposal.

CONCLUSION: HARMONIZING PERSPECTIVES ON DRUG USE AND HIV/AIDS

Public health efforts to control the spread of HIV/AIDS and other blood-borne infections must respect the legitimate concerns of the community and law enforcement about the moral and societal aspects of drug use. Law enforcement and community leaders (eg, police, churches, businesses, parents,

teachers, and residents) are understandably concerned that allowing access to syringes sends the wrong message, encourages initiation into drug use, and accelerates the disintegration of families. Residents and business owners fear increased street crime, lower property values, and health risks from discarded syringes. Respecting community views requires both public health and law enforcement to work closely with neighborhood groups.

The evidence suggests that deregulation of syringe sale and possession would reduce morbidity and mortality associated with blood-borne disease among IDUs, their sexual partners, and their children and can be implemented without harmful social repercussions. Deregulation of syringe sale and possession does not itself increase the availability of illicit drugs and is not equivalent to condoning drug use. These observations, however, require rigorous ongoing evaluation.

Finally, it is important to emphasize that deregulation of syringe sale and possession should constitute only one component of a comprehensive, well-financed strategy to impede the dual epidemics of drug use and HIV/AIDS.[105] A realistic and sound national program must devote sufficient resources for expanded access to high-quality treatment for drug and alcohol dependency; education and counseling regarding the harms of illicit drugs; effective community efforts to discourage drug use; crime prevention in schools and communities; rehabilitation for offenders; and support and community activities for families and young people. Ultimately, both law enforcement and public health seek the same end—to promote the health and safety of the population through a comprehensive program designed to prevent HIV/AIDS and drug dependency.

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Drugs-needle exchange

RICHARD A. GEPHARDT
MISSOURI
DEMOCRATIC LEADER

H-204 U.S. CAPITOL
202-225-0100

Congress of the United States
House of Representatives
Office of the Democratic Leader
Washington, DC 20515–6537

February 17, 1998

The Honorable Donna Shalala, Secretary
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Dear Madame Secretary:

As you know, compromise language in the FY 1998 Labor-HHS-Education Appropriations Act preserves your authority to make a determination that would allow the use of federal funds for clean needle exchange programs. Your role in achieving that compromise helped keep the debate focused on science. While the compromise language prohibits the use of federal funds for needle exchange through March 31, your determination on the issue is not restricted. The language in the appropriations law also provides reasonable requirements for assuring that federal dollars, should their use become available, will be used wisely.

A clear and unequivocal message from you on this issue is critical at this time, should you be convinced, that based on the best available scientific evidence, needle exchange programs are effective in decreasing HIV transmission and do not encourage the use of illegal drugs -- the conditions set forth in the Act that would allow federal funds to be used. If the Administration joins with the American Medical Association, the American Public Health Association, the American Academy of Pediatrics and AIDS organizations in recognizing needle exchange to be a scientifically sound and effective tool in our arsenal to fight the AIDS epidemic it would help maintain that focus should authorizing committees choose to address this issue further in the coming months.

Public health considerations on this issue must prevail over politics. I opposed the Hastert amendment to the House version of the appropriations bill last fall for precisely that reason. As the HIV and AIDS epidemic affects more women, more children, more communities of color and other difficult to reach populations, we must be willing to support local authorities in utilizing the most effective prevention tools. That is why I believe that your timely action on this matter can help convince many people who have opposed clean needle exchange programs in the past of the efficacy and necessity of those programs.

Thank you for all you have done in our battle against HIV/AIDS. I look forward to continuing to work with you in this fight.

Sincerely,

Richard A. Gephardt

Richard A. Gephardt, M.C.
House Democratic Leader

Congress of the United States
House of Representatives
Washington, DC 20515

February 9, 1998

The Honorable Donna Shalala
Secretary, Department of Health & Human Services
200 Independence Avenue, SW
Room 615-F
Washington, DC 20201

Dear Secretary Shalala,

As Chairs of the Congressional Black Caucus and the Hispanic Caucus, we urge you to make an immediate determination that needle exchange programs reduce the risk of HIV transmission and do not promote the use of illegal drugs. Having successfully preserved your authority from legislative attack, we strongly urge you to make available federal funds after the moratorium expires on March 31, 1998. We believe there is ample scientific data to make such a determination and exercise your authority. We are equally concerned that you exercise this authority expeditiously in order to avoid future efforts to codify a ban in the Fiscal Year 1999 Labor, Health and Human Services Appropriations bill or any other legislative "vehicle."

By issuing a determination immediately, you will help keep the focus of the debate on science and not politics. Congress would construe an immediate determination as a less political response than if you waited until the end of the Congressional moratorium. If some of our colleagues are successful in further restricting the use of federal funds, the Administration will be able to send the right public health message.

Needle exchange programs are a proven HIV prevention tool and will save lives, particularly among the constituencies we represent. Half of all new HIV infections are attributed to injection drug use. Among African Americans diagnosed with AIDS through June 1997, injection drug use accounted for 36% of the total cases in men and 46% of the total cases in women (compared with 9% for white men and 43% of white women). In 1996, of the Latinos diagnosed with AIDS, injection drug use accounted for 39% of the total cases in men and 51% of the total cases in women.

Minority populations are disproportionately affected by HIV/AIDS and this scientifically proven intervention is one way to stop this trend. Although overall AIDS deaths have declined since the first time the epidemic started, these declines have been much less dramatic for minority populations. **AIDS is still the number one killer of African Americans and Latinos between the ages of 25 and 44.** It is estimated that 33 American men, women, and children are infected with HIV every single day that would not be infected if comprehensive needle exchange was implemented in this country.

Minority communities recognize the importance of needle exchange programs because of their linkages to drug treatment services, primary health care, job counseling, psychosocial services, testing and counseling, and public assistance. These services are very important to minority populations who often do not receive services and referrals in other venues. As

you stated in your February 1997 report, "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."

Needle exchange programs have been proven to reduce the risk of HIV transmission without increasing the use of illegal drugs. Furthermore, needle exchange programs are also very cost-effective. The cost of a needle is only 10 cents compared to the $119,000 lifetime cost of treating one HIV infected person. We appreciate your continued support in issues dealing with people living with HIV/AIDS. We look forward to your cooperation on this important matter.

Sincerely.

Maxine Waters
Chair, Congressional Black Caucus

Xavier Becerra
Chair, Congressional Hispanic Caucus

Drugs-needle exchange

RICHARD A. GEPHARDT
MISSOURI
DEMOCRATIC LEADER

H-204 U.S. CAPITOL
202-225-0100

Congress of the United States
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Washington, DC 20515-6537

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Sincerely.

Maxine Waters
Chair, Congressional Black Caucus

Xavier Becerra
Chair, Congressional Hispanic Caucus

Drugs - Needle Exchange

Jose Cerda III 01/15/98 04:23:04 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Needle Exchange

EK:

I sent the attached question to OMB and was told that you were working on this w/Josh Gothbaum at OMB. I've asked because ONDCP is making calls to the Hill saying that OMB is considering including different/new language on needles. Biden's office called me to recommend that we not start off the year on the wrong foot by making needle exchange an issue.

Jose'

---------- Forwarded by Jose Cerda III/OPD/EOP on 01/15/98 03:44 PM ----------

Jose Cerda III 01/15/98 02:49:04 PM

Record Type: Record

To: Kevin P. Cichetti/OMB/EOP

cc:
Subject: Needle Exchange

Kevin:

Where are we w/respect to "needle exchange" language in the budget. Folks at the AIDS office tell me that we're simply transmitting the same language from appropriations bills past, but several folks on the Hill have called to express concern that our budget will include new/different language that might be controversial to some.

Jose'

Bruce —

Drugs - needle exchange

Sandra Thurman 01/14/98 01:11:13 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: ONDCP Concerns About Needle Exchange

---------- Forwarded by Sandra Thurman/OPD/EOP on 01/14/98 01:21 PM ----------

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

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

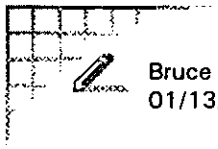
Record Type: Record

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 exhcange 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" drrug 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

Drugs - needle exchange



Bruce N. Reed
01/13/98 05:08:05 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Re: Needles/Embryos/Abortion and Other Selected L/HHS General Provisions SPEAK NOW OR...

That sounds right, though we should work with Rich on the timing of our mtgs. The fact that McCaffrey is against it should be a clue to Sandy: no doubt he's against law enforcement sign-off because it makes needle exchange politically viable.

Drug-needle exchange

Richard Socarides 01/12/98 02:01:19 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Re: Needles/Embryos/Abortion and Other Selected L/HHS General Provisions SPEAK NOW OR...

here's the e-mail from Sandy which discusses timing.
---------- Forwarded by Richard Socarides/WHO/EOP on 01/12/98 02:00 PM ----------

Sandra Thurman 01/12/98 10:35:44 AM

Record Type: Record

To: Richard Socarides/WHO/EOP

cc: Maria Echaveste/WHO/EOP
Subject: Re: Needles/Embryos/Abortion and Other Selected L/HHS General Provisions SPEAK NOW OR...

We did comment on the proposed language on needle exchange after consulting with both Chris Jennings and Kevin Thurm. I will forward a copy of the memo to you.

I had a lengthy discussion with Kevin last week regarding this issue. HHS does not plan to do anything on needle exchange until Satcher is confirmed, assuming that will happen in February. If indeed the confirmation is held up for some reason,we will have to revisit the timing of any action.

Contrary to what Scott Hitt may have told you, the AIDS community is still vehemently opposed to any law enforcement component in any compromise we might propose. So are General McCaffrey and I. In fact, it may well be the only point upon which we agree on this issue.

I am meeting again this week with the national AIDS groups to discuss where we are on needle exchange. I'll keep you posted.

Sandy

Drugs - needle exchange

JOSHUA
GOTBAUM
01/12/98 10:45:59 PM

Record Type: Non-Record

To: See the distribution list at the bottom of this message

cc: See the distribution list at the bottom of this message
Subject: IMPORTANT: ADMINISTRATION POSITION ON NEEDLE EXCHANGE

In the FY99 budget, the Administration includes language concerning a number of sensitive issues. OMB staff have solicited comments from the various EOP agencies and HHS and would like to propose the following compromise positions. **If you disagree and we need to meet, please contact me at 395-9188 no later than 2:00 pm Tuesday.**

We propose language that repeats the FY 1997 (NOT FY98) enacted language:

> ***Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles and 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 do not encourage the use of illegal drugs.***

ONDCP recommended raising the test for certification to require that these programs **reduce** illegal drug use, rather than merely **not encouraging** it. This would seem to be a change in Administration position.

HHS/ONAP recommend repeating the FY 1998 enacted language -- which would require that HHS also establish criteria for such programs. ONDCP opposes this requirement, arguing that it makes the programs seem more established than they are. ONAP supports the idea of removing the criteria, but was concerned that doing so could send a signal that the Administration was pulling away from the compromise worked out for FY 1998. However, it was not the Administration's compromise, and we think the simpler formulation can more easily and correctly be presented as the Administration's longstanding position.

Message Sent To:

Bruce N. Reed/OPD/EOP
Elena Kagan/OPD/EOP
Janet L. Crist/ONDCP/EOP
Sandra Thurman/OPD/EOP
Maria Echaveste/WHO/EOP

Soc. says o/c

Message Copied To:

Drugs - needle exchange

Richard Socarides 12/24/97 10:33:24 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Sandra Thurman/OPD/EOP
Subject: Law Enforcement Consultation on Needle Exchange

Sandy is away. Scott Hitt called to follow-up on his meeting w/ Erskine. After talking with several key advocates on needle exchange, he now believes that we could successfully argue that we needed to have a "law enforcement consultation clause in whatever we worked out. Progress.

Message Sent To:

Bruce N. Reed/OPD/EOP
Elena Kagan/OPD/EOP
Maria Echaveste/WHO/EOP
Sylvia M. Mathews/WHO/EOP
Christopher C. Jennings/OPD/EOP

Drugs - Needle exchange

Sandra Thurman 10/30/97 11:00:05 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: See the distribution list at the bottom of this message
Subject: Compromise on needle exchange

It appears that we have a tentative agreement on compromise language on needle exchange. It preserves the Secretary's authority and adds the Pelosi language which puts reasonable conditions on removing restrictions on federal funding. The one addition that we had not previously discussed is the prohibition on the use of federal dollars to fund needle "distribution" programs as opposed to needle "exchange" programs. This was included to appease some of our more conservative friends who fear that outright distribution as opposed to one on one exchange might increase the use of drugs. While the AIDS groups will be less than happy about it, the fact is that the biggest and most successful needle exchange programs in the country are "exchange only" programs.

This looks good. Keep your fingers crossed..... they are in conference now.

FYI...The situation in Chautaugua County, NY continues to generate a tremendous amount of interest. Fortunately, this is an example of public health, law enforcement and the judicial system effectively working together in the interest of their citizens. Unfortunately, their best efforts could not prevent this tragedy.

HHS(particularly Eric Goosby) has done an excellent job at spearheading the federal response and, in fact, was in New York yesterday with the Congressman from the district.

Message Copied To:

Sylvia M. Mathews/WHO/EOP
Ann F. Lewis/WHO/EOP
Maria Echaveste/WHO/EOP
Elena Kagan/OPD/EOP
Christopher C. Jennings/OPD/EOP
Richard Socarides/WHO/EOP

Drugs-Needle Exchange

Sandra Thurman 09/26/97 11:48:19 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Sylvia M. Mathews/WHO/EOP, Elena Kagan/OPD/EOP, Richard Socarides/WHO/EOP
Subject: Update on Needle Exchange

Hi There! How are you surviving over there?

As I am sure you know by now, Daniel Zingale of the AIDS Action Council and Winnie Stachelberg of the Human Rights Campaign have met with John Podesta and Rahm Emmanuel to discuss the needle exchange issue. They (Daniel and Winnie) felt that both meetings were quite productive.

I have all of the polling data and talking points that they shared with them and will be happy to get them to you or brief you on them, if that is helpful. However, understanding that this just might not be the only thing on your agenda today....here it is in a nutshell:

1) Recent polls conducted by The Tarrance Group (R) and Lake Sosin Snell & Associates (D) and the Kaiser Family Foundation show that a majority (55%, 55%, 66% respectively) of Americans support needle exchange programs.

2) Needle exchange has become symbolic of the Administration's commitment to AIDS, particularly among those who perceive that the Administration is abandoning AIDS as the epidemic moves into communities of color.

3) Mainstream organizations support needle exchange programs:

American Medical Association
American Bar Association
American Public Health Association
American Nurses Association
American Academy of Pediatrics
United States Conference of Mayors
Association of Schools of Public Health
National Black Caucus of State Legislators
National Association of County and City Health Directors
National Academy of Sciences

4) Major newspapers have expressed support in editorials:

New York Times
Washington Post
Los Angeles Times
Chicago Tribune
Seattle Times
Plain Dealer (Cleveland)

5) If we are unsuccessful at protecting the Secretary's waiver authority in conference, the AIDS community is working with Congress to introduce legislation that would give the

authority to the Surgeon General (where it was intended to be originally), which could have an effect on the Satcher nomination.

We are working on a memo outling possible "next steps" which might advance this issue ways that best serve the President and the public health and AIDS communities. In the mean time I need your help on the legislative stategy. While Mr. Specter et. al. are happy to chat with me about this issue, any committment on their part will require a push someone higher up on the totem pole than I.

With a little strategy and finnese this"sticky" issue can be managed effectively.

Thanks for your help.

Sandy

Drugs - needle exchange

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503
December 5, 1997

Dear Mr. Bowles:

Want to share with you a copy of General McCaffrey's letter to Alan Leshner, Director of the National Institute on Drug Abuse, outlining our concerns about Federal funding for needle exchange programs.

Recently there has been discussion within the Administration about the possibility of lifting the statutory ban on the use of Federal funds for needle exchange programs (current HHS appropriations language mandates a total ban for 90 days, after which the Secretary of HHS may lift the ban if she determines needle exchange prevents HIV transmission, and does not encourage drug use). The Director wanted to make clear ONDCP's thinking on the issue, and in particular to make the case for additional targeted research to answer critical questions about the relationship between needle exchange programs, drug use, and HIV transmission.

The Director or I would be pleased to answer any questions you may have about the letter or the issue generally.

Respectfully,

Janet Crist
Chief of Staff

Mr. Erskine B. Bowles
Chief of Staff
The White House
Washington, DC 20500

CHIEF OF STAFF TO THE PRESIDENT

(1) Send to Rahm, Bruce Reed, Elena Kagan

(2) Copy back to me.

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

December 4, 1997

Alan Leshner, PhD
Director
National Institute on Drug Abuse
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Leshner:

Last August 22, following your visit to discuss the research on needle exchange programs and its implications for drug policy, my Chief of Staff Janet Crist provided you with additional research questions which we believe would help to further inform federal policy on this important issue. Since our August discussion, we have become even more convinced that additional research is needed if we are to arrive at a federal policy that is humane, effective, and consistent with the goals and objectives of the *National Drug Control Strategy*. The research now underway does not address the questions we have outlined. Need to restate some of our concerns about Federal support for needle exchange programs, and to urge you and the national research community to seek answers to the questions we pose.

The drugs/AIDS nexus presents an enormous tragic challenge. The dramatic reduction in overall American drug use during the past 15 years (50 percent) is offset by increases in youth heroin and cocaine use and deterioration in youth attitudes toward drugs in general. Similarly, a general reduction in new AIDS cases masks increases among minority and female populations and among drug users, especially intravenous drug users, and their sexual partners and children.

It is the judgement of ONDCP that we should not endorse the use of Federal funds (including CDC funds) to support needle exchange programs. Effective drug treatment offers the better long-term policy for both drug control and AIDS prevention. Lifting the ban on Federal funding for needle exchange programs at this time would present serious and complex issues regarding drug use and drug control policy. There is the troubling question of how such a message would be received by our young people during this period of rising heroin and methamphetamine use. In addition, ONDCP is concerned that needle exchange programs might be considered as a low cost substitute for much needed drug treatment. Finally, we are opposed to diverting Federal drug treatment resources to states and communities that are not prohibited from operating their own programs with non-Federal funds. More than 100 communities already support needle exchange programs without Federal funding.

Many health and law enforcement professionals are concerned about the narrow logic that would focus on needles or injecting drug use behavior as the essence of the problem. This perspective fails to take into account the complex human drug behavior involved. NIDA research demonstrates that drug addiction changes and trains the brain, creating a web of destructive and high risk behaviors. The resulting unemployment, crime, illness, social erosion, and frequently agonizing deaths flow from the compulsive behaviors associated with addiction, not just from the act of injecting. The provision of clean needles will not alone contain or alter this destructive lifestyle. Federal resources to provide a free 20 cent needle will not change the reckless, compulsive drug behavior that accompanies a $200 a day heroin, cocaine or methamphetamine habit. The only proven answer lies in effective drug treatment -- comprehensive in scope, intensive in application, and adequate in capacity.

The real challenge America faces is the more than 60 percent shortfall in drug treatment capacity for our 3.6 million addicted. Research sponsored by NIDA has shown that untreated opiate addicts die at a rate between 7 and 8 times higher than patients with similar characteristics in methadone programs. We also know that needle sharing rates have been reduced by more than two-thirds among injecting drug users during treatment. The positive role and record of drug treatment are clear. ONDCP strongly supports the outreach models developed by NIDA to bring injecting drug users into treatment. In particular, we must develop a greatly increased drug treatment capability for the drug dependent among the 1.6 million Americans currently behind bars at the local, state, and Federal levels.

SAMHSA's soon to be released report of findings from the Services Research Outcome Study (SROS) found significant and sustained reductions in drug use and criminal behavior following drug treatment. This is the first study of treatment outcomes to be based on a national probability sample, and its findings mirror other national treatment outcome studies, such as DATOS and NTIES.

NIDA's Drug Abuse Treatment Outcome Study (DATOS) demonstrated that participants in outpatient methadone treatment reduced heroin use by 70 percent and illegal activity by 57 percent. Treatment participation increased their full time work by 24 percent. Equally impressive, participants in long-term residential treatment reduced heroin use by 71 percent, cocaine use by 68 percent, and illegal activity by 62 percent. Full time work among this group more than doubled.

SAMHSA'S National Treatment Improvement Evaluation Study (NTIES) determined extremely positive results for substance abuse treatment among predominately poor, inner-city populations. Use of illicit drugs dropped an average of 50

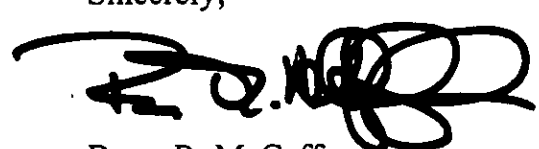
percent, drug selling by 78 percent, and arrests by 64 percent. Exchange of sex for money or drugs dropped by 56 percent, homelessness by 43 percent, and receipt of welfare income by 11 percent. Employment increased 19 percent.

Drug treatment has a solid record. It saves lives, reduces crime and health costs, and saves taxpayer money. Yet only enough capacity is available at this time to treat less than half of those in severe need. Methadone capacity is sufficient for only 25 percent of the estimated 600,000 American heroin addicts. Methadone regulation reforms, thankfully now being developed by HHS, will have a significant impact and have the strong support of ONDCP. However, more resources will be required for needed drug treatment capacity expansion. The requirement to increase drug treatment capacity should continue to be a key part of our Administration message until the shortfall has been remedied. In fiscal year 1998, the Congress under-funded the prevention and treatment block grant by $10 million. Congress must be persuaded to join us in supporting the critical role of drug treatment in the long-term *National Drug Control Strategy.*

We share a common view that our efforts to expand drug treatment must be based on a broader, consistent message of "no use." Visits to youth treatment programs around the country have made some things painfully clear to me. The importance of the drug prevention message we send to young Americans cannot be overstated. Heroin use has taken a terrible upward turn among our young people. We note recent press accounts of the deaths of 11 young people from heroin overdoses in a wealthy suburb of Dallas, Texas. Strongly agree that the message to our children must be an unambiguous "no use" message. If they should become ensnared by compulsive drug using behavior we should offer them a way out through drug treatment -- not a means to continue their addiction through needle exchange.

Clearly we need to know more about the treatment of compulsive drug behavior. A copy of our previous research questions on drug use and needle exchange programs is attached for consideration by your research team. ONDCP appreciates your outstanding leadership and contribution to the science base for drug abuse treatment and prevention.

Sincerely,



Barry R. McCaffrey
Director

Attachment
cc: Dr. Harold Varmus, Director, National Institutes of Health
Ms. Sandra Thurman, Director, Office of National AIDS Policy

August 21, 1997

ONDCP QUESTIONS FOR RESEARCH CONSIDERATION REGARDING THE EFFECT OF NEEDLE EXCHANGE PROGRAMS ON DRUG USE

1. The Anti-drug message. The overriding concern of ONDCP, as reflected in Goal 1 of the *National Drug Control Strategy*, is reducing youth drug use. Preliminary data from the most recent National Household Survey are a source of continuing worry regarding marijuana and heroin use by youth, and a source of renewed concern regarding future cocaine use. A consistent "no use" message must remain an integral part of Federal efforts to reduce youth drug use.

What light does the research shed on the consequences of mixed messages to youth? What does the research tell us regarding the perception by American youth of local government provision of needles for the injection of illegal drugs?

2. Monitoring drug use. Measures of the impact of needle exchange programs on the level of drug use have relied on macro indicators of drug use (e.g. DUF) and its consequences (e.g., DAWN). Some suggest that, had such macro indicators been used to measure HIV transmission, it would have been virtually impossible to reach any conclusions. ONDCP shares the concern expressed by the Institute of Medicine (IOM) that the long-term impact of needle exchange on community drug use patterns is uncertain. The continuous monitoring of local NEPs called for by the IOM will be essential, especially if local needle exchange programs increase in number.

How will existing and future research monitor and report on local drug use at the community level?

3. The specific impact of needle exchange. NIH-funded research has strongly established the effectiveness of drug treatment in reducing HIV transmission and of outreach in getting heavy users to enter treatment. However, it appears that much of the research supporting needle exchange programs seems to focus on a collection of services that includes needle exchange rather than on needle exchange effectiveness itself.

What credible local research addresses the impact of a needle exchange programs that are not combined with other services? If no such research exists, is it possible to isolate the specific impact of needle exchange from the research on multiple services?

More specifically, will research permit the development of relative cost/effectiveness measures for needle exchange programs, for outreach programs (without needle exchange), and for drug treatment?

4. The significance of contrary findings. Research is not universally positive regarding needle exchange. Some studies seem to indicate increases in injecting, increases in drug use, and increases in HIV transmission.

What relative weight should be given to these negative studies? How should research track these possible increases in destructive, compulsive drug behavior?

5. Alternative approaches to making sterile equipment available. There is evidence of a reported reduction in needle sharing in Connecticut after state drug paraphernalia and prescription practices were modified.

What does the research say about the rates of HIV transmission among states with differing legal and practical restrictions on access to sterile needles? In other words, what does the research tell us about the relative impact of access to sterile needles compared to free provision of sterile needles? Do the Connecticut data, where needle exchange programs preceded the statewide changes, offer insights into the relative impact of each?

6. The impact of compulsive, injecting drug use on compliance with HIV medical regimes. There appears to be a basis for serious danger that HIV-infected drug users would be less compliant with complex medications regimes. Many are concerned that addicts would be more subject to accelerating illness, increased contagiousness, and potential mutation of a partially-treated virus. Does the research shed any light on this?

7. The impact of continued, injecting drug use on risk behaviors. There appears to be a serious basis for concern that continued injecting drug use would increase the likelihood of risk behaviors including needle sharing. What does the research tell us?

Drugs - Needle exchange
(and)
Monkey - Budger
(and)
Climing

CLICK ON THE SECTIONS BELOW FOR BACKGROUND ON NEEDLES AND CLONING

NEEDLE EXCHANGE

Statutory Restrictions on the Use of Federal Funds for NEPs:

Since 1988, US Appropriations or Authorization law has placed a conditional prohibition on the use of Federal funds for the operation of needle exchange programs.

Currently, there are three statutory restrictions on the use of Federal funds for the operation of needle exchange programs:

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, prohibits the use of Substance Abuse and Mental Health Services Administration Block grant funds for needle exchange programs unless the Surgeon General determines that they are effective in reducing the spread of HIV and the use of illegal drugs. The statute does, however, allow Federal research and evaluation of existing needle exchange programs. ✓

Section 422 of the 1996 Ryan White CARE Act reauthorization places a flat prohibition on the use of Ryan White funds for needle exchange.

Sections 505 & 506 of the FY 1998 L/HHS / Ed Appropriations bill read:

505: Not withstanding any other provision 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.

506: Section 505 is subject to the condition that after March 31, 1998, a program for exchanging such needles and syringes (referred to in this section as an "exchange project") may be carried out in a community if (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by such Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

This limitation has been in Labor/ H appropriations language in some form since 1990. In the FY 1998 Appropriations bill, the Appropriators split the provision into two provisions and added the six-month moratorium on certification and the language requiring that the exchange programs must be operated in accordance with criteria established by the Secretary.

In the past, the Administration has worked to avoid an outright ban on the use of Federal funds for NEPs (like the current Section 505) and maintain the authority of the Secretary to certify that Federal funds can be used for such programs.

RECOMMENDATION:

There have been several studies done on the efficacy of NEPs in recent years, and there is current data available to meet the first requirement in this language (e.g. that NEPs are successful in preventing the spread of HIV), but HHS maintains that the data on the second provision (that NEPs do not encourage the use of illegal drugs) is still inconclusive. HHS is expecting the results of additional studies on NEPs in the coming year and wants to maintain the Secretary's authority to continue to evaluate the evolving scientific data on this issue and to certify that Federal funds can

be used for NEPs.

To maintain maximum flexibility for the Secretary, we recommend bracketing (deleting) Section 506 and modifying Section 505 by re-proposing the language that was proposed in the FY 1998 Budget on this issue:

505: Not withstanding any other provision 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 Surgeon General determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.

[Note: The words "or syringes" were added in FY 1998 enacted language -- they were not proposed in the 98 Budget. Our recommendation would repeat "or syringes" in the FY 1999 Budget.]

ALTERNATE RECOMMENDATION:

In addition to bracketing section 506, we could add a footnote similar to that placed on the Hyde language deletions: *The Administration proposes to delete this provision and will work with Congress to address this issue.*

Also, rather than repeat the language in the FY 1998 Budget that gave the authority to certify NEPs to the Surgeon General to the Secretary of Health and Human Services, we could maintain the language that was made by Congress in the FY 1997 Labor/HHS/Ed Appropriations bill that gave such authority to the Secretary of Health and Human Services. This may be something the Administration wants to consider given the upcoming confirmation hearings for Surgeon General nominee David Satcher.

Background on Human Embryos/Cloning

Both the House and Senate L/HHS bills for FY 1998 extended the FY 1996 and FY 1997 appropriations Act ban on using Federal funds on human embryo research, and modified it to include research involving "human diploid cells." NIH staff advise that in practice, this extension does not differ from the original ban on human embryo research and would have no effect on NIH's present research efforts. The words "human diploid cells" were apparently added in an attempt to address cloning.

A diploid cell is produced after fertilization occurs in humans -- it is one stage of a developing embryo. Diploid cells could theoretically be produced via somatic cell nuclear transfer, which is more commonly referred to as "cloning." The FY 1996 and FY 1997 L/HHS Acts barred Federal funding for the creation of human embryos for research purposes or performing research on human embryos that subjects them to significant risk. The prohibition on creating embryos for research purposes would, de facto, prohibit creating a human embryo through cloning technology. This is why including diploid cells in the embryo research ban does not differ practically from banning the creation of human embryos.

The FY 1998 Budget proposed to delete the embryo research ban, stating that the Administration "does not support addressing this issue in legislation." In December 1994, the President had issued a statement barring the use of Federal funds for creating human embryos for research purposes. On June 9, 1997, the President announced that he was sending proposed legislation to the Congress, the "Cloning Prohibition Act of 1997," which would prohibit any attempt to create a

human being using somatic cell nuclear transfer. The Administration did not oppose the language in the FY 1998 bill in its letters or SAP's.

Observations: Last year's budget's proposal to delete this provision came before the cloning debate of last spring (e.g., Dolly).

Given the President's proposed legislation on prohibiting cloning, and the fact that SAP's did not oppose the language during the FY 1998 appropriations process, the Administration may not want to bracket the language again, even with the footnote that says the Administration does not support addressing this issue in legislation.

Message Sent To:

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Message Copied To:

L/HHS/Ed. General Provisions for FY 1999 Budget
"Side-by-Side" Comparison for Selected Provisions
Titles II and V of L/HHS Bill

FY 1998 Enacted Section No./ Provision	FY 97 Enacted	FY 98 President's Budget	FY 98 Enacted	Recommended FY 99 Language
Sec. 505. Needle Exchange	SEC. 505. Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles 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 do not encourage the use of illegal drugs.	SEC. 505. Proposed transfer of authority from the "Secretary of Health and Human Services" to the "Surgeon General".	Sec. 505. Notwithstanding any other provision 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.	**OMB Staff**: Repeat FY 98 Budget language. **HHS:** No position yet. Alternatives: (1) Give authority to Secretary as opposed to Surgeon General; (2) use footnote approach, i.e., delete provision and say the Administration will work with Congress to resolve.
Sec. 506. Condition on Needle Exchange			Sec. 506. Section 505 is subject to the condition that after March 31, 1998, a program for exchanging such needles and syringes for used hypodermic needles and syringes (referred to in this section as an "exchange project") may be carried out in a community if - (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by such Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.	**OMB Staff:** Delete. Alternative: Footnote saying we will work with Congress. **HHS:** No position yet.

FY 1998 Enacted Section No./ Provision	FY 97 Enacted	FY 98 President's Budget	FY 98 Enacted	Recommended FY 99 Language
Sec. 513. Use of funds for embryo research--limitations	SEC. 512. (a) None of the funds made available in this Act may be used for— (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term ''human embryo or embryos'' include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.	Proposed deletion with a footnote that states that the Administration does not support addressing this issue in legislation.	Sec. 513. Same as FY 97 enacted except end of last sentence changed to "...or more human gametes or human diploid cells."	**OMB Staff and HHS:** Repeat FY 98 Budget, i.e., propose deletion with the same footnote: "The Administration proposes to delete this provision and does not support addressing this issue in legislation."
Sec. 509. Appropriation limitations for abortion procedures (Hyde language)	SEC. 508. None of the funds appropriated under this Act shall be expended for any abortion except when it is made known to the Federal entity or official to which funds are appropriated under this Act that such procedure is necessary to save the life of the mother or that the pregnancy is the result of an act of rape or incest.	Proposed deletion with footnote that the Administration will work with Congress to address this issue.	Sec. 509. (a) None of the funds appropriated under this Act shall be expended for any abortion. (b) None of the funds appropriated under this Act shall be expended for health benefits coverage that includes coverage of abortion. (c) The term "health benefits coverage" means the package of services covered by managed care provider or organization pursuant to a contract or other arrangement.	**OMB Staff and HHS**: Repeat FY 98 Budget, i.e., propose deletion, and add footnote:"The Administration proposes to delete this provision and will work with Congress to address this issue."

FY 1998 Enacted Section No./ Provision	FY 97 Enacted	FY 98 President's Budget	FY 98 Enacted	Recommended FY 99 Language
Sec. 510. Appropriation limitations for abortion procedures (Hyde language)			(New provision) Sec. 510. (a) The limitations established in the preceding section shall not apply to an abortion - (1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed. (b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State locality, entity, or private person of State, local, or private funds (other than a State's or locality's contribution of Medicaid matching funds). Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).	**OMB Staff and HHS:** Delete provision and add footnote: "The Administration proposes to delete this provision and will work with Congress to address this issue."

FY 1998 Enacted Section No./ Provision	FY 97 Enacted	FY 98 President's Budget	FY 98 Enacted	Recommended FY 99 Language
Sec. 212. Appropriation of funds for entities under title X of the Public Health Service Act	SEC. 518. None of the funds appropriated in this Act may be made available to any entity under title X of the Public Health Service Act unless it is made known to the Federal official having authority to obligate or expend such funds that the applicant for the award certifies to the Secretary that it encourages family participation in the decision of the minor to seek family planning services.	SEC. 513 . Same as FY 97 Enacted.	Sec. 212. None of the funds appropriated in the Act may be made available to any entity under title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.	**OMB Staff**: Repeat FY 98 enacted. **HHS**: No position yet.
Sec. 514. Use of funds for promotions of controlled substances--limitations	SEC. 513. (a) LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES.—None of the funds made available in this Act may be used for any activity when it is made known to the Federal official having authority to obligate or expend such funds that the activity promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812). (b) EXCEPTIONS.—The limitation in subsection (a) shall not apply when it is made known to the Federal official having authority to obligate or expend such funds that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally-sponsored clinical trials are being conducted to determine therapeutic advantage.	SEC. 511. Same as FY 97 enacted.	Sec. 514. Same as FY 97 enacted and FY 98 President's Budget.	**OMB Staff**: Repeat FY 98 Budget language. Same as enacted.

File: Drugs - Needle Exchange

THE WHITE HOUSE

WASHINGTON

March 12, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Eric Goosby, Interim Director, ONAP

RE: Update on Status of Needle Exchange Programs

There have been a number of recent events involving needle exchange programs. On February 13, a National Institutes of Health Consensus Conference Statement recommended lifting the ban on use of federal funds for needle exchange programs. On February 18, HHS sent a Congressionally requested report to the Senate Appropriations Committee reviewing the scientific data on needle exchange programs to date. This memo provides background to put the issue in context, with a discussion of these recent events.

Current Statute. There are three statutory restrictions on the use of federal funds for needle exchange programs. (1) The Substance Abuse and Mental Health (SAMHSA) block grant prohibits use of federal funds for needle exchange unless the Surgeon General determines that they are effective in reducing the spread of HIV and the use of illegal drugs. The statute does permit federal research and evaluation of existing needle exchange programs. (2) The 1996 Ryan White CARE Act reauthorization places a flat prohibition on the use of Ryan White funds for needle exchange. (3) The Labor/HHS Appropriations bill prohibits funding of needle exchange unless the Secretary determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.

Epidemiology of HIV Infection. Thirty six percent of AIDS cases are directly or indirectly caused by IV drug use. Up to fifty percent of new HIV infections may be related to IV drug use. The effects of IV drug use have become a driving force in the HIV epidemic.

Number of Needle Exchange Programs. There are over 100 needle exchange programs in the US, with most programs distributing through two or more sites. As of 1996, twenty-eight States had local needle exchange programs.

Federally Sponsored Research. The National Institute on Drug Abuse (NIDA) at NIH has funded 15 demonstration projects to evaluate the impact of needle exchange programs on rates of HIV infection and patterns of drug use (including the effectiveness of these programs as gateways to substance abuse treatment). Only two of the 15 studies are completed at this time. There has also been a significant amount of privately funded research on needle exchange programs through foundations and other nonprofit groups.

State and Local Government. At their recent winter meeting, the National Governors Association passed a resolution stating: "Federal restrictions or requirements on the use of available funding interfere with the ability of States to develop comprehensive prevention strategies." The Association of State and Territorial Health Officers (ASTHO) passed the following resolution in December 1995: "The federal government should repeal the ban on the use of federal funds for needle exchange services to allow interested States and localities the financial flexibility to support successful prevention and treatment initiatives within their jurisdictions." The US Conference of Mayors also supports lifting the ban on use of federal funds for needle exchange.

HHS Report to Senate Appropriations. Report language was included in the September 1996 Senate L/HHS Appropriations bill requesting that HHS provide a report on the status of current research projects, an itemization of previously funded research, and findings-to-date regarding the efficacy of needle exchange programs for reducing HIV transmission and not encouraging illegal drug use. The report prepared by HHS reviewed all published studies of US needle exchange programs, including one by the Institute of Medicine; it did not attempt to determine if the Congressional standard has been met for lifting the ban on federal funding. The summary section of the report contains the following: "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."

NIH Consensus Conference. A NIH Consensus Development Conference on Interventions to Prevent HIV Risk Behaviors was held February 11-13, 1997. This conference was developed and directed by a non-Federal panel of experts, predating the Congressional request for an HHS report. The resulting Consensus Conference Statement is an independent report of an expert panel, not a policy statement of the NIH. This Statement, released on February 13, concluded that needle exchange programs are effective in reducing both HIV transmission and IV drug use and recommended lifting the legislative restrictions on needle exchange programs.

Analysis of Evidence on Needle Exchange Programs and IV Drug Use. The preponderance of data collected so far suggests a stable or declining level of drug use among needle exchange participants. About half of the studies on the effects of needle exchange show a decline in drug use. Two studies show an increase in drug use, but these studies have been discounted by expert panel as outliers. In addition, almost all studies indicate that needle exchange program participants tend to be older (median age 33 to 41 years old) and tend to be long-term users (duration of use 7 to 20 years). There is no data to suggest needle exchange programs increase new initiates into drug use, and the age of participants often increases over time.

It is important to note, however, that most studies have methodological weaknesses, inherent to the population and subject, that are nearly impossible to overcome. These methodological problems include: 1) reliance upon individuals' self-reporting of drug use; 2) the difficulties of creating a control group that does not receive clean needles yet continues participating in the

study; and 3) the difficulties of isolating the effects of needle exchange programs from the many other factors that may influence drug use in a given population.

The Administration's Response. HHS, ONDCP, and the White House jointly developed a response to questions about the HHS report and NIH Conference Statement. This response states that data on the effect of needle exchange programs in reducing HIV seroprevalence is solid, but that data on the effect of these programs on drug use patterns is less clear. The response further states that HHS will continue research efforts to evaluate new data on needle exchange programs and will work with the Congress on effective HIV prevention strategies. General McCaffrey strongly believes that the Administration should not challenge or raise questions about the current legislative restrictions on needle exchange programs.

Next Steps for HHS in Evaluating Effects on Drug Use. HHS will conduct a scientific review of the data presented at the NIH Consensus Conference. The data has not yet been through the peer review process required for publication and needs close examination. A second step will be an analysis of data already collected through the NIDA demonstration projects, which have not yet been specifically studied for effect on drug utilization patterns.

Congressional Climate and Community Expectations. The HHS report was released during the Congressional recess, and Hill reaction has been muted to date. Harold Varmus, Director of the NIH, received direct questions on needle exchange from Reps. Dickey (R-AR) and Wicker (R-MS) during an NIH Appropriations hearing. Secretary Shalala also received one question on lifting the federal funding ban prior to release of the report.

Both the House and Senate generally have punted the issue of needle exchange programs to HHS. The exception is last year's prohibition on use of Ryan White treatment funds for needle exchange programs, which passed unanimously. The Congressional response to any attempt to lift restrictions on funding likely would be hostile. The climate, however, may be softening somewhat. Senator Specter, Chair of the L/HHS Appropriations Subcommittee, has come to support needle exchange programs (Philadelphia has one of the largest); Rep. Rangel, once adamantly opposed to needle exchange programs, is reported to be shifting in his stance; and the state flexibility arguments advanced by NGA and ASTHO may also start to have an effect.

The AIDS community is united in seeking an end to the ban on federal funding of needle exchange programs. With some exceptions, however, the national AIDS organizations understand the downside of demanding that the ban be lifted before the necessary educational and political groundwork is laid. What the community wants from the Administration at this point is not so much an immediate lifting of the restrictions as a strong indication that the Administration generally will let science guide policy in combating HIV transmission.

substantive memo on needles
background
st of research
no options.

options memo?
like to discuss?

?? ⟹ Not many ops – still want overturn ban

reduce drug use by
getting into treatment.

Mtg this afternoon –
strategic approach

Ed
Welfare
Ws Health
DC

Melanne
Raines
Sperling
Reed
W-Ann
Chris
Hilley
Rubin
Me
Podesta
Rahm
Doug
Vicky

Cigarette tax.

Drugs - Needle exchange Weekly

Date: 10/09/97 Time: 08:51
AAIDS panel weighs protest resignation over needle exchanges

WASHINGTON (AP) Several administration AIDS advisers are threatening to quit because the White House refuses to spend federal money to buy clean needles for drug addicts.

Some members of the Presidential Advisory Council on AIDS said Wednesday they also are upset the administration has not implemented other council recommendations.

''I think it's fairly serious,'' Dr. Scott Hitt, a Los Angeles physician who chairs the 30-member council, said of the resignation threats.

Leading the protest is council member Robert Fogel, a Chicago lawyer and Clinton fund-raiser. He said Wednesday he plans to seek a vote on the resignation at the council's next meeting in December.

''Somebody up there is thinking more about politics than health,'' Fogel said. ''If they're not going to listen to us and do the right thing, I for one, and a number of other people on the council, can't think of any more excuses or apologies to give on this subject.''

Fogel said ''quite a few'' members of the council would consider resigning, mostly because of anger over needle exchanges but also because they feel the administration is not being aggressive enough in a number of other areas.

''This administration has an extraordinary record in fighting the HIV/AIDS epidemic,'' responded Melissa Skolfield, a spokeswoman for Health and Human Services Secretary Donna Shalala, who met with concerned council members last month.

Congress in 1988 outlawed federal money for needle exchanges until there is proof they don't encourage drug use. That question ''has not been answered conclusively,'' said Skolfield.
APNP-10-09-97 0854EDT

Bruce wants a really short paragraph on this story for the weekly + to attach this memo

Drugs - Needle exchange

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

September 3, 1997

MEMORANDUM TO ERSKINE BOWLES AND BRUCE REED

FROM: R. Scott Hitt, Chair, on behalf of the Presidential Advisory Council on HIV and AIDS

The Council understands that an AIDS-related amendment will likely be offered when the House considers the Labor/HHS Appropriations bill this week. This amendment will revoke or effectively revoke the authority of the Secretary of HHS to lift the prohibition on using federal funds for needle exchange programs.

We have vigorously urged the President and Secretary Shalala, most recently in letters sent by the Council in late July and early August, respectively (attached) to exercise this authority. In June in a meeting with community groups, Bruce Reed expressed the President's commitment to ensure at minimum that, if challenged, the Secretary's waiver authority be preserved.

We are extremely concerned by this threatened action and hope that it will not deter Secretary Shalala from acting promptly to lift the ban on federal funding for needle exchange. Achieving the President's stated goal of reducing new HIV infections to zero, thereby saving tens of thousand of lives, creates an urgent need for swift action.

Fairly or unfairly, the community will measure the President's commitment to ending the AIDS epidemic by the vigor of Administration opposition to this Congressional challenge. The White House position must be clear and forcefully put forth.

In light of the overwhelming scientific support for the efficacy of needle exchange programs in preventing new HIV infections, the ban on federal funding of needle exchange should be lifted immediately. According to the Centers for Disease Control and Prevention one-third of all reported AIDS cases are directly or indirectly related to injection drug use. Secretary Shalala's own report to Congress makes clear the scientific support for lifting the ban.

It is paramount that the President provide personal leadership by directing that his Administration implement a viable strategy for lifting the ban, ensure that all relevant Administration personnel are on board and committed to implementing that strategy, and ensure that the full weight of White House support for preserving the Secretary's authority is being exerted.

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

Many organizations have expressed support for needle exchange programs and their potential for reducing new HIV infections and saving lives. Some of these are the:

American Bar Association;
American Medical Association;
American Public Health Association;
Association of State and Territorial Health Officials;
National Academy of Sciences;
National Black Caucus of State Legislators; and
United States Conference of Mayors.

In addition, major newspapers across the country have expressed their support. Some of these are:

Chicago Tribune
Los Angeles Times
The New York Times
Washington Post
The Plain Dealer (Cleveland)
The Seattle Times

Needle exchanges still stir debate

Programs slow AIDS, but some say bad message is sent

By Gary Fields
USA TODAY

Respected organizations such as the American Bar Association and American Medical Association have endorsed needle-exchange programs as a way to combat AIDS.

But critics, including the Clinton administration, say such programs encourage drug abuse and send the wrong message to the nation's youth.

In 29 states and the District of Columbia, 112 programs provide intravenous drug users with clean syringes. A soon-to-be-released report by the Association of State and Territorial Health Officials says more than 14 million syringes were distributed in 1996.

The exchange programs were established after a link was found between the sharing of needles by intravenous drug users and the transmission of blood-borne diseases and the virus that causes AIDS.

According to the Centers for Disease Control and Prevention in Atlanta, 36% of the 573,000 cases of AIDS among adults reported through December 1996 were the result of intravenous drug use.

In addition to reducing the incidence of AIDS, supporters of needle-exchange programs say the practice also brings drug abusers into regular contact with counselors, who often can steer them into drug treatment programs.

But opponents say that providing free syringes to addicts only encourages the addicts to continue using drugs and also suggests that such drug use is acceptable.

Most states require prescriptions to buy syringes, which typically are used by individuals to inject themselves with insulin and other prescription medicines. Only Connecticut sells syringes over the counter and does not consider them illegal paraphernalia.

David Purchase of the North American Syringe Exchange Network says a study of a program in Tacoma, Wash., shows that the percentage of intravenous drug users who tested positive for HIV has dropped by a third since the program started in 1988. Purchase says the study also shows that those in the group now are four times less likely to contract hepatitis B and 65% less likely to be infected or reinfected with hepatitis C.

"We have scientific proof that syringe exchanges help reduce the incidence of HIV and other blood-transmitted disease," Purchase says.

The Family Research Council, a conservative family policy organization that lobbies on issues such as sex education, opposes needle exchanges.

On Wednesday, it released the findings of a survey it commissioned, in which 51% of 1,000 people surveyed said that they think the programs are irresponsible.

"The American people are saying, 'Look, Congress, we don't want this,'" the council's Robert Maginnis says. "We're all concerned about the AIDS epidemic, but it must be handled with good public policy."

Administration anti-drug czar Barry McCaffrey says that at a time when he is pushing for a $170 million ad campaign to keep teens off drugs, syringe exchanges send "the wrong message."

The federal government provides no funding for needle exchange programs. And only a handful of states provide funds. In most cases, the costs of the programs are covered by private organizations.

Contributing: Andrea L. Mays

Drug-Needle exchange

08/22/97 FRI 08:42 FAX 202 632 1096 ; 8-21-97 :12:16PM : AIDS POLICY → 202 632 1096:# 2/ 2 002

Bruce -

FYI, I take it Donna called Erlene to complain. The result is a meeting during the week of the 2nd in Erlene's office with Donna, the General, Yvn, Rahm, and Chris.

Elena

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

August 20, 1997

OFFICE OF NATIONAL DRUG CONTROL POLICY COMMENTS ON NEEDLE EXCHANGE RESEARCH RELEASED AUG. 20 BY THE FAMILY RESEARCH COUNCIL

The Office of National Drug Control Policy released the following comments in connection with a survey announced Aug.20, in Washington D.C., by the Family Research Council regarding the issue of needle exchange programs:

"The National Drug Control Strategy focuses on the need for drug treatment to help addicts free themselves from addiction and its terrible health and social consequences. Federal treatment funds should not be diverted to short term 'harm reduction' efforts like needle exchange programs. The problem to be addressed is effective intervention to reduce the number of addicted Americans, currently 3.6 million, who suffer and cause such terrible damage to society from compulsive drug taking activity. The Office of National Drug Control Policy strongly supports drug treatment, and outreach to get addicts into drug treatment, as the proven effective means to deal with the twin epidemics of drug use and HIV/AIDS."

Contact Don Maple, (202) 395-6618

Drugs: Needle exchange

Richard Socarides 09/13/97 08:46:45 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Politics Defeats Science in Needle Exchange Deabte as House

---------- Forwarded by Richard Socarides/WHO/EOP on 09/13/97 08:46 AM ----------

Doug.Case @ sdsu.edu
09/12/97 11:40:00 PM

Record Type: Record

To: Stuart D. Rosenstein, Richard Socarides

cc:
Subject: Politics Defeats Science in Needle Exchange Deabte as House

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NEWS from the
Human Rights Campaign

1101 14th Street NW
Washington, DC 20005
email: kim.mills@hrc.org
<A HREF="http://www.hrc.org">
WWW: http://www.hrc.org
</A>

FOR IMMEDIATE RELEASE
Thursday, Sept. 11, 1997

POLITICS DEFEATS SCIENCE IN NEEDLE EXCHANGE DEBATE AS HOUSE PASSES ILL-CONSIDERED AMENDMENT

Human Rights Campaign Calls on House-Senate Conferees To Strike Measure From Final Bill

WASHINGTON -- Politics trumped science today as the House of Representatives passed a wrong-headed amendment that would prevent the use of federal funds for needle exchange programs, according to the Human Rights Campaign.

"The House of Representatives turned a collective blind eye to

science today so that some members could sound tough on drugs," said Seth Kilbourn, HRC's senior policy advocate for health issues. "What they did in reality, however, was vote to strip local communities of this chance to save lives.

"There is ample evidence that needle exchange programs save lives by stemming the spread of HIV and AIDS without encouraging illegal drug use. But a majority of the House decided not to let the facts get in the way of demagoguing the issue."

By a vote of 266 to 158, the House passed an amendment to the $270 billion Labor-Health and Human Services appropriations bill. The amendment would remove the ability of the Health and Human Services secretary to allow local communities to use federal funds for needle exchange programs. The amendment was originally written by Rep. Tom Coburn, R-Okla. It was introduced by Reps. Dennis Hastert, R-Ill., and Roger Wicker, R-Miss.

The Senate version of the appropriations bill retains the secretary's authority to determine federal policy.

"The Human Rights Campaign will work with House and Senate conferees to make sure that the final bill allows science, not politics, to lead this issue," Kilbourn said.

Needle exchange programs provide intravenous drug users with sterile syringes in exchange for used ones. Such programs have been implemented in more than 100 communities around the country, and have been shown to stem the spread of HIV and other blood-borne diseases transmitted through the sharing of injection equipment.

Approximately one-third of reported AIDS cases are related to intravenous drug use.

Current law says that federal funds may not be used for needle exchange programs unless the Department of Health and Human Services gives the green light, which it has not done.

In February, a report by HHS found that needle exchange programs are effective in slowing the spread of HIV and AIDS. Six federally funded studies have reported that needle exchange programs reduce HIV transmission and do not increase drug use.

Also in February, a panel of public health experts at the National Institutes of Health concluded that needle exchange programs are a powerful and proven weapon in the war against HIV and AIDS.

Plus, a majority of the American public -- 55 percent -- favors needle exchange programs as a method to curb the spread of HIV and AIDS, according to a bipartisan poll conducted for the Human Rights Campaign.

The poll found 55 percent "strongly favor" or "somewhat favor" needle exchange programs while 38 percent "somewhat oppose" or "strongly oppose" them. The poll was conducted for HRC by the Tarrance Group, a Republican firm, and Lake Sosin Snell and Associates, Democratic pollsters.

The results are based on a survey of 1,000 registered voters contacted between April 8-10.

The poll found that 64 percent of Democrats, 58 percent of independents and 45 percent of Republicans favor needle exchange programs. In addition, needle exchange finds support in ever region of the country, with 64 percent of Americans favoring it in the West, 60 percent in the Northeast, 51 percent in the South and 49 percent in the Midwest. The poll's margin of error is +/- 3.1 percent.

In July, the American Medical Association endorsed needle exchange programs, joining such groups as the American Public Health Association, the Association of State and Territorial Health Officials, the National Academy of Sciences, the National Alliance of State and Territorial AIDS Directors, the National Black Caucus of State Legislators and the U.S. Conference of Mayors. The American Bar Association endorsed them in August.

The Human Rights Campaign is the largest national lesbian and gay political organization, with members throughout the country. It effectively lobbies Congress, provides campaign support and educates the public to ensure that lesbian and gay Americans can be open, honest and safe at home, at work and in the community.

- 30 -

Drugs - Needle exchange

FOR IMMEDIATE RELEASE
Monday, August 18, 1997
Contacts: Mike Shriver 1-202-898-0414; Communication Works 1-415-255-1946

U.S. Needle Exchange Programs Successfully Approach Nine-Year Mark; Prove Efficacy

Public Health Experts Urge Clinton Administration to Lift Federal Ban on Funding of Syringe Exchange

WHEN: **Wednesday, August 20th, 1997; 11:30am**

WHERE: **Zinger Room, National Press Club, 529 14th St., NW**

WHAT: Public health officials, doctors, researchers, AIDS activists and drug treatment professionals will discuss nine years of successful and safe operation of U.S. syringe exchange programs, and urge the Clinton Administration to lift the ban on Federal funding for such programs. The group will highlight the extensive body of scientific evidence which demonstrates that removing HIV contaminated syringes from circulation and replacing them with sterile ones is the most effective form of AIDS prevention for drug users, their sexual partners and their children; and that needle exchange programs do not encourage drug use. In fact, such programs provide a gateway to drug treatment.

WHY: The Clinton Administration has the opportunity to save, literally, tens of thousands of lives in the next several years, if it lifts the ban now. Secretary Shalala, in a February 1997 report to Senators Specter and Harkin, concluded that needle exchange programs can be effective. To date, however, despite a growing chorus of voices urging her to do so, the Secretary has not acted. The assembled group will urge the Clinton Administration to consider the science, not politics, when it comes to matters of public health. Current information indicates that:

- ➤Syringe exchange, according to every study of such programs in the United States, reduces the transmission of AIDS and does not increase drug use
- ➤Cases of AIDS to date are related to needle sharing behavior, or one third of the total; injection drug use or sex with an injector accounted for over 90% of new AIDS cases among women from July 1994 to July 1996 (where an exposure category was identified); over 93% of new AIDS cases in the same period among children was related to injection drug use by parent or parents' sexual partner (where parental exposure category was identified)
- ➤Each preventable case of AIDS costs American taxpayers conservatively $100,000, while the cost of a syringe is as low as 10 cents; and
- ➤Two previous polls, conducted by the Kaiser Family Foundation and the Tarrance Group/Lake Sosin Snell & Associates, both found that a majority of the American public favors needle exchange programs to stop the spread of AIDS.

WHO: Speakers (list in formation):
Mohammad Akhter, MD, MPH, Executive Director, American Public Health Association
Victoria L. Sharp, MD, Director, AIDS Center Program, St. Lukes-Roosevelt Hospital
Denise Paone, Ed.D, Assistant Director of Research, Beth Israel Chemical Dependency Institute
Jane Silver, MPH, Public Policy Director, American Foundation for AIDS Research
Harry Simpson, Executive Director, Community Health Awareness Group, Detroit, MI
Jim Graham, Executive Director, Whitman-Walker Clinic, Washington, DC

Sponsors:
AIDS Action Council, National Association of People with AIDS, National Coalition to Save Lives Now!

Drugs - needle exchange

Richard Socarides 08/13/97 02:55:51 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: FRC Press Release on Needle Exchange Programs

---------- Forwarded by Richard Socarides/WHO/EOP on 08/13/97 02:54 PM ----------

Doug.Case @ sdsu.edu
08/13/97 01:31:00 PM

Record Type: Record

To: Stuart D. Rosenstein, Richard Socarides

cc:
Subject: FRC Press Release on Needle Exchange Programs

FAMILY RESEARCH COUNCIL
PRESS RELEASE

Recieved 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 8, 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 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.

****

Drugs - Needle exchange

Chris - FYI. Elena

HUMAN RIGHTS CAMPAIGN

1101 14th Street NW
Washington, DC 20005
phone 202 628 4160
fax 202 347 5323

FAX TRANSMISSION

DATE: 8-18-97

TO: Bruce Reed, Assistant to the President for Domestic Policy

FAX #: (202)456-2878

NUMBER OF PAGES: 4 **(Including cover)**

FROM: Winnie Stachelberg

If you have any problems with this transmission, please call (202) 628-4160.

MEMORANDUM

TO: Interested Parties
FROM: NORA Needle Exchange Working Group
SUBJECT: Family Research Council Needle Exchange Press Conference
DATE: August 15, 1997

On Wednesday, August 20, the Family Research Council will release the results of a poll that they say will declare "what the American people really think about needle exchanges." At this point, it is unclear what the underlying questions and specific findings of the FRC poll are. However, we wanted to make you aware of this press conference in the event that you are asked to respond and to encourage you to provide a positive public health message. Also, we have included the following which may be helpful in a potential response.

- Approximately one-third of reported AIDS cases are related to injection drug use. Sixty-six percent of all AIDS cases among women -- and more than half of such cases among children -- are related to injection drug use. Intravenous drug use is responsible for the greatest number of new AIDS cases among the heterosexual population.

- The Department of Health and Human Services issued a report in February concluding that needle exchange programs can be effective in slowing the spread of HIV and AIDS. HHS reviewed all the available scientific literature on the subject before reaching this conclusion.

- Six federally funded studies have reported that needle exchange programs reduce HIV transmission and do not increase drug use.

- Also in February, a panel of public health experts at the National Institutes of Health concluded that needle exchange programs are a powerful and proven weapon in the war against AIDS. They also asserted that misguided politics continue to block institution of such programs.

- Needle exchange programs have been implemented in more than 100 communities around the country and have been shown to stem the spread of HIV and other blood-borne diseases transmitted through the sharing of injection equipment. Such programs have reduced by 80 percent the amount of needle sharing among drug users, the NIH committee found, leading to an estimated 30 percent reduction in new HIV infections. These programs can offer HIV prevention information and medical and support services to hard-to-reach populations.

- Needle exchange programs can offer a bridge to drug treatment. Virtually every needle exchange program operating in this country provides referrals to drug treatment programs and can demonstrate a clear track record in linking injecting drug users to drug treatment. Needle exchange programs are a critical component of a comprehensive strategy that includes drug treatment to reduce HIV infection among injecting drug users, their sex partners and their children.

- A growing number of respected organizations are in favor of needle exchange programs, including the American Bar Association, the American Medical Association, the American Public Health Association, the Association of State and Territorial Health Officials, the National Academy of Sciences, the National Black Caucus of State Legislators and the United States Conference of Mayors.

- Beyond the support from public health, scientific and legal experts, needle exchange programs are earning favor with a majority of Americans. Fifty-five percent of voters support such programs, according to a bipartisan poll commissioned by the Human Rights Campaign and conducted April 8-10 by the Tarrance Group, a Republican firm, and Lake Sosin Snell and Associates, a Democratic polling company.[1] In addition, a March 1996 survey by the Kaiser Family Foundation found that 66 percent of Americans favor "having clinics make clean needles available to IV drug users to help stop the spread of AIDS."

- The Family Research Council, attempting to make a case against needle exchange programs, cited one ill-conceived experiment in Switzerland. That program, which began in 1988 and ended in 1992, coincided with a tidal wave of hard drugs hitting Europe as a result of the United States' cracking down on illegal drugs and saturation of the U.S. drug market. Plus, Switzerland allowed the open use of hard drugs in some cities. Clearly, the Swiss experiment bears little resemblance to needle exchange programs in the United States, none of which tolerate the open use of hard drugs.

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[1] The overall margin of error was plus or minus 3.1 percent.

THE TARRANCE GROUP ***Lake Sosin Snell & Associates***

Date: April 29, 1997

To: The Human Rights Campaign

From: Lori Gudermuth
The Tarrance Group (R)

Celinda Lake, Jennifer Sosin and Dana Stanley
Lake Sosin Snell & Associates (D)

Re: **AMERICANS SUPPORT NEEDLE EXCHANGE**

A new national poll by the Tarrance Group (R) and Lake Sosin Snell & Associates (D) shows that a majority (55%) of the American public favors needle exchange programs:

Some local communities have adopted "needle exchange" programs as a way to curb the spread of AIDS and HIV. "Needle exchange" programs allow drug users to trade in USED needles for CLEAN needles. Generally speaking, do you FAVOR or OPPOSE these kinds of "needle exchange" programs?

[FOLLOW-UP:] Is that STRONGLY (favor/oppose), or SOMEWHAT (favor/oppose)?

strongly favor	*32*	*55*
somewhat favor	*23*	
somewhat oppose	*9*	
strongly oppose	*29*	*37*
(don't know)	*8*	

Republicans are split evenly on this issue (45% favor, 48% oppose, 7% don't know), and moderate-liberal Republicans favor needle exchange by 17 percentage points (57% favor, 40% oppose, 3% don't know). Strong majorities of both independents (58% favor, 33% oppose, 9% don't know) and Democrats (64% favor, 29% oppose, 7% don't know) are in favor. Needle exchange also finds support in every region of the country: 60%-32% in the Northeast, 49%-44% in the Midwest, 51%-40% in the South, and 64%-30% in the West.

This memorandum reports the findings from a national survey of 1,000 adults who indicated they are registered to vote, conducted April 8-10, 1997, by The Tarrance Group and Lake Sosin Snell & Associates. The overall margin of error is ±3.1 percent.

201 NORTH UNION, SUITE 410
ALEXANDRIA, VA 22314
703/684-6688

1730 Rhode Island, Suite 400
Washington, DC 20036
202/776-9066

~~Aids~~ Drugs - Needle exchange

SF AIDS FOUNDATION
SAN FRANCISCO AIDS FOUNDATION P.O. BOX 426182, SAN FRANCISCO, CALIFORNIA 94142-6182

P.I to Bruce —
We should ~~probably~~ meet with all These guys, shouldn't we? — if for nothing else, than to plan on how to stop Congress from making matters & worse

June 25, 1997

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the Board of Directors, staff and clients of the San Francisco AIDS Foundation, I want to thank you for your insightful remarks regarding HIV prevention at the U.S. Conference of Mayors meeting here in San Francisco this week. Indeed, the ability of local communities to address the dual epidemics of HIV and substance abuse is at the very heart of our concerns regarding the issue of federal support for needle exchange programs.

Yes, let's meet w/ whoever Richard says.
BR

Subsequent to your address to the mayors, the U.S. Conference of Mayors passed a forceful resolution calling on the Secretary of Health and Human Services to exercise her authority and immediately grant the use of federal funds for needle exchange programs. This resolution is fully supported by the scientific, public health and HIV advocacy communities. This week, local political leaders joined the call for your Administration to demonstrate its support for this sound public health approach to curbing the growth of the epidemic among injection drug users, their partners and children.

Since February our organization has respectfully called upon the Administration to join with us in a collective strategy to exercise the waiver and to protect that action and the waiver authority in Congress. We have been disappointed that no collective action has occurred to date.

We urgently request that the principal Administration officials in the Department of Health and Human Services, the Office of the Domestic Policy Advisor and the National AIDS Policy Coordinator's Office meet in the next few days with AIDS leaders working on this issue to develop a joint plan for exercising the waiver and protecting the Secretary's authority. Each day the Administration delays, another 50-100 Americans become infected with HIV as a result of injection drug use.

To Richard Socarides —
Let's do Rasking-y meeting — whenever you want, with whomever you want.
Elena

10 UNITED NATIONS PLAZA

National Report

The New York Times

FRIDAY, JUNE 27, 1997

A.M.A. Backs Drug-User Needle Exchange

Drugs - needle exchange

By KATHARINE Q. SEELYE

Lenon Wilson, a longtime heroin addict in Chicago with puffy scars the size of leeches on his arms, climbed into an unmarked silver van and unfurled a paper bag concealing 28 dirty hypodermic needles.

"If the van wasn't here, I'd use the same needle three, four, five times, even when it's dirty and has bacteria running through it, and then I'd use somebody else's when I couldn't use mine anymore," said Mr. Wilson, known as Smoky, as he scooped up 33 clean needles in exchange for his 28. The volunteers for the Chicago Recovery Alliance at this mobile van in Harvey, Ill., 25 miles from downtown Chicago, like to give out a bonus of five to their regulars.

"You get a better hit with a clean needle, and it leaves less of a scar," Mr. Wilson said. "It's more hygienic all the way around."

It was people like Mr. Wilson that the American Medical Association had in mind yesterday when it joined a growing chorus of voices and called for a change in laws to allow intravenous drug users easier access to clean needles to help block the spread of H.I.V., the virus that causes AIDS.

More than one-third of all new AIDS cases in the nation are caused by contaminated needles or sex with drug users. And drug users now account for the highest rates of new H.I.V. infection — at nearly twice that of homosexual men.

The medical association had previously "encouraged" needle-exchange programs, in which addicts turn in dirty needles in exchange for clean ones. But yesterday, citing an "urgent public health need," it was broader and more emphatic. The association's policy-making House of Delegates, meeting in Chicago, voted overwhelmingly to work with members of Congress to initiate legislation revoking the 1988 ban on Federal financing for needle-exchange programs and to encourage state medical societies strongly to initiate state legislation relaxing drug paraphernalia laws so users can legally buy and possess needles.

"There is more and more evidence that the advantages of needle exchange outweigh the disadvantages," Dr. Nancy Dickey, chairwoman of the board of trustees and president-elect of the medical association, which represents half the nation's doctors, said in an interview. "We're addressing a public health epidemic."

The association said that if the ban continued to the year 2000, the United States would have failed to prevent up to 11,000 cases of AIDS, including those among heterosexual partners of drug users and their children, at a cost of up to $630 million for medical treatment.

Public health professionals applauded the association, saying that its action, combined with a similar bipartisan resolution from the United States Conference of Mayors earlier this week, could increase pressure on the politically sensitive Clinton Administration and a reluctant, conservative Congress to reverse the Federal ban on financing needle-exchange programs.

In San Francisco, Roslyn Allen, project director at the AIDS Foundation H.I.V. Prevention Project, the nation's largest needle-exchange program, said of the medical association's decision, "It sends a message to other agencies that still view this as a dark and sinister practice."

Outside, Allison, a 26-year-old prostitute with bruises on her arm, said the clean needles were safer. Referring to the bad needles she used until recently, she said: "Works would get clogged, broken and it was pretty common for people to pass them around."

Dr. Peter Lurie, a researcher at the University of Michigan who is one of the world's foremost experts on needle exchange programs, said the public health benefits of needle

exchange had been evident for years.

"If an infection is spread from person to person by an inanimate object, you can prevent it by removing that object," he said. "This is not rocket science."

But what is obvious to public-health professionals is less clear-cut for politicians. The medical group's action was greeted coolly in Washington, which remains fearful of putting its official imprimatur on something that many perceive as tantamount to promoting drug use.

Some critics see needle exchange as a foot in the door toward legalizing drugs. They say that the exchange may help addicts avoid AIDS, but that they may die instead of overdoses. Focusing on needle exchange, they argue, takes attention away from treatment.

An influential group speaks out to help drug users avoid AIDS.

Beyond that, while many programs offer condoms to those who arrive for clean needles, critics say the needle exchange ignores the vast number of cases of H.I.V. infection that are transmitted through sex. And addicts still need money for drugs, so clean needles do nothing to reduce robberies or violent crime.

One critic of needle exchange is Representative Charles B. Rangel, a Democrat whose Harlem district is home to some of the worst drug infestations in urban America. Mr. Rangel said needle exchange is acceptable as part of a drug rehabilitation program, but, "if the budget is just for clean needles, I don't want it."

When Congress prohibited the spending of Federal money for needle exchange, it said the ban could be lifted only when such programs met two conditions: that they be shown to reduce transmission of H.I.V. and not to increase illegal drug use. The medical association came to just that conclusion yesterday.

Previously, numerous studies, including ones by the Federal Centers for Disease Control and Prevention, the National Institutes of Health, the General Accounting Office and the National Academy of Sciences, have generally found that needle exchanges are effective in slowing the spread of H.I.V. and that they have not increased drug use.

But no one in Congress has even tried to lift the ban, and signals from the Clinton Administration, which has the authority to lift the ban, have been cautious.

Dr. David Lewis, director of the Brown University Center for Alcohol and Addiction Studies, said of the mood: "The Administration is scared. If they move to bring the issue up, Congress will be even more strict and make it harder for addicts to obtain clean needles."

Representative Jesse L. Jackson Jr., Democrat of Chicago, who supports needle exchange, said the "demagoguing" on the issue "sometimes makes it hard for politicians to vote or do the right or healthy thing."

But Gary Bauer, president of the Family Research Council, a conservative group, said the collective mind-set in Congress was so opposed to needle exchange that conservatives felt no need to organize against the issue. "It strikes the average voter in the gut as being against common sense," he said. He said the matter was "untouchable" for Mr. Clinton because drug use had gone up on his watch. "I don't see how this Administration could do anything on this that wouldn't blow up in their face," he said.

Drugs - Needle exchange

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 (National 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 vigorously 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. They are perfectly willing to do some "heavy lifting"to insure a positive outcome. 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)

* HHS has been meeting with AIDS advocacy groups,scientists, members of Congress, and others to determine the best course of action. Ask the Secretary to report their progress and plans to you ASAP.

* 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.

DRAFT
June 17, 1997 (5:16pm)

TALKING POINTS ON NEEDLE EXCHANGE

Injection drug use plays a major role in continuing the spread of the AIDS epidemic.

- 50% of new infections are from injection drug users, their partners, and children (these are occuring in the 96 largest metropolitan areas)
- 1/3 of all AIDS cases to date are associated with injection drug use
- injection drug use is the leading factor for current spread of the epidemic in the United States, including among women and children

The science supports the efficacy of needle exchange in reducing the transmission of HIV without promoting illegal drug use.

- there have been 3 major reviews (NIH, CDC, NAS) of over 100 programs
- these reviews report overwhelming evidence that needle exchange programs can have a positive impact on curbing the spread of HIV among users, their partners, and children
- found no evidence that needle exchange programs increase drug use by program participants or in the communities in which programs are located
- Yale University study, for example, estimated a 33 percent reduction in new HIV infections in the New Haven, Connecticut program

Local communities and public health officials should be supported if they decide to utilize needle exchange programs in AIDS prevention campaigns.

- needle exchange will be available to--not imposed upon--local communities as part of comprehensive HIV prevention strategies
- mayors and city councils, including those in Boston, San Francisco, New York, Los Angeles and New Haven, have approved needle exchange programs

Needle exchange programs will provide a pathway to medical and drug treatment as well as addiction recovery services.

- they should be closely linked to drug treatment, HIV counseling and testing, and prevention education
- the hope offered by the new AIDS treatments can be used as a powerful incentive to program users to get off and stay off illegal drugs

Needle exchange programs have been endorsed as a component of comprehensive HIV prevention strategies by numerous national organizations, including:

- American Medical Association
- National Association of County and City Health Officials
- American Public Health Association
- American Nurses Association
- Association of State and Territorial Health Officers
- National Alliance of State and Territorial AIDS Directors

Capsule quotation from report by Secretary Shalala to Congress:

"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."

* Background Note

I believe that the Administration and Congress should follow the science on needle exchange, which supports their use as part of a comprehensive HIV prevention strategy. However, neither Congress nor the Office of National Drug Control Policy are on the program at this point. A premature decision to lift the ban on the use of federal funds for needle exchange could be counterproductive at this point (as happend with the gays in the military and HIV immigration restriction issues). We need to do our homework with Congress and other members of the Administration for this to work.

Drugs - Needle exchange

LEGAL ACTION CENTER

236 Mass. Ave. NE, Suite 505 • Washington, DC 20002 • (202) 544-5478 • FAX: 544-5712

June 26, 1997

The Honorable William Jefferson Clinton
President of the United States
The White House
Washington, D.C. 20500

Dear Mr. President:

Legal Action Center, a nonprofit law and policy firm working on drug, alcohol, and HIV/AIDS issues, requests that you convene a meeting between the principals working on federal needle exchange policy from the White House, Vice President Gore's office, the Department of Health and Human Services, the Office of Management and Budget, Ms. Sandra Thurman from the Office of National AIDS Policy and members of the National Organizations Responding to AIDS (NORA) Needle Exchange Working Group, of which Legal Action Center is a member.

A meeting between Administration principals and the Working Group is urgently needed at this time, because members of the House Appropriations Subcommittee on Labor, Health and Human Services and Education are working to remove Secretary Shalala's authority to lift the ban on federal funding for needle exchange programs. A coordinated strategy between the Administration and the community is necessary to avoid having the Administration stripped of its public health authority.

We appreciate that you voiced in your remarks to the U.S. Conference of Mayors the need for identifying sound public health strategies that enable local communities to address the related problems of HIV and substance abuse. One step toward achieving this goal is to lift the ban on federal funding for needle exchange so that local communities have the flexibility to implement needle exchange as one part of a comprehensive HIV prevention strategy. If Congress removes Secretary Shalala's authority to lift the ban, many communities will never have the opportunity to implement the life saving strategy of needle exchange.

Legal Action Center is committed to collaborating with your Administration to prevent the spread of HIV infection among drug users, their partners and their children. We look forward to discussing needle exchange policy with Administration principals.

Sincerely,

Catherine O'Neill
Executive Vice President and
HIV/AIDS Projects Director

Jennifer Collier
Legislative Counsel

cc: Vice President Al Gore
Erskine Bowles, Chief of Staff to the President
Donna Shalala, Secretary of Health and Human Services
Sandra Thurman, Director of the White House Office of National AIDS Policy
Donald Gips, Chief Domestic Policy Advisor to the Vice President
Toby Donenfeld, Office of the Vice President
Bruce Reed, Assistant to the President for Domestic Policy
Franklin Raines, Office of Management and Budget
Nancy Ann Min, Office of Management and Budget
William Corr, HHS Chief of Staff
Kevin Thurm, HHS Deputy Secretary
Eric Goosby, Director of HHS Office of HIV/AIDS Policy

~~Re~~ Drugs - Needle exchange

SF AIDS FOUNDATION SAN FRANCISCO AIDS FOUNDATION P.O. BOX 426182, SAN FRANCISCO, CALIFORNIA 94142-6182

P. I to Bruce —
We should at least meet with all These guys, shouldn't we? — if for nothing else, than to plan on how to stop Congress from making matters & worse. Elena

June 25, 1997

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the Board of Directors, staff and clients of the San Francisco AIDS Foundation, I want to thank you for your insightful remarks regarding HIV prevention at the U.S. Conference of Mayors meeting here in San Francisco this week. Indeed, the ability of local communities to address the dual epidemics of HIV and substance abuse is at the very heart of our concerns regarding the issue of federal support for needle exchange programs.

Subsequent to your address to the mayors, the U.S. Conference of Mayors passed a forceful resolution calling on the Secretary of Health and Human Services to exercise her authority and immediately grant the use of federal funds for needle exchange programs. This resolution is fully supported by the scientific, public health and HIV advocacy communities. This week, local political leaders joined the call for your Administration to demonstrate its support for this sound public health approach to curbing the growth of the epidemic among injection drug users, their partners and children.

Since February our organization has respectfully called upon the Administration to join with us in a collective strategy to exercise the waiver and to protect that action and the waiver authority in Congress. We have been disappointed that no collective action has occurred to date.

We urgently request that the principal Administration officials in the Department of Health and Human Services, the Office of the Domestic Policy Advisor and the National AIDS Policy Coordinator's Office meet in the next few days with AIDS leaders working on this issue to develop a joint plan for exercising the waiver and protecting the Secretary's authority. Each day the Administration delays, another 50-100 Americans become infected with HIV as a result of injection drug use.

Once again, thank you for your remarks on this issue at the U.S. Conference of Mayors meeting. We remain hopeful that we can establish a partnership with your Administration in order to carry out the vision you articulated so well in your remarks. As you pointed out in San Francisco, our elected officials are hired "to mobilize people, unite people and get things done. Denial is not an option." We couldn't agree more.

Very Respectfully Yours,

Pat Christen

Pat Christen
Executive Director

cc: Secretary Shalala
Bruce Reed
Sandra Thurman
Vice-President Gore

NATIONAL ORGANIZATIONS RESPONDING TO AIDS

HAND DELIVERED

June 26, 1997

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

Dear Mr. President:

On behalf of the NORA (National Organizations Responding to AIDS) Coalition, we are writing to request a meeting with all the principals within the Administration who are working on federal policy regarding needle exchange programs. As you know, NORA is a coalition comprised of over 175 health, labor, religious, professional, and advocacy groups representing a broad consensus on issues concerning HIV/AIDS policy, legislation, and funding.

We are extremely concerned about efforts by some members of the House Appropriations Subcommittee on Labor, Health and Human Services and Education to remove Secretary Shalala's authority to lift the restrictions on using federal funds for needle exchange programs.

We appreciate your remarks at the U.S. Conference of Mayors (USCM) meeting in San Francisco regarding HIV prevention and fully support your call for identifying sound public health strategies that enable local communities to address the twin epidemics of HIV and substance abuse. However, if the authority of the Department of Health and Human Services to determine public health policy is removed, many communities will be denied the opportunity to implement an important, proven, and life-saving HIV prevention intervention.

As you know, the USCM passed a resolution on Tuesday calling for Secretary Shalala to lift the restrictions on federal funding for needle exchange programs. In passing the resolution, the USCM is calling for a partnership with the federal government to implement these life saving programs. We agree with the mayors, as well as the scientific and public health communities that the Secretary should allow localities to use federal funds for needle exchange programs, if they so choose.

NORA
A coalition convened by
AIDS Action Council
1875 Connecticut Ave., NW
Suite 700
Washington, DC 20009
202 986 1300
202 986 1348 fax

A meeting with the principals is urgently needed to discuss the Administration's plan for preserving the Secretary's authority, the timing for lifting the restrictions on federal funding, and the strategy for ensuring that science and public health drive the discussion of this issue. In February, when Department officials met with community leaders on the day the Secretary released her report on needle exchange to Senator Specter, the Administration pledged to hold such a meeting. Given this pledge and the threat that now exists to the Secretary's authority, we feel that a meeting is necessary immediately.

Thank you for your commitment to local flexibility in implementing life-saving public health interventions. We appreciate your efforts and look forward to discussing needle exchange policy with Administration principals.

Sincerely,

Christine Lubinski, AIDS Action Council
David Harvey, AIDS Policy Center for Children, Youth and Families
Jane Silver, American Foundation for AIDS Research
Seth Kilbourn, Human Rights Campaign
Jenny Collier, Legal Action Center
Amy Slemmer, Mother's Voices
B.J. Harris, National Alliance of State and Territorial AIDS Directors
Mike Shriver, National Association of People with AIDS
Miguelina Maldonado, National Minority AIDS Council
Charles King, Housing Works

cc: Vice President Albert Gore
Secretary Donna Shalala
Erskine Bowles
Sylvia Mathews
John Podesta
Sandy Thurman
Donald Gips
Toby Donnenfeld
Bruce Reed
Franklin Raines
Nancy Ann Min DeParle
Kevin Thurm
William Corr
Marsha Martin
Eric Goosby

Drugs - Needle Exchange

6-3-97 E. Goodby.

NORA - letter

ONDCP going to AMA tomorrow to comment on their resolution for needle exchange

AMA's pos sim to HHS - mentions/states could use NE progs. as effective means

If ONDCP comes out adamantly opp - it will create a wave.

File: Drugs - Needle Exchange CONFIDENTIAL

April 28, 1997

DETERMINED TO BE AN ADMINISTRATIVE MARKING
INITIALS: JGP DATE: 5/21/10
2009-1006-F

MEMORANDUM FOR BRUCE REED

FROM: Eric Goosby M.D., Office of National AIDS Policy

RE: Strategic Plan for Needle Exchange Issue

This memorandum will review where key stakeholders, Congress and HHS currently are on the ban on federal funds for needle exchange programs, and lay out strategy options for handling the issue.

HHS Secretary Shalala has indicated her readiness to move on lifting the ban imposed under the L/HHS Appropriations language -- affirming that needle exchange programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs. The February 1997 HHS report to the Appropriations Committee was moving in this direction, supporting a role in HIV prevention but maintaining some distance around data on drug utilization. Since the release of this report, the Director of NIH Harold Varmus testified before the House Appropriations Committee that -- in his personal opinion -- the data standards had been met to lift the L/HHS statutory ban. There has been no new research published since February.

Office of National AIDS Policy Sandy Thurman has publicly stated that science, not politics, must drive this issue. She is also acutely aware that politics, not science, should dictate the timing of Administration movement on this issue or else the long-term goal of actually enhancing HIV prevention will be lost. She is in accord with the contents of this memo.

ONDCP I have had two meetings with Gen. McCaffrey's staff, and I think there is room to reach an agreement on modifying the ban (see below). A discussion between Varmus and McCaffrey would contribute to ONDCP's comfort level around the data, and this can be arranged. The most compelling case for needle exchange at ONDCP would be the success of these programs as conduits for reaching and guiding IV drug users into treatment, with ultimate demand reduction.

Congress The first opportunity for Congressional action on this issue will come in May when the House Appropriations Committee marks up its bill. Reps. Wicker (R-MS) and Dickey (R-AR) are likely to lead a Republican effort to narrow or eliminate the waiver authority currently held by the Secretary of HHS, particularly if Secretary Shalala moves to lift the ban before markup. L/HHS Subcommittee Chair Porter (R-IL) has large needle exchange programs in his Chicago district, and might be helpful if convinced of the scientific integrity of efficacy data on needle exchange programs. He holds Varmus in high esteem. Given the composition of the Committee, proactively altering the language of the ban would be a high risk move. No reliable vote counts on this issue have been taken. It would be the safest course to hold further action steps on the ban until the House has completed action on the FY 1998 L/HHS/Education Appropriations bill.

The Senate is marginally more favorable on the needle exchange issue, with Sens. Spector (R-PA) and Harkin (D-IL) leading the L/HHS Appropriations Subcommittee. Both have expressed political reservations regarding taking any action on needle exchange, and a good vote count

would be needed before their support was guaranteed. Spector has very active needle exchange programs in Philadelphia. Both the National Governors Association (NGA) and Association of State and Territorial Health Officers (ASTHO) have more drag in the Senate, and a carefully orchestrated revision of the needle exchange ban language combined with a House-Senate conference strategy would be needed to come out with greater flexibility in use of federal funds.

The Congressional Black Caucus has not come out clearly on the issue of lifting the ban yet. Rep. Waters (D-CA) is ready to support needle exchange. Some advocates from the minority community are actively working the membership, and CBC is likely to sponsor a Hill briefing on this issue.

Community Groups The AIDS community remains split over strategies to lift the ban. Some voices in the gay press are strident in demanding that Shalala act affirmatively. A range of advocacy and research community voices continue to accuse the Administration of playing politics instead of following science and saving lives. The national AIDS groups in Washington are slowly coming around to realizing that even the Secretary's waiver authority could be lost if adequate groundwork with Congress is not laid down first. As a result, the NORA (National Organizations Responding to AIDS) Coalition is spending April-May in a grassroots and Hill educational campaign around needle exchange. The intelligence from these visits is still coming in. NORA indicated in their meetings with you and Kevin Thurm of HHS their interest in working with the Administration to achieve a good end result.

New Organizational Endorsements The US Conference of Mayors is likely to adopt a resolution supporting flexible use of federal funds for needle exchange programs in jurisdictions which want to pursue them at their June 20-24 meeting. They would join the NGA and ASTHO in making this local and states right argument. The National Medical Association, the minority counterpart of the AMA, is also drafting a resolution supporting limited needle exchange programs -- the text isn't yet available.

STRATEGY OPTIONS

1. Preferred Option Wait until the House Appropriations bill is completed. Tie Administration action on lifting the ban on L/HHS funds to the June 1997 US Conference of Mayors meeting (which POTUS is scheduled to attend) **after USCM passes an affirmative resolution on local flexibility.** With the nation's mayors, governors, and public health officials on record supporting local decision-making on use of HIV prevention funds, there is good political cover for allowing more flexible use of funds as long as the scientific data continues to support it. Recognizing that reasonable people may disagree on this issue, POTUS could indicate his support for local control while in San Francisco (where there's strong support for needle exchange) and the next day Secretary Shalala could lift the ban. The advocacy groups and Administration would then need to coordinate to hold a reasonable position in the Senate Appropriations process.

To help this position fly politically, several key conditions on funding need to be laid down in modified Appropriations language and Administration rhetoric:

1) Only HIV prevention funds (i.e. CDC) may be used for needle exchange programs, not SAMHSA drug treatment dollars. This makes sense as needle

exchange is being advanced primarily as an HIV prevention strategy. HIV prevention funds flow primarily to States, with smaller amounts going to the chief elected official in 7 large cities and a categorical minority CBO grant program. Use of Ryan White CARE Act funds was prohibited in last year's reauthorization bill.

2) In order for grantees to utilize federal funds for needle exchange, they must certify that:

a) the chief elected official of the State (where State is the grantee) or of the city/county (where the City or a local CBO is the grantee) supports needle exchange programs in their jurisdiction as an effective HIV prevention measure;

b) any needle exchange program using federal funds must provide referral access to medical and drug treatment, and provide HIV counseling;

c) needles are provided on a replacement basis and not a free-standing distribution program; and

d) needle exchange programs comply with established standards for hazardous medical waste disposal (minimizing stray needles in public places)

These conditions would ensure that needle exchange programs go forward only in those jurisdictions where there is local support (government, public health and law enforcement) and linkages to a broader continuum of drug treatment and medical care.

2. **A fallback strategy** would be stalling action until the Winter 1997 Congressional recess to lift the ban. Congressional backlash would be delayed until February, but the Administration would have to be ready to protect the policy in 1998 election year. This would be hard for Congressional Democrats.

3. **A third option** is to leave the ban in place and take the heat from constituent advocacy and public health groups claiming that the Administration is willing to put politics above public health. With both the New York Times and Washington Post writing editorials in support of lifting the ban, the groups can be expected to drive a media strategy and push local flexibility arguments. This will become a more difficult option over time.

Drugs - Needle exchange

Eric P. Goosby
04/23/97 04:47:02 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:

Subject: Needle Exchange

I hope you are both well. There has been a good deal of confusion in the office, Sandy's start date, my role, the location of the office, staffing issues, etc. I believe we are coming to some final agreements with HHS and I should be able to re-engage here soon (1 wk or so) . In the interim I wanted to assure you I have not dropped either the Needle Exchange Issue or the Vaccine issue, and have continued working on them from HHS.

I have met twice with Office National Drug Policy staff to review the needle exchange literature at length and feel there was some movement on their interpretation of the data. Sandy has scheduled an appointment with Mr. McCaffrey sometime early next month. I am working on a plan that will be in concert with HHS , and hope to have this ready for your review sometime next week.

The Vaccine proposal has been more difficult to come up with a plan I am excited about. I have been working with NIH to make this more substantive. I will have something for you next week that will have HHS sign off as well.

The Treatment Guidelines for HIV infected Patients is in its final round of comments from the committee. As you remember these are long awaited guidelines for the use of protease inhibitors. The recommendations will move the time at which one would consider putting someone on them to an earlier stage of disease (some real cost implications etc. We had discussed the possibility of the President being involved in the announcement (this will be perceived in the AIDS community as a big contribution). I will have something on this in the next couple of weeks but I wanted keep this in the back of your minds.

I will be in the Blood Safety Advisory Council meeting tomorrow and Friday at NIH, but I remain available on beeper as always.

Eric

Fik - Needle Exchange

THE WHITE HOUSE

WASHINGTON

March 12, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Eric Goosby, Interim Director, ONAP

RE: Update on Status of Needle Exchange Programs

There have been a number of recent events involving needle exchange programs. On February 13, a National Institutes of Health Consensus Conference Statement recommended lifting the ban on use of federal funds for needle exchange programs. On February 18, HHS sent a Congressionally requested report to the Senate Appropriations Committee reviewing the scientific data on needle exchange programs to date. This memo provides background to put the issue in context, with a discussion of these recent events.

Current Statute. There are three statutory restrictions on the use of federal funds for needle exchange programs. (1) The Substance Abuse and Mental Health (SAMHSA) block grant prohibits use of federal funds for needle exchange unless the Surgeon General determines that they are effective in reducing the spread of HIV and the use of illegal drugs. The statute does permit federal research and evaluation of existing needle exchange programs. (2) The 1996 Ryan White CARE Act reauthorization places a flat prohibition on the use of Ryan White funds for needle exchange. (3) The Labor/HHS Appropriations bill prohibits funding of needle exchange unless the Secretary determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.

Epidemiology of HIV Infection. Thirty six percent of AIDS cases are directly or indirectly caused by IV drug use. Up to fifty percent of new HIV infections may be related to IV drug use. The effects of IV drug use have become a driving force in the HIV epidemic.

Number of Needle Exchange Programs. There are over 100 needle exchange programs in the US, with most programs distributing through two or more sites. As of 1996, twenty-eight States had local needle exchange programs.

Federally Sponsored Research. The National Institute on Drug Abuse (NIDA) at NIH has funded 15 demonstration projects to evaluate the impact of needle exchange programs on rates of HIV infection and patterns of drug use (including the effectiveness of these programs as gateways to substance abuse treatment). Only two of the 15 studies are completed at this time. There has also been a significant amount of privately funded research on needle exchange programs through foundations and other nonprofit groups.

State and Local Government. At their recent winter meeting, the National Governors Association passed a resolution stating: "Federal restrictions or requirements on the use of available funding interfere with the ability of States to develop comprehensive prevention strategies." The Association of State and Territorial Health Officers (ASTHO) passed the following resolution in December 1995: "The federal government should repeal the ban on the use of federal funds for needle exchange services to allow interested States and localities the financial flexibility to support successful prevention and treatment initiatives within their jurisdictions." The US Conference of Mayors also supports lifting the ban on use of federal funds for needle exchange.

HHS Report to Senate Appropriations. Report language was included in the September 1996 Senate L/HHS Appropriations bill requesting that HHS provide a report on the status of current research projects, an itemization of previously funded research, and findings-to-date regarding the efficacy of needle exchange programs for reducing HIV transmission and not encouraging illegal drug use. The report prepared by HHS reviewed all published studies of US needle exchange programs, including one by the Institute of Medicine; it did not attempt to determine if the Congressional standard has been met for lifting the ban on federal funding. The summary section of the report contains the following: "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."

NIH Consensus Conference. A NIH Consensus Development Conference on Interventions to Prevent HIV Risk Behaviors was held February 11-13, 1997. This conference was developed and directed by a non-Federal panel of experts, predating the Congressional request for an HHS report. The resulting Consensus Conference Statement is an independent report of an expert panel, not a policy statement of the NIH. This Statement, released on February 13, concluded that needle exchange programs are effective in reducing both HIV transmission and IV drug use and recommended lifting the legislative restrictions on needle exchange programs.

Analysis of Evidence on Needle Exchange Programs and IV Drug Use. The preponderance of data collected so far suggests a stable or declining level of drug use among needle exchange participants. About half of the studies on the effects of needle exchange show a decline in drug use. Two studies show an increase in drug use, but these studies have been discounted by expert panel as outliers. In addition, almost all studies indicate that needle exchange program participants tend to be older (median age 33 to 41 years old) and tend to be long-term users (duration of use 7 to 20 years). There is no data to suggest needle exchange programs increase new initiates into drug use, and the age of participants often increases over time.

It is important to note, however, that most studies have methodological weaknesses, inherent to the population and subject, that are nearly impossible to overcome. These methodological problems include: 1) reliance upon individuals' self-reporting of drug use; 2) the difficulties of creating a control group that does not receive clean needles yet continues participating in the

study; and 3) the difficulties of isolating the effects of needle exchange programs from the many other factors that may influence drug use in a given population.

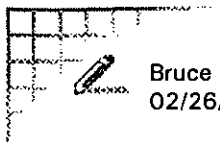
The Administration's Response. HHS, ONDCP, and the White House jointly developed a response to questions about the HHS report and NIH Conference Statement. This response states that data on the effect of needle exchange programs in reducing HIV seroprevalence is solid, but that data on the effect of these programs on drug use patterns is less clear. The response further states that HHS will continue research efforts to evaluate new data on needle exchange programs and will work with the Congress on effective HIV prevention strategies. General McCaffrey strongly believes that the Administration should not challenge or raise questions about the current legislative restrictions on needle exchange programs.

Next Steps for HHS in Evaluating Effects on Drug Use. HHS will conduct a scientific review of the data presented at the NIH Consensus Conference. The data has not yet been through the peer review process required for publication and needs close examination. A second step will be an analysis of data already collected through the NIDA demonstration projects, which have not yet been specifically studied for effect on drug utilization patterns.

Congressional Climate and Community Expectations. The HHS report was released during the Congressional recess, and Hill reaction has been muted to date. Harold Varmus, Director of the NIH, received direct questions on needle exchange from Reps. Dickey (R-AR) and Wicker (R-MS) during an NIH Appropriations hearing. Secretary Shalala also received one question on lifting the federal funding ban prior to release of the report.

Both the House and Senate generally have punted the issue of needle exchange programs to HHS. The exception is last year's prohibition on use of Ryan White treatment funds for needle exchange programs, which passed unanimously. The Congressional response to any attempt to lift restrictions on funding likely would be hostile. The climate, however, may be softening somewhat. Senator Specter, Chair of the L/HHS Appropriations Subcommittee, has come to support needle exchange programs (Philadelphia has one of the largest); Rep. Rangel, once adamantly opposed to needle exchange programs, is reported to be shifting in his stance; and the state flexibility arguments advanced by NGA and ASTHO may also start to have an effect.

The AIDS community is united in seeking an end to the ban on federal funding of needle exchange programs. With some exceptions, however, the national AIDS organizations understand the downside of demanding that the ban be lifted before the necessary educational and political groundwork is laid. What the community wants from the Administration at this point is not so much an immediate lifting of the restrictions as a strong indication that the Administration generally will let science guide policy in combating HIV transmission.



Bruce N. Reed
02/26/97 05:54:19 PM

Record Type: Record

To: Eric P. Goosby/OPD/EOP

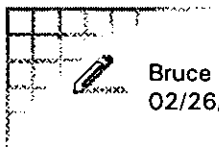
cc: Elena Kagan/OPD/EOP
Subject: Needles memo

Thank you for your memo. It's an excellent summary of the issue, and underscores how lucky we are that you're over here.

I wonder if you could e-mail us a few more paragraphs on what seems to be a central scientific issue, which is how much do we know about whether needle programs reduce or don't reduce drug use, why it is methodologically complicated, etc. He would be interested in your scientific insights on this. Also, could you give us a concluding paragraph on what lies ahead -- fleshing out the last sentence on how HHS will evaluate this data, and what pressures we might expect from the community on the one hand and Congress on the other.

Sorry for the extra work, but the President is really interested in this issue, so I want him to hear more of the things you told me.

Thanks again. I'll be out for the next few days, so send your e-mail to Elena Kagan.



Bruce N. Reed
02/26/97 06:01:22 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: aids memo

Cathy has the disk from Eric of his original memo. He'll send some more graphs on the research. You might also add a sentence or two on McCaffrey's position.

Let me know what else you might change. It's short, but pretty clear.

DEPARTMENT OF HEALTH & HUMAN SERVICES

SPECIAL PHS

Office of the Secretary

Washington, D.C. 20201

February 11, 1997

CLOSE HOLD

To: The Secretary

Through: The Deputy Secretary _____
Chief of Staff _____
The Executive Secretary _____

From: Glen Harelson
Policy Coordinator

Subject: Your meeting on Clean Needle Exchange Programs for Substance Abusers, Wednesday, February 12, 1997, ~~4:00~~ 6:15 PM, Secretary's Office--**BRIEFING**

PARTICIPANTS

Kevin Thurm
Bill Corr
Claudia Cooley
Jacquelyn White
Melissa Skolfield
Richard Sorian
Richard Tarplin
John Callahan
Jo Ivey Boufford
Eric Goosby
Harold Varmus
Nelba Chavez
David Satcher

PURPOSE

Attached is the most recent draft of the needle exchange report and a draft transmittal letter to Senator Arlen Specter, Chairman, Subcommittee on Appropriations. The Committee requested that the Department submit a report by February 15, 1997 which reviews completed and ongoing research on the efficacy of needle exchange programs in reducing HIV transmission and their impact on illegal drug use. The report was prepared by the Office of Public Health and Science.

The purpose of this meeting is to review the report with you prior to submitting it to the Appropriations Committee.

Attachment

DRAFT

CLOSE HOLD

The Honorable Arlen Specter
Chairman, Subcommittee on Appropriations for
the Departments of Labor, Health and Human
Services, and Education and Related Agencies
United States Senate

Dear Mr. Chairman:

In accordance with the request of the Committee included in Senate Report 104-368, I am transmitting the enclosed report reviewing completed and ongoing research on the efficacy of needle exchange programs in reducing HIV transmission and their impact on illegal drug use.

Needle exchange programs have been developed in many communities to reach IV drug users who are unable or unwilling to stop using drugs and are unable to enter standard treatment programs. The goal of needle and syringe exchange programs is to provide an entry into treatment programs and to reduce the transmission of hepatitis and HIV.

The intravenous use of illegal drugs is wrong and is clearly a major public health problem as well as a law enforcement concern. Among the many secondary health consequences of injection drug use are the transmission of hepatitis, HIV and other bloodborne diseases. The Department supports a range of activities to cope with these public health issues, from basic research supported by the National Institute on Drug Abuse (NIDA) to substance abuse prevention and treatment programs at the community level.

HIV disease is also an urgent public health problem in our nation as the leading cause of death among adults age 25-44, and the seventh leading cause of death for all Americans. Injecting-drug use (IDU) is the second most frequently reported risk behavior for HIV infection, accounting for a growing proportion of new HIV infections among users, their sexual partners and their children. To realize our goal of effective HIV prevention, it is vital that we identify and evaluate sound public health strategies to address the twin epidemics of HIV and substance abuse.

The Department has played an important role in supporting evaluations of needle exchange programs as they impact HIV transmission and patterns of drug use. As requested, this report provides the Committee with the findings of published studies conducted in our country, and a description of current research and interim findings where these are available.

Sincerely,

Donna E. Shalala

REPORT TO THE COMMITTEE ON APPROPRIATIONS FOR
THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES,
EDUCATION AND RELATED AGENCIES

NEEDLE EXCHANGE PROGRAMS IN AMERICA: REVIEW OF PUBLISHED STUDIES AND ONGOING RESEARCH

Introduction

On September 12, 1996, the Committee on Appropriations for the Departments of Labor, Health and Human Services, Education and Related Agencies made the following request of the Department of Health and Human Services:

> "The Committee understands the Department is continuing to support research, reviewing the effect of clean needle exchange programs on reducing HIV transmission, and on whether such programs encourage illegal drug use. The Committee requests that the Secretary provide a report by February 15, 1997, on the status of current research projects, an itemization of previously supported research, and the findings to date regarding the efficacy of needle exchange programs for reducing HIV transmission, and not encouraging illegal drug use." Senate Report 104-368, p.68

In response to the Committee's request, this report provides an overview of the current status of knowledge regarding needle exchange programs (NEPs) with a compilation of relevant reviews and abstracts pertinent to the issues of efficacy of NEPs in reducing HIV transmission and their effect on utilization of illegal drugs. In reviewing the body of literature gathered, it is important to note the wide range of methodologic approaches utilized and the impact of these study design choices on the conclusions drawn. For example, studies varied significantly in terms of study populations, survey instruments, and assumptions made in the design of mathematical models used to predict seroincidence and seroprevalence. Given the significantly different design elements, making comparisons or drawing conclusions across studies requires an understanding of these complexities.

In the Department's assessment, providing the findings and conclusions from specific studies without benefit of the context of their specific methodologies would not facilitate a sound understanding of this issue, as the nature of the findings are not consistent. For these reasons, the original reviews and source documents with their discussions of methodological issues are being provided to the Committee for consideration along with the findings and conclusions. The data presented are limited to published studies conducted in the United States, consistent with the approach taken by the National Academy of Sciences, as the legal and cultural environments of other countries differ sufficiently enough to raise questions about whether the conclusions are applicable to the United States.

The report is presented in four parts. Part One provides a review of completed studies and published abstracts addressing the efficacy of needle exchange programs for reducing HIV transmission and their effect on illegal drug use. Several major reviews, including a report by the National Research Council/Institute of Medicine (NRC/IOM) analyzes those studies published prior to 1995; subsequent studies are identified individually. Part Two describes the status of federally supported evaluation studies of needle exchange programs, with preliminary findings noted where these are available. Part Three provides the results of a national survey of State and local regulation of syringes and needles. Part Four is a set of Appendices which include the reviews of needle exchange programs described in Part One, two studies published since the NRC/IOM review, and relevant abstracts presented at the XI International AIDS Conference in Vancouver, BC in July, 1996.

I. Review of Published Studies

Three reviews of the literature on needle exchange programs have been commissioned by the federal government: (1) Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy, United States General Accounting Office, March 1993; (2) The Public Health Impact of Needle Exchange Programs in the United States and Abroad, prepared by the faculty and research staffs of the San Francisco and Berkeley campuses of the University of California for the Centers for Disease Control and Prevention, U.S. Public Health Service, in September 1993; and (3) Preventing HIV Transmission: The Role of Sterile Needles and Bleach, National Research Council and Institute of Medicine, September 1995.

Report of the U.S. General Accounting Office

The U.S General Accounting Office (GAO) was requested by the Chairman of the House Select Committee on Narcotics Abuse and Control to: (1) review the results of studies addressing the effectiveness of needle exchange programs in the United States and abroad, (2) assess the credibility of a forecasting model developed at Yale University that estimates the impact of a needle exchange program on the rate of new HIV infections, and (3) determine whether federal funds can be used in support of studies and demonstrations of needle exchange programs.

The GAO conducted a literature review and site visits to two needle exchange programs. While the GAO noted that there were 32 known needle exchange programs in operation in 27 different U.S. cities or counties, their staff visited only those programs located in Tacoma, Washington and New Haven, Connecticut. Needle exchange programs studied by GAO were located in Australia (1), Canada (1), Netherlands (2), Sweden (1), United Kingdom (3), and the United States (1).

The full report with data from nine needle exchange programs and GAO findings are provided at Appendix A. The Results in Brief are abstracted below:

"Measuring changes in needle sharing behaviors is an indicator often used to assess the impact of needle exchange programs on HIV transmission. We identified nine needle exchange projects that had published results. Only three of these reported findings that were based on strong evidence. Two of these three reported a reduction in needle sharing while a third reported an increase.

One concern surrounding needle exchange programs is whether they lead to increased injection drug use. Seven of the nine projects looked at this issue, and five had strong evidence for us to report on outcomes. All five found that drug use did not increase among users; four reported no increase in frequency of injection and one found no increase in the prevalence of use. None of the studies that addressed the question of whether or not the needle exchange progams contributed to injection drug use by those not previously injecting drugs had findings that met our criteria of strong evidence. Our review of the projects also found that seven reported success in reaching out to injection drug users and referring them to drug treatment and other health services.

We also found the forecasting model developed at Yale University to be credible. This model estimated a 33 percent reduction in new HIV infections among New Haven, Connecticut, needle exchange program participants over 1 year. Based on our expert consultant review, we found the model to be technically sound, its assumptions and data values reasonable and the estimated 33 percent reduction in new HIV infections defensible. This reduction stems from the program's ability to lessen the opportunity for needles to become infected, to be shared, and to infect an uninfected drug user. To gather data in assessing program impact for use in the New Haven model, the researcher developed a new system for tracking and testing for HIV in returned needles.

While these findings suggest that needle exchange programs may hold some promise as an AIDS prevention strategy, HHS is currently restricted from using certain funds to directly support the funding of needle exchange programs. Under the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, block grant funds authorized by title XIX of the PHS Act may not be used to carry out any needle exchange program unless the Surgeon General determines that they are effective in reducing the spread of HIV and the use of illegal drugs. However, HHS does not have the authority to conduct demonstration and research projects that could involve the provision of needles." Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy, GAO/HRD-93-60, pages 3-4.

Report of the University of California

Under a contract with the Centers for Disease Control and Prevention (CDC), faculty of the University of California, at Berkeley and San Francisco, undertook a review and analysis of the literature on needle exchange programs to answer a set of 14 research questions, including the effect of needle exchange programs on HIV infection rates and prevention of HIV infection and effect on drug using behavior. At the time this study, 37 active needle programs were known to exist in the U.S.; the 33 programs which were up and running for sufficient time to be included in this review operated a total of 102 sites. Over 1900 data sources were analyzed and ranked according to the quality of study design and evidence reported; study results report only on those judged to be of acceptable quality, or better. A complete summary of findings and data sources utilized is provided in the final report at Appendix B.

The Executive Summary of the report is provided below:

"**How and Why did Needle Exchange Programs Develop?**
Needle exchange programs have continued to increase in number in the US and by September 1, 1993 at least 37 active programs existed. The evolution of needle exchange programs in the US has been characterized by growing efforts to accomodate the concerns of local communities, increasing likelihood of being legal, growing institutionalization, and increasing federal funding of research, although a ban on federal funding for program services remains in effect.

How do Needle Exchange Programs Operate?
About one-half of US needle exchange programs are legal, but funding is often unstable and most programs rely on volunteer services to operate. All but six US needle exchange programs require one-for-one exchanges and rules governing the exchange of syringes are generally well enforced. In addition to having distributed over 5.4 million syringes, US needle exchange programs provide a variety of services ranging from condom and bleach distribution to drug treatment referrals.

Do Needle Exchange Programs Act as Bridges to Public Health Services?
Some needle exchange programs have made significant numbers of referrals to drug abuse treatment and other public health services, but referrals are limited by the paucity of drug treatment slots. Integrating needle exchange programs into the existing public health system is a likely future direction for these programs.

How Much Does it Cost to Operate Needle Exchange Programs?
The median annual budget of US and Canadian needle exchange programs visited is relatively low at $169,000, with government-run programs tending to be more expensive. Some needle exchange programs are more expensive because they also provide substantial non-exchange services such as drug treatment referrals. The

annual cost of funding an average needle exchange program would support about 60 methadone maintenance slots for one year.

Who Are the IDUs Who Use Needle Exchange Programs?
Although needle exchange program clients vary from location to location, the programs generally reach a group of injecting drug users with long histories of drug injection who remain at significant risk for human immunodeficiency virus (HIV) infection. Needle exchange program clients in the US have had less exposure to drug abuse treatment than IDUs not using the program.

What Proportion of All Injecting Drug Users in a Community Uses the Needle Exchange Program?
Studies of adequately funded needle exchange programs suggest that the programs do have the potential to serve significant proportions of the local injecting drug user population. While some needle exchange programs appear to have reached large proportions of local drug injectors at least once, others are reaching only a small fraction of them. Consequently, other methods of increasing sterile needle availability must be explored.

What Are the Community Responses to Needle Exchange Programs?
Unlike in many foreign countries, including Canada, proposals to establish needle exchange programs in the US have often encountered strong opposition from a variety of different communities. Consultation with affected communities can address many of the concerns raised.

Do Needle Exchange Programs Result in Changes in Community Levels of Drug Use?
Although quantitative data are difficult to obtain, those available provide no evidence that needle exchange programs increase the amount of drug use by needle exchange program clients or change overall community levels of non-injection and injection drug use. This conclusion is supported by interviews with needle exchange program clients and by injecting drug users not using the programs, who did not believe that increased needle availability would increase drug use.

Do Needle Exchange Programs Affect the Number of Discarded Syringes?
Needle exchange programs in the US have not been shown to increase the total number of discarded syringes and can be expected to result in fewer discarded syringes.

Do Needle Exchange Programs Affect Rates of HIV Drug and/or Sex Risk Behaviors?
The majority of studies of needle exchange program clients demonstrate decreased rates of HIV drug risk behavior but not decreased rates of HIV sex risk behavior.

What is the Role of Studies of Syringes in Injection Drug Use Research?
The limitations of using the testing of syringes as a measure of injecting drug users' behavior or behavior change can be minimized by following syringe characteristics over time, or by comparing characteristics of syringes returned by needle exchange program clients with those obtained from non-clients of the program.

Do Needle Exchange Programs Affect Rates of Diseases Related to Injection Drug Use Other than HIV?
Studies of the effect of needle exchange programs on injection-related infectious diseases other than HIV provide limited evidence that needle exchange programs are associated with reductions in subcutaneous abscesses and hepatitis B among injecting drug users.

Do Needle Exchange Programs Affect HIV Infection Rates?
Studies of the effect of needle exchange programs on HIV infection rates do not and, in part due to the need for large sample sizes and the multiple impediments to randomization, probably cannot provide clear evidence that needle exchange programs decrease HIV infection rates. However, needle exchange programs do not appear to be associated with increased rates of HIV infection.

Are Needle Exchange Programs Cost-effective in Preventing HIV Infection?
Multiple mathematical models of needle exchange programs impact support the findings of the New Haven model. These models suggest that needle exchange programs can prevent significant numbers of infections among clients of the programs, their drug and sex partners, and their offspring. In almost all cases, the cost per HIV infection averted is far below the $119,000 lifetime cost of treating an HIV-infected person." The Public Health Impact of Needle Exchange Programs in the United States and Abroad, Volume 1, pp.iii-v.

Report of the National Academy of Sciences

In 1992, Congress included a provision in the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act directing the Secretary of DHHS to request the National Academy of Sciences (NAS) to conduct a study of the impact of needle exchange and bleach distribution programs on drug use behavior and the spread of infection with the human immunodeficiency virus (HIV). The National Research Council and the Institute of Medicine (NRC/IOM) of the NAS convened an expert panel in 1993, conducted a thorough review of the scientific literature on these issues, and published the report Preventing HIV Transmission: The Role of Sterile Needles and Bleach, in September, 1995. Approximately 75 needle exchange programs had been initiated in 55 US cities at the time of this report. Data was also newly available assessing the effects of a 1992 Connecticut law decriminalizing the possession of syringes without a prescription.

The scope of the NRC/IOM study extended well beyond the information requested for this report. A review of the scientific data on the effects of needle exchange programs on reduction in HIV transmission rates and impact on drug utilization is presented in Chapter Seven of the report. The text of the full report is provided at Appendix C. The study reviewed and expanded on the previous studies of the GAO and University of California as well as analyzing subsequently published studies through 1994. The NRC/IOM study panel included a discussion of experimental study design and data quality issues in weighing the contribution of published studies. The conclusions and recommendations of the report were based in part on an assessment of the patterns of evidence, and not solely on the quality of evidence in individual studies.

Provided here is a summary of the conclusions of the NRC/IOM panel on the scientific assessment of needle exchange program effectiveness:

Scientific Assessment of Program Effectiveness

" On the basis of its review of the scientific evidence, the panel concludes:

- Needle exchange programs increase the availability of sterile injection equipment. For the participants in a needle exchange program, the fraction of needles in circulation that are contaminated is lowered by this increased availability. This amounts to a reduction in an important risk factor for HIV transmission.

- The lower the fraction of needles in circulation that are contaminated, the lower the risk of new HIV infections.

- There is no credible evidence to date that drug use is increased among participants as a result of programs that provide legal access to sterile equipment.

- The available scientific literature provides evidence based on self-reports that needle exchange programs do not increase the frequency of injection among program participants and do not increase the number of new initiates to injection use.

- The available scientific literature provides evidence that needle exchange programs have public support, depending on locality, and that public support tends to increase over time." Preventing HIV Transmission: The Role of Sterile Needles and Bleach, Executive Summary, page 4.

Other Recent Studies

Other studies and abstracts published since the NRC/IOM report which address the effects of needle exchange programs on HIV transmission and drug-using behavior are provided at Appendix D. These include: (1) a study published by Des Jarlais et al in Lancet, October 1996 researching the question if NEPs have an individual-level protective effect against HIV transmission, (2) an evaluation commissioned by the Massachusetts Department of Public Health on the effects of a pilot needle exchange program, presenting Year One and Year Two data, and (3) abstracts accepted at the XI International Conference on AIDS held in Vancouver, BC July 1996. Although many abstracts included findings relevant to NEPs, only those designed to specifically study the research questions raised by the Appropriations Committee are included in this report.

(1) Des Jarlais DC, et al. HIV incidence among injecting drug users in New York City syringe-exchange programmes. Lancet 1996; 348: 987-991.

This study employed meta-analytic techniques to compare HIV incidence among injecting drug users participating in syringe-exchange programs in New York City with that among non-participants. Data from three cohorts (total n=1630) was pooled to assess HIV incidence rates.

" **Findings** HIV incidence among continuing exchange users in the Syringe Exchange Evaluation was 1.58 per 100 person-years at risk (95% CI 0.54, 4.65) and among continuing exchange users in the Vaccine Preparedness Initiative it was 1.38 per 100 person-years at risk (0.23, 4.57). Incidence among non-users of the exchange in the Vaccine Preparedness Initiative was 5.26 per 100 person-years at risk (2.41, 11.49), and in the National AIDS Demonstration Research cities (non-exchange users) 6.23 per 100 person-years at risk (4.4, 8.6). In a pooled-data multivariate proportional-hazards analysis, not using the exchanges was associated with a hazard ratio of 3.35 (95% CI 1.29, 8.65) for incident HIV infection compared with using the exchanges.
Interpretation We observed an individual-level protective effect against HIV infection associated with participation in a syringe-exchange programme. Sterile injection equipment should be legally provided to reduce the risk of HIV infection in persons who inject drugs." p. 987.

(2) The Medical Foundation, Final Report: First Year of the Pilot Needle Exchange Program in Massachusetts, October 1995; and Second Year Update: Program Characteristics of Massachusetts Needle Exchange Programs, 1994-95, August 1996.

These two reports were prepared by The Medical Foundation under contract to the Massachusetts Department of Public Health, to evaluate

the effects of a pilot needle exchange program (AHOPE) authorized by State law in 1993. Two needle exchange programs served 1,315 and 1,999 unduplicated clients in 1994 and 1995, respectively. The Executive Summary of the 1995 report and the Second Year Update of 1996 summarize study results to the following questions:

- o What were the demographic characteristics of people who enrolled in the program and did the program reach those at risk for HIV infection in Metro Boston and Cambridge
- o What were the reported injection behaviors and risks of program clients
- o How many client-contacts did the program have and what supplies were distributed
- o Did the program act effectively as a "bridge to treatment" for needle exchange clients
- o Did crime increase in areas with needle exchange sites compared to areas without needle exchange sites
- o Did needle stick injuries to public service workers increase as a result of the program

"**Conclusion** Upon completion of its first full year of operation, AHOPE has been successful in enrolling 1,315 clients, exchanging 37,575 syringes, and linking 16.6% of the eligible clients to drug treatment. Many of the major concerns regarding the establishment of the program -- namely the danger of increased crime, the initiation of young people into drug use and injection, the attraction of addicts from wide geographic areas into Boston, and the possibility of needle stick injuries to public workers -- did not come to pass. AHOPE appears to have significantly contributed to the reduction of HIV risk among a diverse population at high risk for HIV infection and transmission with little negative community impact." Final Report: First Year of the Pilot Needle Exchange Program in Massachusetts, October 1995, p.7.

"**Conclusion** The program is expanding into areas of the state where there is much need for prevention services while maintaining continuity of care in areas where the program is already established. There is no evidence that the program is attracting young or new injectors, there have been no other negative community impacts. The programs have had significantly positive impacts, both in preventing HIV through the provision of sterile syringes and prevention supplies and education and in the form of enhanced drug treatment linkage for the older, impoverished long-term addicts who utilize the program." Second Year Update: Program Characteristics of Massachusetts Needle Exchange Programs, 1994-1995, August 1996, p.3.

(3) Abstracts from the XI International Conference on AIDS, Vancouver, BC, July 1996. The following two abstracts reported on US needle exchange programs in Baltimore, MD and New York City.

Vlahov, D et al. Evaluation of the Baltimore Needle Exchange Program: Preliminary Results. [Abstract Mo.D.361] The following key variables were addressed in the abstract: frequency of drug injection, frequency of needle exchanges, needle sharing patterns, use of shooting galleries, number of injections on the street, and disposal of used needles on the street.

"**Conclusion** This NEP has recruited a large number of IDUs and preliminary data suggest that the NEP attracts high risk IDUs, and that a reduction in HIV risk drug use is observed."

Schoenbaum, EE et al. Needle Exchange Use Among a Cohort of Drug Users. [Abstract Tu.C.2523] The abstract reports on a prospective study of injection behaviors among IDUs enrolled in a methadone maintenance program who did and did not utilize a local needle exchange program in the Bronx, New York City between 1985-1993. The following key variables were addressed in the abstract: the percent of clients injecting over time, percent of clients using the needle exchange program, needle sharing behavior, and HIV seropositivity status.

"**Conclusion** Methadone treated IDUs with access to a needle exchange decreased injection and needle sharing. This pattern of harm reduction, which began years before the needle exchange program opened, occurred in those who did and did not utilize the needle exchange. Needle exchange, as a strategy to decrease injection-related harm, should not be viewed as discordant with methadone treatment."

II. Current Federally Supported Research on Needle Exchange Programs

The Department has taken an active interest in evaluating the public health impact of needle exchange programs since 1992, in light of the opportunity to reduce bloodborne transmissible diseases among IDUs and to serve as a gateway to substance abuse treatment. These research activities have been centered at the National Institute on Drug Abuse (NIDA). A description of NIDA's needle exchange research portfolio which includes 15 funded studies is described in Appendix E. All federally sponsored research is limited by statute to evaluations of existing NEPs and does not support the purchase or distribution of needles.

Of the 15 studies funded by NIDA, only two have been completed. A summary of findings to date follows here. Of 4 studies reporting data on frequency of injection, three report no evidence of increased injection frequency, and one shows a decreased rate of injections. All four of the 15 studies reporting data on multi-person reuse, or sharing, of syringes show a decrease in the reuse of syringes. Data on the prevalence or incidence of hepatitis and HIV is available for 2 of the 15 projects. In one study between 51% - 55% of syringes returned were seropositive; of note, multiple syringes may have been returned by a single individual affecting interpretation of these results. In the other study, a 33 percent relative

reduction in HIV incidence in needle exchange program users was predicted based on a mathematical model. This model was reviewed and assessed to be methodologically sound in the GAO report found at Appendix A.

III. National Survey on the Regulation of Syringes and Needles

A recent national survey of laws and regulations governing the sale and possession of needles and syringes in the United States and its territories is included at Appendix F, to provide the Committee with additional background on the variety of state and local drug paraphernalia laws, syringe prescription statutes, and pharmacy regulations in effect. A number of states and local ordinances have created exceptions to laws and regulations for operators of syringe exchange programs and their participants. An overview of the legislative history and the specifics of exemptions are included along with the results of the national survey.

Summary

[This review provides the Committee with an overview of the current status of knowledge regarding the impact needle exchange programs may have on the seroincidence of HIV and their impact on drug using behavior of needle exchange participants.] 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.

IV. Appendices

Appendix A. Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy. U.S. General Accounting Office. 1993

Appendix B. The Public Health Impact of Needle Exchange Programs in the United States and Abroad, Volume 1. San Francisco, CA: University of California. 1993

Appendix C. Preventing HIV Transmission: The Role of Sterile Needles and Bleach. National Research Council and Institute of Medicine. 1995.

Appendix D. Des Jarlais DC, Marmor M, Paone D et al. HIV Incidence Among Injecting Drug Users in New York City Syringe-Exchange Programmes. Lancet. 1996;348:987-991.

First year report (October 1995) and Second Year Update (August 1996) of the Pilot Needle Exchange Program in Massachusetts. The Medical Foundation, for the Massachusetts Department of Public Health.

Abstracts from the XI International Conference on AIDS, Vancouver, BC July 1996:

1) Vlahov D. et al. Evaluation of the Baltimore Needle Exchange Program: Preliminary Results. Abstract Mo.D.361

2) Schoenbaum, E. et al. Needle Exchange Use Among a Cohort of Drug Users. Abstract Tu.C.2523

Appendix E. NIDA's Needle Hygiene and Needle Exchange Evaluation Research Program Portfolio, 1992 - Present.

Appendix F. Gostin LO, Lazzarini JD, Jones TS, Flaherty K. Prevention of HIV/AIDS and Other Blood-Borne Diseases Among Injection Drug Users. JAMA. 1997;277:53-62.

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Stopping AIDS,310
Needle exchanges, sex education effectivc against AIDS, panel says

WASHINGTON (AP) Strong scientific evidence shows that clean needle exchanges, safe sex education and drug abuse treatment can significantly reduce the spread of the AIDS virus, but these efforts often are blocked by moral and government objections, a panel of experts said today.

``The AIDS epidemic is a current and pressing public health emergency'' that can be lessened by behavior modification programs such as clean needle exchanges, said Dr. David Reiss of George Washington University Medical Center, chairman of the study committee appointed by the National Institutes of Health.

Reiss said there are ``significant policy and legal barriers'' that are blocking intervention programs and that this attitude ``places public health in great jeopardy.''

The committee found, for example, that scientific studies show that clean needle exchange programs can significantly reduce the spread of the AIDS virus in a community, but that current regulations ban federal funding of such efforts.

``Thousands of lives are at risk if this ban is not removed,'' Reiss said at a news conference.

A welfare reform law that permits only the teaching of abstinence in sex education programs also should be changed, said Reiss, because ``it is not consistent with the scientific findings'' of what is effective in teaching young people about how to avoid an AIDS virus infection.

He said safe sex education, which can include recommending the use of condoms and limiting partners, is the most effective way to reduce the sexual spread of AIDS.

The 12-member committee consists of medical experts from around the country selected by NIH to make an independent evaluation of AIDS prevention strategies.
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Talking points:
NIH Consensus Conference Statement on
"Interventions to Prevent HIV Risk Behaviors"
2/14/97
(Victor Zonana, HHS: 202-690-6343)

Background: This morning's Washington Post carries a Page One story on the report of a panel of outside experts called together by the National Institutes of Health to assess interventions to prevent HIV risk behavior. The report found a "dangerous chasm" between science and public policy, and argued that political considerations have prevented this country from adopting proven weapons in the fight against AIDS transmission. Most notably, the panel called for a lifting of the ban on federal funding for needle exchange programs, and criticized a teen-pregnancy prevention program that focuses exclusively on abstinence.

- This is the report of **an outside panel of non-government scientists.** We at the White House haven't seen the report, and it's our understanding that the policy makers at HHS haven't even had a chance to review it.

- The Clinton Administration had reponded aggressively to the threat of HIV/AIDS. Overall funding for AIDS-related programs has risen 55% in the first four years of the Clinton Administration, including a 40% increase at the NIH (research); a 24% increase at the CDC (prevention) and a 173% increase at the Health Resources and Services And (treatment). **Drugs approved by the FDA in record time have turned the corner on AIDS treatment, prolonging and enhancing lives.**

- The $50 million teen-pregnancy program referenced by the report was designed to fight **teen pregnancy, not HIV.** It is part of the bipartisan welfare reform legislation enacted by Congress and signed by the President.

- For prevention of the sexual spread of HIV, this Administration favors a **balanced approach.** Our HIV public service announcements for young adu;ts stress that abstinence is the surest way to prevent the sexual spread of HIV; but for those who are sexually active, we advise the correct and consistent use of condoms. It is up to **individual communities** to choose the most appropriate HIV prevention approaches for their communities.

- On the question of needle exchange programs, **Congress has enacted some very high hurdles to the federal funding of needle exchange programs.** However, Congress has funded research into the efficacy of such programs, and we note that this country has over 100 locally-funded needle exchange programs. Again, we believe **it is up to local communities to decide which types of HIV prevention programs are most appropriate.**