

Policy Analysis:

Disease Prevention Demonstration Project (SB 1159)

in Santa Barbara County

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Policy Analysis Problem Definition

Blood borne illnesses are often spread through the sharing of contaminated needles among injection drug users (IDUs). In 1997, The Centers for Disease Control¹ and Prevention recommended that IDUs who are unable to stop using drugs should “use a new, sterile syringe to prepare and inject drugs.” In Santa Barbara County, 25% of those infected with HIV/AIDS list injection drug use as the mode of disease transmission (see Figure 1 Appendix A). Figure 2 and Figure 3 in Appendix A depict the trends of blood borne viral illnesses HIV, Hepatitis B and C in Santa Barbara County over the last several years. Although the incidence rates have dropped for these viral illnesses, these diseases still are prevalent in the County and no significant decrease in the incidence rate has occurred in the last few years. Approximately 60% of those HIV positive clients accessing the Needle Exchange and Education Program at the Pacific Pride Foundation (a local syringe exchange program) are co-infected with Hepatitis C². California Senate Bill 1159 (Vasconcellos) created the Disease Prevention Demonstration Project to prevent the spread of blood-borne diseases among IDUs, their sexual and needle sharing partners, and their children.

Disease Prevention Demonstration Project Summary

This project, subject to local authorization, is in effect from January 1, 2005 through December 31, 2010. This project will:

- Allow licensed pharmacies that are registered with the Public Health Department (PHD) to furnish (distribute or sell) up to 10 syringes (needles) without a prescription.
- Authorize a person to possess up to 10 syringes with proof of acquisition from an approved provider (pharmacist or physician).
- Implement criminal penalties for the improper disposal of syringes to specified public areas (parks, beaches, school playgrounds and other locations).

- Remove the requirement of identity and record keeping of nonprescription sales of syringes from the pharmacies by the State Department of Health Services.
- Require the Department of Health Services to evaluate the efficacy of the project and to submit an evaluation report to the Governor and Legislature by January 15, 2010.

Potential Community Risks for a local Disease Prevention Demonstration Project

California is one of only five States that requires a prescription for the sale of syringes. Many other States have implemented Enhanced Syringe Access Programs (ESAPs). In 2002, the Centers for Disease Control (CDC) held a conference focused on evaluations of existing ESAPs and to encourage the development of additional programs. Subsequently the Journal of the American Pharmaceutical Association published a supplemental edition³ dedicated to elements of ESAPs. From the conference and Journal information, the following community risks were identified:

- Increase in injection drug use
- Increase in improper/illegal disposal of used syringes
- Increase in incidence rate of blood borne illnesses
- Increase in crime associated with drug activity
- Reduction in property values adjacent to participating pharmacies

Additional risks were identified that are specific to the participating pharmacies and disposal locations. These included: improper syringe disposal on premises; illegal drug activity on or adjacent to premises; and increased staff liability associated with handling and disposing of sharps generated medical waste.

Reviews of multiple existing ESAPs^{4,5,6,7,8,9} have shown that there was no: significant increase in drug activity; significant increase in illegal syringe disposal at or around participating pharmacies; significant increase in crime associated with drug activity; and marked decrease in property values around syringe collection sites.

Lewis (2002)¹⁰ conducted interviews of thirty-two pharmacists' attitudes toward ESAPs in Denver, Colorado. Approximately one third of the pharmacists indicated opposition to the sale of syringes without a prescription because of their perception of a conflict between "prevention of disease and prevention of drug abuse." Eleven of sixteen pro-sales pharmacists indicated that the presence of IDUs in their stores had little or no detrimental effect on business. The five pro-sale pharmacists that reported problems indicated examples of theft, concern for staff and customer safety or finding used syringes on store premises. However, these same pharmacists also indicated the health benefits outweighed their business concerns.

Community Benefits for a Local Disease Prevention Demonstration Project

The primary goal for the DPDP is the reduction of blood borne illnesses. A study by Friedman *et al* (2001)¹¹ compared injection drug use and rates of HIV among IDUs in ninety- six US cities. Sixty of the cities required a prescription for syringe sales while the remaining thirty- six cities did not. There was no statistical difference in the prevalence of injection drug use among the cities. However, the rate of HIV among injection users was twice as high in the cities that prohibited sales of syringes (13.8% vs. 6.7%).

In 1993, The Government Accountability Office (GAO)¹² reviewed existing literature on ESAPs and Syringe Exchange Programs. The GAO, citing a Yale University model that predicts a 33% decrease in HIV transmission as a result of successful syringe exchange or distribution programs.

Additional benefits associated with ESAPs include: reduction in syringe sharing through increased access to clean syringes; reduced needle stick injuries for law enforcement and solid waste haulers; increased proper disposal of used syringes through education and enhanced disposal capacity; and enhanced collaborations among pharmacies, law enforcement and local public health jurisdictions

Novotney *et al* (2002)¹³ performed a survey of customers (IDUs) of Minnesota ESAP pharmacies located in known heavy drug use areas. Novotney determined that customers of participating pharmacies reported that they had decreased their needle sharing activities by up to 17% collectively. They also indicated that pharmacies were their primary source of clean needles rather than pimps or other street sources.

Steven Lawitts (2002)¹⁴ examined needlestick injuries and sightings by the New York City Department of Sanitation from 1997 to 2001. Sanitation worker sightings of illegal needle disposal dropped from 1 in 1,600 trash truck trips to 1 in 4,145 trash truck trips during this period and needlestick injuries decreased from thirty-three to eleven per year.

Program Options and Alternatives

Maintain Existing Disease Prevention Efforts

Local disease prevention efforts have made great strides in reducing the incidence of blood borne illness in Santa Barbara County. However, since the mid-1990's, the incidence rates have persisted albeit at lower levels (see Appendix A, Figure 2). New transmissions will occur, and limited public health resources will continue to be used for the care and treatment of the infected individuals. The Department of Health and Human Services¹⁵ estimates that treatment for an HIV/AIDS infected individual averages \$20,000 annually while treatment for chronic liver disease is \$15,000 - \$20,000 annually with the one-time cost of a liver transplant at \$300,000.

Existing syringe disposal options include free disposal through the community-based Needle Exchange and Education Program, through the Home Sharps Generated (HSG) Disposal Program and through the municipal or county trash collection services. The HSG Disposal Program is a collaboration of the County Solid Waste Division and the County PHD. The Solid Waste Division provides free sharps containers that are exchanged for sharps containers full of contaminated needles at the County PHD's three clinical laboratories located in Santa Barbara, Santa Maria and Lompoc. The Needle Exchange and Education Program relies on private donations and provides one-for-one exchange of clean needles for contaminated needles. These two programs dispose of contaminated needles through the County PHD's medical waste stream. Approximately 0.5 million contaminated needles are disposed of by the PHD annually¹⁶ at a cost of over \$10,000 per year (see Table 1, Appendix C). Pharmacy prescription syringe sales in Santa Barbara County are in the range of 1.8 million to 2.8 million annually¹⁷. These figures indicate that the vast majority of used needles are being disposed of in the solid waste disposal system. To date, there have been no significant or ongoing problems with illegal disposal of contaminated syringes in parks, school grounds or beaches¹⁸. Neither have there been a significant number of needle stick incidents for waste handlers¹⁹.

Pharmacy Sales and Existing Disposal Programs

Under this option, customers could purchase needles from participating pharmacies and needle disposal would be through the existing three public health clinic sites. Based upon the expectation of increased needle sales⁴ and supply in the community, an increase in costs and use of resources is likely (see Appendix C, Table 1).

This is the least level of effort and cost for pharmacies, but may trigger additional trash or illegal needle disposal. There are eight incorporated cities in Santa Barbara County. It is

unlikely that residents in cities without a HSG Disposal Program location (PHD clinical laboratory site) would travel to dispose of their needles at these locations. Without additional sources of funding , all disposal costs would be borne by the PHD budget.

Evaluation of community outcomes for a program in Harlem, New York²⁰ has demonstrated that: pharmacies opting to participate in this program model increases over time (49% to 79% in the first year of the program); pharmacies as the primary source of syringes for IDUs increased from 3.4% pre-ESAP to 5.3% post-ESAP; syringe sales increase (no specific percentage of increase is cited); and disposal of used needles in the municipal trash did not increase.

Pharmacies in Santa Barbara, San Francisco and Alameda Counties²¹ sell used needle (sharps) mail back kits. The purchase price (just under \$30) pays for the sharps container that holds up to 100 used syringes, postage, pre-addressed mailing carton and disposal of the syringes at the disposal location (where the package is mailed- proof of proper disposal is returned to the customer). An IDU with a twice- daily injection frequency will generate enough used syringes to require approximately \$200-300 of annual disposal costs using the described mail back program. Without changing existing regulations or providing subsidies (e.g. free postage paid mail back sharps containers), it is unlikely that IDUs will consistently use a mail back program in lieu of trash disposal.

Pharmacy Sales and Pharmacy Disposal

A model of this program is depicted in Appendix B, Figure 3. Under this program option, pharmacies could chose to participate in the DPDP and would be required to accept contaminated syringes for disposal. IDUs would have the current used needle disposal options and the additional option of disposing of the used needles at the pharmacies where they purchase

the needles. There are a number of this program model currently operating in other states and one program in California (San Francisco)²².

Under this option it is likely that both clean needle supply in the community and contaminated needle disposal will increase: given an option for disposing of needles where purchased increases disposal capacity and convenience for IDUs.

Currently the Santa Barbara County pharmacies²³ are concerned about the additional cost, potential liability, potential link to increased injection drug use and risk to pharmacy staff to handle contaminated needles. To make this a viable option, a dedicated funding source must be developed to limit pharmacy liability and for contaminated needle disposal. Under the EHAP Program in New York City²⁴, pharmacies purchase outdoor or indoor disposal devices that allow customers to drop in contaminated needles. A contracted medical waste hauler services the disposal devices to prevent pharmacy staff exposure to used needles. Funding is provided from the existing PHD programs budgets. In San Francisco and other jurisdictions, a proportion of solid waste disposal fees is used for proper needle disposal. Finally, in northern California, some newly established DPDPs²⁵ are exploring the implementation of a needle disposal surcharge/sales tax.

Pharmacy Sales and Community Program Disposal

Under this option, customers could purchase needles from participating pharmacies and needle disposal would be through an enhanced community program. The community program would include the development of additional needle disposal sites such as County and or City fire stations, hospitals, private medical clinics, recycling centers and/or pharmacy locations. A similar program has been operating successfully in Florida²⁶ since the late 1980s. It should be

noted that a similar effort to increase disposal sites for the HGS Disposal Program was previously unsuccessful²⁷.

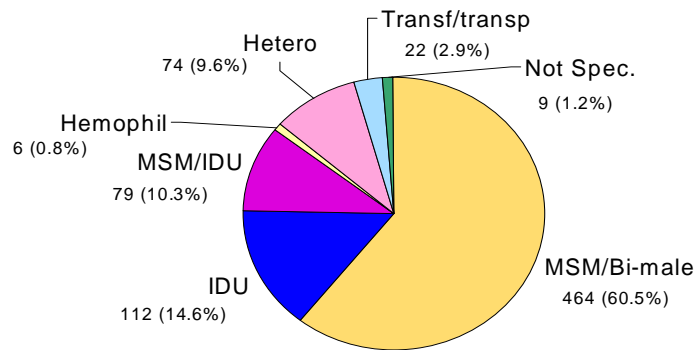
Conclusions

1. Prevention is always more cost effective than treatment. Based upon previous studies, program implementation will likely reduce needle sharing and blood borne illness transmission. A modest reduction in transmission (e.g. 5%) would prevent approximately 15 Hepatitis virus and 1-2 HIV transmissions over the demonstration period. This would reduce treatment costs of those infected by over \$400,000 over the same time period at \$15,000 annual treatment costs per infection.
2. A gap exists between used syringes properly disposed and those disposed of in the trash of 1.3 M to 2.3 M annually. It is clear that implementation of a DPDP will increase syringe sales and the concurrent educational requirements for the safe and proper disposal of used needles may generate support for proper disposal. Existing disposal options are limited. Additional disposal capacity is recommended.
3. Santa Barbara County pharmacists, as in other areas, have mixed support for a DPDP. Over twenty pharmacists in Santa Barbara County have committed to supporting a program. As in other ESAPs, the flexibility for pharmacies to participate after startup is important to increasing program participation.
4. If the program is to expand over time, combining a mail back program with existing needle disposal options for start up used needle disposal would be a proper temporary solution for ongoing pharmacy and community negotiations, planning and evaluation to determine the most appropriate means for developing additional disposal capacity and dedicated funding.

Appendix A

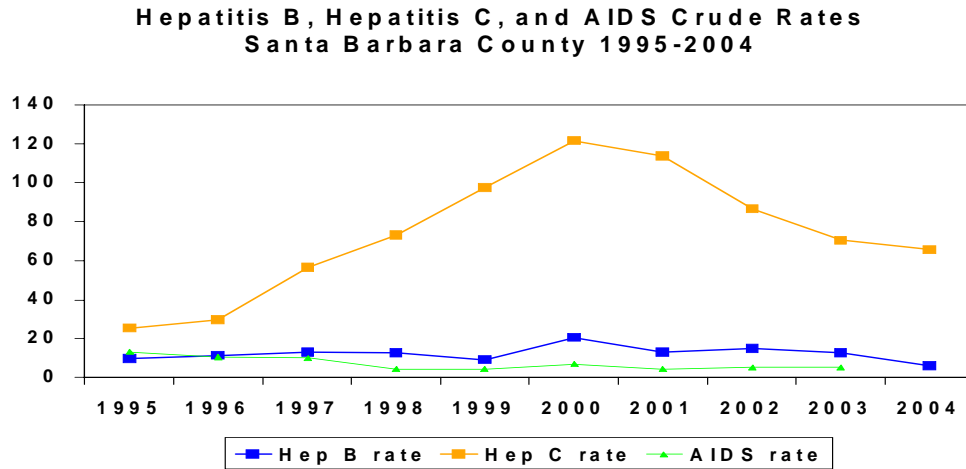
Figure 1. HIV/AIDS Modes of Transmission

**Adult/Adolescent AIDS Cases by Transmission Mode
Santa Barbara County 1981-2004 (as of 11/04)
N = 767**

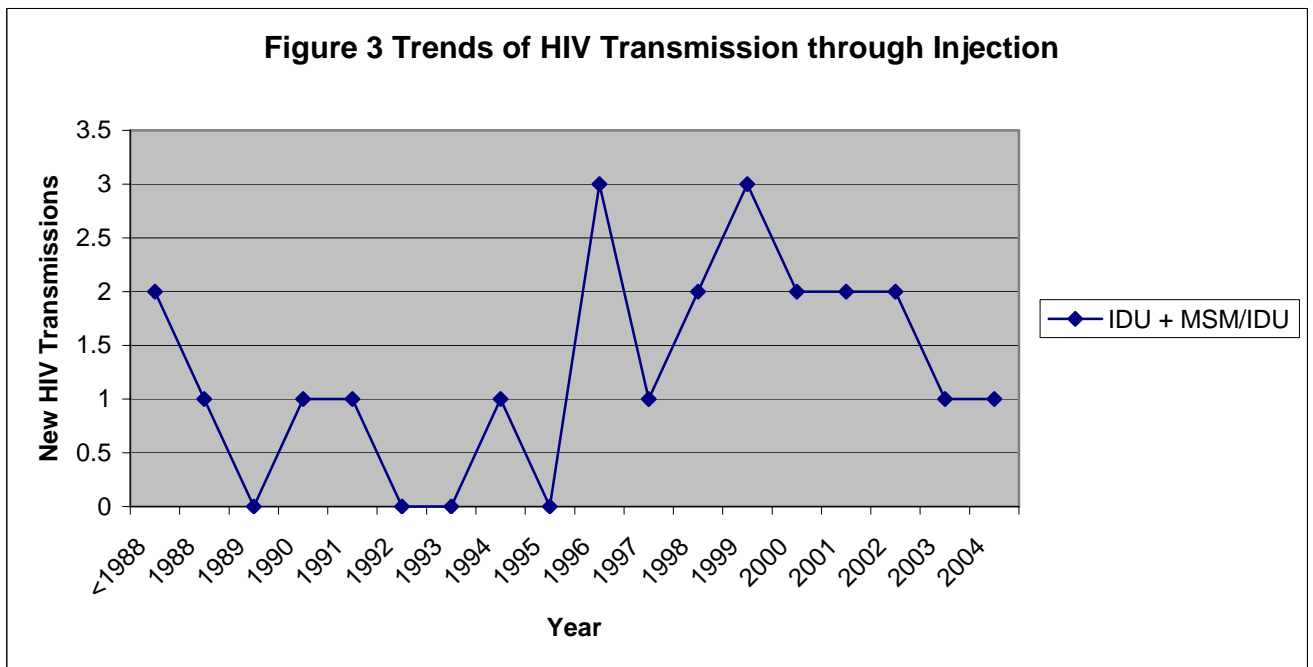


Source: HARS reports. Not shown one person with mother with HIV/HIV risk.

Figure 2. Incidence of HIV, Hepatitis B and Hepatitis C

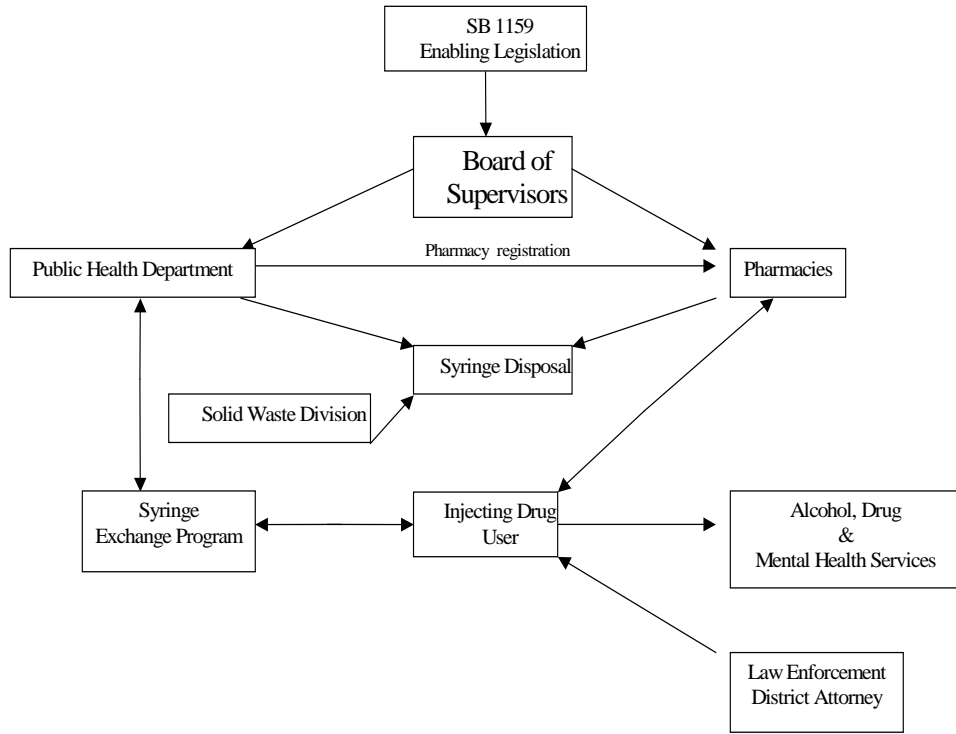


Source: Confidential Morbidity Reports; HARS
State of California, Department of Finance, *County Population Estimates and Components of Change, July 1, 2000-2001, with Historical Estimates, 1990-2000*. Sacramento, CA, January 2002.



IDU = Injection Drug User MSM = Men having Sex with Men

Figure 3. Disease Prevention Demonstration Project Model



Appendix C

Table 1. Projected Outcomes of Alternative ratings based upon selection criteria.

Program Alternative	Potential for Pharmacy Liability	County costs for needle disposal	Likely funding sources for program alternatives	Community Outcomes
No Change	N/A	X	Private donations, Solid Waste disposal fees and County General Fund	Blood borne illness transmission continuation at present rate.
Pharmacy sales only	Y	X + A	Private donations, Solid Waste disposal fees and County General Fund	Needle sharing rate decrease and increase of trash disposal of additional used needles
Pharmacy sales and pharmacies as needle disposal site	Y + J	X + B	Private donations, Solid Waste disposal fees, County General Fund and pharmacy customer funding	Needle sharing rate decrease and increase of proper disposal of additional needles
Pharmacy sales, pharmacies as needles disposal site and community disposal program	Y + J	X + C	Increased Private donations, Solid Waste disposal fees, County General Fund and pharmacy customer funding	Needle sharing rate decrease and increase of further increase of disposal of additional needles

X = \$10,430 annually

A, B and C = Program Implementation Costs + Enhanced Needle Disposal Costs

A < B < C

Y = Liability for pharmacies associated with sales to minors or potential for injection drug use on pharmacy property or illegal used needle disposal on pharmacy property

J = Liability for pharmacies associated with collection and disposal of contaminated needles (staff risk)

Table 2 National Groups that Support Pharmacy Syringe Sales Without a Prescription

American Public Health Association	American Bar Association AIDS Coordinating Alliance of State AIDS Directors
American Medical Association	National Associations of State Controlled Substance Authorities
American Pharmaceutical Association	National Association of County & City Health Officials
U.S. Conference of Mayors	National Association of Board Pharmacies

End Notes

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- ¹ “HIV Prevention Bulletin: Medical Advice for Persons Who Inject Illicit Drugs” May 9, 1997 Department of Health and Human Services, PHD, CDC. Online. Available: www.cdc.gov
- ² Personal communications with Rafael Cosio, Director of Education and Prevention Services, Pacific Pride Foundation on October 27, 2004.
- ³ (2002) *Preventing Blood-Borne Infections Through Pharmacy Syringe Sales and Safe Community Syringe Disposal*. December/November Volume 42, Number 6, Supplement 2. Pgs S1–S119.
- ⁴ Fuller, Crystal M. *et al* (2002) *Impact of Increased Syringe Access: Preliminary Findings on Injection Drug User Syringe Source, Disposal, and Pharmacy Sales in Harlem, New York*. Journal of the American Pharmaceutical Association, 42 (supplemental 2) Pg S77-82.
- ⁵ Novotny, Gary A. *et al* (2002). *The Minnesota Pharmacy Syringe Access Initiative: A Successful Statewide Program to Increase Injection Drug User Access to Sterile Syringes*. Journal of the American Pharmaceutical Association. 42 (supplemental 2) Pgs S21-22.
- ⁶ Lewis, Beth A., Koester, Stephen K., and Bush, Trevor W. (2002). *Pharmacists’ Attitudes and Concerns Regarding Syringe Sales to Injection Drug Users in Denver, Colorado*. Journal of the American Pharmaceutical Association. 42 (supplemental 2) Pgs S46-51.
- ⁷ Information on the New York Enhanced Syringe Access Program (ESAP). Online. Available: www.health.state.ny.us/nysdoh/hivadis/esap/regover.htm
- ⁸ Turnber, Wayne L. *et al* (2002). *Community Needle Collection and Disposal Programs in Florida*. *Journal of the American Pharmaceutical Association*. 42 (supplemental 2) Pgs S108-109.
- ⁹ Lawitts, Steven (2002). *Needle Sightings and On-the-Job Needle-Stick Injuries Among New York City Department of Sanitation Workers*. Journal of the American Pharmaceutical Association. 42 (supplemental 2) Pgs S92-93
- ¹⁰ Lewis, Beth A., Koester, Stephen K., and Bush, Trevor W. (2002). *Pharmacists’ Attitudes and Concerns Regarding Syringe Sales to Injection Drug Users in Denver, Colorado*. Journal of the American Pharmaceutical Association. 42 (supplemental 2) Pgs S46-51.
- ¹¹ Friedman, Sam R. *et al* (2001) *Laws Prohibiting Over-the-Counter Syringe Sales to Injection Drug Users: Relations to Population Density, HIV Prevalence, and HIV Incidence*. American Journal of Public Health. 2001;91:791-793
- ¹² *Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy* Government Accountability Office House of Representatives Document-93-60 March 1993. Online. Available: <http://archive.gao.gov/d44t15/148846.pdf>
- ¹³ Novotny, Gary A. *et al* (2002). *The Minnesota Pharmacy Syringe Access Initiative: A Successful Statewide Program to Increase Injection Drug User Access to Sterile Syringes*. Journal of the American Pharmaceutical Association. 42 (supplemental 2) Pgs S21-22.
- ¹⁴ Lawitts, Steven (2002). *Needle Sightings and On-the-Job Needle-Stick Injuries Among New York City Department of Sanitation Workers*. Journal of the American Pharmaceutical Association. 42 (supplemental 2) Pgs S92-93
- ¹⁵ Cost of viral blood borne illness treatment at Department of Health and Human Services. Online: www.cdc.gov
- ¹⁶ (2005) Personal communications with Gabriel Brown, Clinical Director, Santa Barbara County Public Health Department Clinical Lab director and Rafael Cosio, Pacific Pride Foundation, Needle Exchange and Education Program Director.
- ¹⁷ Annual pharmacy sales estimated based upon sales information for the Longs Drugstore, Inc. located in Santa Barbara County. Personal communication from, Colleen Carter and Cooky Quandt, Longs Drugstore, Inc. Santa Barbara County on April 21 and May 9, 2005.
- ¹⁸ (2005) Personnel communications with Rick Wheeler, Santa Barbara County Parks Department, Field Supervisor.
- ¹⁹ (2005) Personal communications with Leslie Wells, Recycling Specialist and Mark Schleich, Deputy Director, Santa Barbara County Solid Waste Division. Waste haulers have noted only two needle stick incidents in the last 5 years (1999-2004).
- ²⁰ Fuller, Crystal M. *et al* (2002) *Impact of Increased Syringe Access: Preliminary Findings on Injection Drug User Syringe Source, Disposal, and Pharmacy Sales in Harlem, New York*. Journal of the American Pharmaceutical Association, 42 (supplemental 2) Pg S77-82.

End Notes

²¹ (2004) *Community Options for Safe Needle Disposal*. United States Environmental Protection Agency online at www.epa.gov/osw

²² Information on the San Francisco AIDS Foundation HIV Prevention Project (Needle Exchange). Online. Available: <http://www.sfaf.org/prevention/needleexchange>

²³ Ten Longs Drugstore Pharmacies, nine Rite Aid Pharmacies and two Walgreens pharmacies have committed to participation in an authorized local Disease Prevention Demonstration Project either verbally or in writing during the period of February to May 2005.

²⁴ Information on the New York Enhanced Syringe Access Program (ESAP) can be found at: www.health.state.ny.us/nysdoh/hivadis/esap/regover.htm

²⁵ Alameda County and Santa Cruz County are exploring the potential for surcharges to be added to syringes for proper disposal, personal communication with Alessandra Ross, State Office of AIDS on May 13, 2005.

²⁶ Turnber, Wayne L. *et al* (2002). *Community Needle Collection and Disposal Programs in Florida*. Journal of the American Pharmaceutical Association. 42 (supplemental 2) Pgs S108-109.

²⁷ Personnel communications with Leslie Wells, Recycling Specialist, County of Santa Barbara, Public Works Department Solid Waste Division and Gabriele Brown, Clinical Lab Director, County of Santa Barbara Public Health Department from February 2005 through May 2005.