



To: Members of PSI's National Dialogue on Medical Sharps
From: Scott Cassel and Sierra Fletcher, PSI
Date: October 30, 2009
RE: Status of PSI's National Dialogue on Medical Sharps

BACKGROUND

Since developing the [Product Stewardship Action Plan for Medical Sharps](#), PSI convened [National Dialogue Meetings](#) in May 2008, September 2008, and January 2009 on the medical sharps issue. We also convened a small group meeting in July 2009. This memo describes our understanding of the current state of the issue with regard to the dialogue goal, agreed to at the first meeting, of *maximizing the safe and environmentally sound disposal of waste sharps that is financially sustainable*.

PSI FUNDING HAS BEEN DEPLETED

Funding for our medical sharps initiative, while greatly appreciated, is now depleted. PSI contributed a significant amount of its own resources to keep this project going. We would very much welcome the opportunity to continue to work with any interested stakeholders to develop model legislation, implement and evaluate a demonstration program, or conduct other funded project work where PSI can add value.

SHARPS SHOULD NOT BE DISPOSED OF IN THE WASTE STREAM

There was agreement at the first meeting that sharps should not be disposed of in the waste stream, and that additional discussion and research are needed to determine the best way to ensure their safe management. Of the estimated 3.1 billion sharps used outside the healthcare setting annually, the majority are going directly into the solid waste stream. While there are differences of opinion - and sparse data - on the *scale of the impact* of sharps in the waste stream, no one has argued that it is *safe* to dispose of sharps this way, and some states have banned it completely. Based on the efforts of a multi-stakeholder workgroup over the summer of 2008, participants in Meeting #2 agreed that needle sticks are not commonly reported in the community setting (e.g., outside healthcare facilities), and we do not know where and how often needle sticks occur outside the healthcare setting. They also agreed that, while the risk of disease transmission from such a needle stick is generally low, costs can be significant for both individuals and their employers.

NEXT STEP: A DEMONSTRATION PROJECT IN MASSACHUSETTS

PSI's workgroup also collected data on the costs associated with different sharps collection systems and programs. By the conclusion of Meeting #3, participants agreed that PSI would attempt to arrive at an agreement with key stakeholders to implement a Demonstration Project in Massachusetts. Stakeholders agreed that further pilot projects were not needed, and that they would collect additional data on the cost and logistics of implementing a statewide sharps collection program. As a key part of the program evaluation, participants would determine the degree to which safe sharps collection reduced the incidence of needle sticks outside the healthcare setting. Participants would use the experience gained in Massachusetts to develop legislation in Massachusetts, California, and other states. Such coordinated

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rollout would streamline the effort required by states to develop programs, and ensure that participating companies would avoid a patchwork of approaches. Without an agreement, it was understood that states would continue to seek legislation for the solutions they need, and this legislation would likely vary as different models emerged across the country.

NO CONSENSUS ON FUNDING A DEMONSTRATION PROJECT IN MASSACHUSETTS

Following Meeting #3, PSI developed a proposed workplan based on input provided at the meeting, and sent this to all dialogue participants. Waste Management proposed, and funded, a small meeting that PSI facilitated in July 2009 to seek agreement among manufacturers of medical sharps devices and self-injected pharmaceuticals to implement the MA Demonstration Project using Waste Management services. If an agreement had been reached, PSI's role would have been to convene a wider stakeholder group to provide input into the project design, implementation (including data needs), and evaluation. To date, no consensus has been reached as to how to fund the MA Demonstration Project. Participation of sharps device manufacturers has been strong throughout the dialogue, with some offering to contribute sharps containers to a Demonstration Project if other conditions were met for wider stakeholder participation. However, only one pharmaceutical company indicated interest in supporting such an effort.

PSI RECOMMENDATIONS TO SOLVE THE MEDICAL SHARPS DISPOSAL PROBLEM

Based on our understanding of the issue, PSI makes the following recommendations:

1. **Legislation is required.** This project offered the opportunity for companies and government agencies to develop a joint solution. Unfortunately, no pharmaceutical company participated consistently in the two-year process, which increased the cost of this initiative and made it difficult to reach the kind of understanding that typically builds from one meeting to the next. Although the opportunity to work collaboratively on a demonstration project, and then model legislation, is still possible, PSI believes that unilateral state legislation is the only alternative to address this problem without relying on public funding. Legislation will "level the playing field" for all pharmaceutical companies, so that each is required to step up to solve this public health problem in an equitable manner.
2. **Primary funding for the solution should come from pharmaceutical companies.** Most sharps devices are used to deliver medications made by pharmaceutical companies. Therefore, these companies are in the best position to bear the primary financial responsibility for implementing programs to eliminate or mitigate the potential impact of sharps devices after their use. The additional cost can best be internalized in the sale of self-injected pharmaceuticals, rather than applied to the typically much less expensive sharps devices. Discussions in the PSI dialogue made it clear that government agencies do not have the funding to address this problem. In addition, consumers cannot be expected to pay for the disposal of sharps *after* the products have already been purchased. PSI believes that pharmaceutical companies making self-injected medications could successfully negotiate with sharps device manufacturers to contribute to such an effort by providing containers. Companies should have the flexibility to determine the most effective collection and disposal methods depending on their product and business relationships. Technological innovations that will improve safety and save money should be considered. Programs designed specifically for injection drug user use, such as the needle exchange programs that are successfully operating in many states, should continue as well. These programs will likely continue to rely on government funding.

3. **Performance goals should be required.** States passing legislation should require that pharmaceutical manufacturers meet collection performance goals that reflect significant progress.
4. **Retail pharmacies should play a strong role.** PSI believes that retail pharmacies provide a key information link to the patient and can serve as a convenient collection point for sharps disposal. Therefore, we believe that a leadership group of retail pharmacists should *voluntarily* step forward to test out collection logistics, costs, and benefits. We also recommend that the costs for retailers to dispose of the sharps be paid for by pharmaceutical companies. We believe that enough retailers will understand that offering collection enhances customer satisfaction, allows stores to provide another service to their customers, and is a powerful incentive to attract customers into the store. To date, however, the interest among retail pharmacies in collecting sharps, even on a voluntary basis, has been growing but tepid.
5. **Stakeholder coordination should continue.** Continuing to share information across states and sectors will provide the greatest possible chance of a coordinated and cost-effective solution. The information gained from one place can inform efforts elsewhere. With a coordinated effort centered around a model program or piece of legislation, companies can avoid managing a patchwork of programs in the future and reduce program costs. This collaboration can only happen through active coordination.

THANK YOU TO OUR DIALOGUE PARTICIPANTS

PSI welcomes the opportunity to work with any of our dialogue participants to reinvigorate the MA Demonstration Project or to pursue model state legislation.

PSI's work benefited from the participation of self-injected pharmaceutical drug manufacturers, device manufacturers, state and local public health officials, medical and solid waste service providers, and consumer and public health advocacy groups. The process was made possible primarily by contributions from Waste Management; the Massachusetts Department of Public Health; and Becton, Dickinson and Co. Diabetes Care. PSI would also like to thank Ulti-Med for its meeting sponsorship, and everyone in the dialogue for the time, resources, and expertise they provided to this process. We continue to appreciate the many efforts underway around the country to provide services and advocate for a safe sharps disposal solution for the large and growing number of people treating themselves with self-injected pharmaceuticals in this country.