



PRODUCT STEWARDSHIP INSTITUTE

Sustainable Solutions to Protect Our Environment

Medical Sharps Product Stewardship Dialogue Stakeholder Meeting #2

DRAFT Meeting Summary

Sacramento, CA

September 23-24, 2008

ATTENDEES

The meeting was attended by 33 participants, with another 20 participating via conference call over the course of the two-day meeting. The final participant list is on the PSI meeting webpage at <http://www.productstewardship.us/MedicalSharpsMeetingSacramentoCA>.

MEETING MATERIALS

This meeting summary, final agenda, PowerPoint presentations, and other materials are posted on the PSI meeting webpage (above). This webpage should be consulted when reviewing these notes.

WELCOME AND INTRODUCTIONS

Rosalie Mulé, Board Member of the California Integrated Waste Management Board, welcomed the group, thanked PSI for its work on the sharps issue, and emphasized the importance of solving the sharps disposal problem. She shared the example of a recycling worker who was stuck by a needle on the job due to improper disposal practices, and the very real costs and fears that he faced. California is a leader on these and other waste issues, and is working to implement SB 1305, which bans the disposal of medical sharps in solid waste, green waste, or recycling.

Thank you to Waste Management for sponsoring this phase of the dialogue, including meeting preparation, facilitation, workgroups, and other follow-up activities.

OVERVIEW OF PSI DIALOGUE PROCESS, GOALS, AND MEETING OBJECTIVES

Scott Cassel (PSI) reminded the group that the task for dialogue participants is to jointly develop and implement collaborative solutions. He restated the goal: *To maximize the safe and environmentally sound collection and disposal of waste sharps by developing a nationally coordinated system that is financially sustainable.* He also restated the focus: *This project will focus on sharps generated outside the traditional health care setting, including households, hotels, casinos, restaurants, airports, and other public venues.* There was agreement from the first meeting that sharps should not be in the waste stream, and that additional discussion and research are needed to determine the best way to make that happen.

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Scott reported that the Data Workgroup met via conference calls after the first meeting with a goal of reaching consensus on the nature & scope of the problem. The Projects Workgroup also met via conference calls after the first meeting with a goal of developing pilot project(s) and/or gathering data from existing programs to design a safe collection and disposal system that is replicable nationwide. During the first meeting, the following issues were put into a “parking lot” for later consideration: model legislation (including disposal ban), public education and outreach (once collection options are deemed adequate), and performance metrics and goals.

CALIFORNIA UPDATE

Update from California, Jim Cropper (CA Integrated Waste Management Board)

The California Integrated Waste Management Board (CIWMB) is currently supporting the implementation of SB 1305, although there is no enforcement mechanism to enforce the disposal ban. The CIWMB has a [website](#) that lists about 500 existing sharps collection locations in the State and is implementing a widespread public education campaign.

A second piece of relevant legislation, AB 501, was vetoed by the Governor following the meeting. It would have required pharmaceutical manufacturers to provide containers, information on safe disposal options, or mail-back with all pre-filled devices at the request of the patient. This requirement would have been satisfied by providing a coupon for a sharps container or a toll-free number or website with information on where approved sharps containers can be purchased. According to Governor Schwarznegger’s veto message to the California State Assembly, the bill would have provided a disincentive for manufacturers to use pre-filled devices, relied too heavily on consumers to access the sharps disposal options, and was not clear enough about who would bear the ultimate cost of the sharps containers.

California Board of Pharmacy stated that its regulations currently do not allow pharmacies to collect sharps, although it intends to resolve this with legislation in the upcoming session.

Local Government Perspective, Rob D’Arcy (Santa Clara County, CA)

Santa Clara’s Household Hazardous Waste (HHW) program manages many problematic waste streams, including waste sharps. Three fire stations have collected an estimated 2% of the waste sharps generated in the County, and the County is now focused on where the other 98% will be collected now that the SB 1305 disposal ban is in effect. At approximately \$60,000 per year, Rob estimated that sharps disposal for the County is significantly less expensive than other problematic waste streams. Since HHW programs are expensive and inconvenient, Rob stated that government should not become bigger to handle this problem. Instead, he believes that manufacturers should pay for disposal, retailers should collect wastes, and that government should implement education and enforcement plans. Currently, the pharmacies voluntarily collecting sharps in Santa Clara County are paying the disposal costs.

BACKGROUND ON WASTE MANAGEMENT

“Municipal Waste Management 101,” Ben Hoffman (Waste Management)

Ben used a diagram to discuss the management flow of municipal solid waste, from collection at households and businesses, to transport to transfer stations or recycling facilities, and to ultimate disposal at landfills and waste-to-energy plants, or to manufacturing plants for recyclable materials. Needle-stick risks are high at single stream recycling facilities where the recyclable

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materials are often sorted by hand. Larry Sweetser added that California's sharps law was driven by concerns about the number of needle-sticks at recycling facilities. Ben estimates that the number of needle-sticks is significantly under-reported.

"Sharps Treatment and Disposal 101," Alex Napier (Stericycle)

The Occupational Safety and Health Administration (OSHA) and the Department of Transportation (DOT), as well as the Centers for Disease Control and National Institutes of Health, govern the packaging, labeling, and documentation, generation, transport, treatment, and disposal of medical waste. The primary treatment methods used today are autoclaving and incineration. Autoclave essentially "pressure treats" the waste to disinfect it, and is preferable for environmental and cost reasons. However, heavily contaminated waste streams may require incineration. Once waste is rendered non-infectious through treatment, it is disposed of in municipal solid waste landfills or incinerators. Treated waste may or may not be required to be rendered unrecognizable, depending on state standards. Transportation represents the largest component of the cost of treating medical waste.

WORKGROUP REPORTS

Data Workgroup, Sierra Fletcher (PSI)

The purpose of the Data Workgroup is to develop consensus on the nature and scope of the problem. Workgroup members compiled and reviewed the available literature on the incidence of needle-sticks in the solid waste industry, costs of needle-stick injuries, viability of diseases outside the body, and the probability of the transmission of various diseases. Overall, data specific to the "community" setting (outside the healthcare context) is sparse, with needle-stick data particularly lacking. Data on sharps disposal practices is limited. The Workgroup concluded that needle-sticks are not commonly reported in the waste industry, the risk of disease transmission from a needle-stick is generally low, and we do not know where and how often needle-sticks are occurring outside the healthcare setting. However, costs can be significant for both individuals and their employers, and of the large number of sharps used for self-injection today, the majority are going into the solid waste stream.

Safety-engineered devices very likely reduce the risk of needle-sticks in the home, although their compaction in trash trucks exposes workers to the needles once again. In addition, dialogue participants expressed concern about whether the cost of requiring the devices in the home would be greater than the benefits derived. They are required in the healthcare setting, but are not reimbursable. In the regulated healthcare setting, such devices must still be treated as medical waste.

The Workgroup's literature review summary tables are available on the [meeting website](#) (link above).

Key Questions Raised by Participants

- What is the cost per pound or unit for various disposal options?
- What might be the benefits of using safety-engineered devices more widely?
- What types of programs are most effective, and how can this be measured?

Next Steps

- The data remaining data questions listed above will be incorporated into the

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Demonstration Project Workgroup established at the end of Dialogue Meeting #2.

- Angela Laramie from the MA Department of Public Health will provide a literature summary on the evidence that using safety-engineered devices reduces the incidence of needle-sticks. The current literature focuses on the healthcare setting, but any available studies addressing the community setting will be captured as well.

Projects Workgroup, Jenny Schumann (Coalition for Safe Community Needle Disposal)

The Workgroup conducted an informal survey of 18 sharps collection programs in different parts of the country, representing both mail-back and collection of sharps at retail pharmacies, public facilities (both HHW and others), and “hybrid” programs that use different types of sites.¹ The Workgroup identified financial sustainability, safety/convenience, and quality of public education as the most important criteria of a program, although performance was determined to be the most important ultimate variable. Many syringe exchange programs have been successful, but often do not have adequate funding to scale up as needed to serve all sharps users. Overall, most programs are financed by government grants and are unable to support on-going public education efforts. Costs were very hard to capture since funding often comes from multiple sources, includes in-kind costs, and/or is difficult to break down. Performance data was not collected at this time.

Key Questions Raised by Participants

- Is a standardized sharps container needed, or will a less costly substitute (e.g., laundry detergent bottle) suffice?
- Who should design and implement public education efforts?
- How much do different types of programs cost
- How can performance be measured? Which types of programs are most effective?

Next Step

- The additional questions (listed above) will be incorporated into the new Demonstration Project Workgroup.

ROLE OF RETAIL PHARMACIES

Eureka Sharps Collection Program, Cherie Fischer (Chrysalis Environmental) with Dave Feeney (Oxnard Pharmacy, Rhode Island)

The Eureka Sharps Collection Program was started in 1999 because of needle-sticks at a Rhode Island Materials Recovery Facility (MRF). Sharps collection kiosks were deployed at 40 retail pharmacies and other public locations. Over 6 million sharps have been collected, and there has been a 50% reduction in loose needles at the MRF. CVS, Walgreens, and independent pharmacies are currently collecting sharps. Dave Feeney, from Oxnard Pharmacy, touted the “turnkey” kiosk solution that was created and reported on overall positive experiences as a retail pharmacist working with the program. His pharmacy started collecting sharps because it was “the right thing to do” to help solve a public health issue and they wanted to keep the business of

¹ The following programs were surveyed: Retail Pharmacies (San Francisco, CA; City of Sioux Falls, SD); Collection at Public Facilities (Boone County, IN; New Hampshire; San Bernadino, CA; Shasta County, CA; Barnstable County, MA; Franklin County, MA); Syringe Exchange Programs (Massachusetts, New Mexico); Residential Special Waste Pick-up (Columbus, GA); Collection at HHW (Pulaski County, AR); “Hybrid” Collection Locations (Eureka Program in Rhode Island; LA County; Scott County, IL and Rock County, IA); and Mail-back from Home (Orange County, CA).

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their customers with diabetes. There have been two minor incidents (when the kiosk was full), but these were managed and future problems averted with modifications to the kiosk design.

Retail pharmacies interested in collecting sharps using the kiosk may face challenges associated with the space needed in their store, liability (if there is an accident), safety for staff and customers, staff time needed for oversight (mitigated, in this case, with the “hands-off” kiosk model), and disposal costs.

Next Step

- The Workgroup will develop a two-page overview of how retail pharmacies can collect sharps safely. The overview will be based on the experiences of retailers who *are* collecting sharps, and the concerns of those who are *not*.

PRODUCT STEWARDSHIP SHARED RESPONSIBILITY AND FINANCING MODELS

California’s Extended Producer Responsibility Framework, Heidi Sanborn (California Product Stewardship Council)

Local governments are unable to properly manage the quantity of waste currently generated. The California Integrated Waste Management Board has adopted a framework approach to waste management that designates the roles of various stakeholders to alleviate the responsibility on local government by making those involved in the manufacture of the product responsible for collection and recycling or disposal. Retailers, local and state government, and other stakeholders also have important contributions. Heidi anticipates that framework legislation will be introduced this year with broad support. More information on the framework is available at: <http://www.calpsc.org/policies/state/epr-framework.html>.

In other examples of producer responsibility systems, product management costs typically come down significantly when the system is designed and implemented by the producers.

During the discussion period, several participants stressed that all products are unique, and that some of the special characteristics of medical sharps are:

- Consumers do not choose to become ill so that they don’t choose to use the product.
- Generally, there is a third party insurer paying for the product (with deductible).

Financial Flows in the Medical System, Margaret Nowak (Avalere, LLC)

Under the Social Security Act, the Centers for Medicare and Medicaid Services (CMS) manages publicly-financed health insurance in the U.S. CMS also sets the standards for many private insurers. Since Part D prescription drug benefits were established by Congress in 2006, many private insurance plans have contracted with Medicare to provide services. Part D covers most prescription medicines and the devices required to use them: this includes insulin and associated syringes, but does *not* include devices accompanying many other self-injected drugs except pre-filled devices. Part D explicitly *excludes* sharps disposal costs. Congress would need to pass legislation for the federal government to reimburse insurance plans for disposal costs. Alternatively, insurance plans could pass costs on to their enrollees. An estimated two-thirds of sharps consumers are insured. (Lancets are covered under Part B.) State laws determine what can or will be covered by private insurers in each state.

Coalition's Legislation

Working with the Coalition for Safe Community Needle Disposal, U.S. Senator Isakson (R-GA) and U.S. Representative Ferguson (R-NJ) introduced companion bills² in 2007 to include sharps disposal coverage under Part D. The bill was scored in the summer of 2008, but no action was taken on it. It would need to be reintroduced in the new session.

Options for Shared Responsibility and Discussion (Scott Cassel, PSI)

While there are many ways to share responsibility, the critical question is which entity (or entities) will actually pay for safe sharps disposal in a potential future system. The following possible options were suggested:

- Medical sharps manufacturers
- Pharmaceutical manufacturers
- Health insurers
- Pharmacy benefit managers (administer services for insurers or provide services directly to self-insured), such as Medco, Caremark, or Express Scripts
- Wholesalers, such as McKesson
- Pharmacies
- Solid waste management companies (which benefit from reducing sticks)

Several dialogue participants stressed that patients should not bear an undue burden. On average, people with diabetes already pay above-average healthcare costs. They fear that, if the costs to collect and safely dispose of sharps are added to the product purchase price, the patient might have one more reason not to take their medications. This could result in higher health care costs (e.g., diabetes could turn into blindness or amputation). There are several options to educate the public about safe sharps disposal, including diabetes educators, nurses, pharmacists, and, to a lesser extent, physicians. Packaging is also an issue in terms of environmental impacts and cost. Some participants were interested in exploring a lifecycle approach to the management of sharps, including the potential for syringe recycling and packaging reuse.

Next Steps

- Ben Hoffman will work with PSI to develop a flow chart showing the chain of responsibility of sharps devices from manufacturer to consumer.
- PSI will work with stakeholders to develop a chart that indicates the devices that are covered by Part D (and those that are not), and will continue to develop a chart that pairs the manufacturers with the devices and drugs they produce.

DISPOSAL OF SHARPS USED ON ANIMALS

Millions of sharps are used each year to vaccinate and treat animals, often outside the bounds of existing regulations. Treatment of pets in the home is increasingly common, and sharps are used in large quantities in the beef, swine, and poultry industries, as well as horse and other types of farms. In most places, large farming operations are subject to at least minimum standards for the management and disposal of used sharps. The dialogue group felt that, while large animal operations should be regulated, this group is focused on sharps generated in the non-regulated residential setting, such as those devices used for the treatment of pets in the home. Special solutions do not need to be developed, although veterinarians could be critical in educating their clients about the disposal of sharps used on their pets at home.

² S. 1909 and HB 2351

Boone County, IN Sharps Collection, David Lamm (Boone County, IN)

Boone County's HHW-managed sharps collection program successfully collects sharps from residential and agricultural users, and includes collection at feed co-ops. There have been no problems caused by collecting the relatively larger quantities of sharps dropped off by farming operations.

Marilyn Corbin, Elanco Animal Health

The beef and swine industries generate an estimated 75% of sharps used in farming operations, with the beef industry alone responsible for roughly 5 million sharps per year. Sharps are used for vaccines, therapy (vitamins, anti-inflammatory treatment), and reproductive management. The voluntary Beef Quality Insurance Program includes the following sharps disposal guidelines:

- For "self-disposal," place sharps in rigid, labeled container with screw-top. Fill with concrete or other substance and seal. Notify landfill of the container's contents upon delivery. Alternatively, heat container to melt needles, then bury on the property. Improper sharps disposal can impact property sale.
- Contract with a veterinary clinic or feed yard for an appropriate container and disposal.
- Pharmaceutical companies may provide disposal as a customer service.

NEXT STEPS: NEW WORKGROUPS

The following two workgroups were formed at the meeting to replace the data workgroup and the projects workgroup:

1. **Retailer Engagement Workgroup:** This Workgroup will develop a 2-page overview of how retail pharmacies can collect sharps safely based on the experiences of retailers who *are* collecting sharps, and the concerns of those who are *not*. The Workgroup will develop and implement a strategy for disseminating this document when final.

Workgroup members:

1. Wesley Badillo, NY Department of Public Health
2. Cherie Fischer, Chrysalis Environmental Services
3. Kathy Gold, American Association of Diabetes Educators
4. Karen LeBoeuf, Chrysalis Environmental Services
5. Donna McMeikan, Can-Am Care
6. Cooky Quandt, Longs Drug
7. Jenny Schumann, Coalition for Safe Community Needle Disposal
8. Karl Schumann, BD

The following contacts were suggested:

1. National Association of Chain Drug Stores (Mary Staples, via Cooky Quandt)
2. Wal-Mart (Donna McMeikan)
3. National Community Pharmacy Association (Karl Schumann)
4. Walgreens (Heidi Barsuglia)
5. CVS (Heidi Barsuglia)
6. Caremark (Heidi Barsuglia)

2. **Demonstration Project Workgroup:** This Workgroup will design a demonstration project for a specific county, state, or region (to be determined by the Workgroup). The Workgroup will identify the type of collection locations, logistics, public education, associated costs, and financing system for a program that meets the needs of all sharps stakeholder groups. Workgroup members:

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1. Wesley Badillo, NY Department of Public Health
2. Lorraine Cancro, GlaxoSmithKline
3. Jim Cropper, CA Integrated Waste Management Board
4. Rob D'Arcy, Santa Clara County
5. Tom Erickson, UltiMed
6. Cherie Fischer, Chrysalis Environmental Services
7. Kathy Gold, American Association of Diabetes Educators
8. Steve Hughes, MA Department of Public Health
9. Burt Kunik, Sharps Compliance, Inc.
10. Karen LeBoeuf, Chrysalis Environmental Services
11. Mollie Mangerich, Sonoma County
12. Alex Napier, Stericycle
13. Roy Petre, MA Department of Public Health
14. Ken Schell, CA Board of Pharmacy
15. Jenny Schumann, Coalition for Safe Community Needle Disposal
16. Karl Schumann, BD

A sub-group of the following individuals will work on developing performance goals/metrics for the demonstration project:

1. Cherie Fischer, Chrysalis Environmental Services
2. Angela Laramie, MA Department of Public Health
3. Karen LeBoeuf, Chrysalis Environmental Services
4. Alex Napier, Stericycle
5. Jack McGurk, Sharps Compliance, Inc.

NEXT STEPS: MEETING #3

Meeting #3 will be held in Boston on January 13-14, 2009, with funding from Becton, Dickinson and Company Diabetes Care.

Missing Stakeholders

1. Service Employees International Union (Angela Laramie)
2. PhRMA
3. Teamsters (Ben Hoffman)
4. American Plastics Council
5. American Chemistry Council
6. Associations associated with sharps consumers (Jenny Schumann)
 - a. Hepatitis
 - b. Fertility
 - c. Arthritis
 - d. MS
 - e. Growth Hormones
7. Environmental Groups
 - a. RiverKeepers
 - b. Marine Councils
 - c. Greenpeace
 - d. Heal the Bay
 - e. Surfriders
8. NASDA (Jenny Schumann)
9. Injection Drug Users Health Association (Wesley Badillo)

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10. Fire/police associations
11. Insurers/PBM (Ken Schell)

