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Congressman Jay Inslee
U.S. House of Representatives
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August 13, 2009

Dear Director Kerlikowske and Congressman Inslee:

Thank you for convening your drug policy roundtable discussion on August 8, 2009. We greatly appreciate your dedication to addressing the serious problem of prescription drug abuse in our communities. As you know many organizations have been working on secure and effective medicine return for several years. This letter offers additional thoughts regarding one of the issues discussed – requirements to count or inventory pills that are collected for disposal through a medicine return program.

We wholeheartedly agree that medicine return programs must be managed with strong security protocols for securing and tracking returned drugs to minimize any opportunity for diversion. However, we do not think that counting or inventorying returned medicines is an effective measure that will decrease the risk of diversion. Our key concerns about requirements to inventory returned medicines are:

Requiring an inventory of each collected pill offers an unnecessary opportunity for diversion by providing an access point to those medicines by pharmacists or other operators of medicine return programs.

Because an unknown amount of medicines will be returned in a take back, there is no mechanism to stop a pharmacist or other operator of the return program from recording a lower number of medicines than what he or she has actually received.

Requiring pharmacists or police to count each pill will greatly increase the cost and time involved in collecting medicines and will discourage organizations (pharmacies, sheriffs' offices, etc.) from offering medicine return programs.

Other procedures that are more effective and less onerous can ensure security at drug drop-off locations.

The following security procedures have been demonstrated at the medicine return program at 25 Group Health and 12 Bartell Drugs locations in Washington State. Although that program does not accept controlled substances, it was designed and operates as if it were collecting them, with a high level of security and strict tracking of the collection containers.

- **Secure and visible containers:** Medicines are collected in secure metal containers that are located in front of the pharmacy counter but in direct view of the pharmacists. The drugs are deposited by residents, and are not handled by pharmacy staff. The containers are bolted to the ground or chained to the wall. Containers are designed so people cannot put their hands into them to retrieve medicines – there are either baffles built into the containers or the container uses a mail-box type opening.

- **Limited pharmacist access:** Containers are equipped with double locks so two pharmacy staff must be present with separate keys to open the container. Inside each metal container is a bucket or box where the medicines are collected. Two pharmacy staff close the bucket or box, and secure it with a uniquely numbered security tag or seal. Once closed, any attempted diversion would require breaking the security tag/seal and tampering would be evident. **Counting medicines prior to closing the security tag would mean additional handling and extended access to unsecured medicines, likely increasing the opportunity for diversion.**
- **Secure tracking and auditing:** The bucket or box is tracked with a unique identification number from the point the bucket or box is closed, to when it is shipped to the central pharmacy warehouse, to final destruction. Tracking paperwork is completed and kept on file for auditing purposes.
- **Government oversight:** The Board of Pharmacy has oversight of the Group Health and Bartell Drugs program. A collection protocol for each location must be approved by the Board of Pharmacy before implementation.

This system has been in operation for 2 ½ years with no indications of attempted diversion. Over 2,000 buckets and boxes containing more than 25,000 pounds of collected drugs from Group Health and Bartell Drugs were all accounted for with no signs of tampering or attempted diversion.

To summarize, we believe that medicine return to pharmacies and police stations can be implemented securely through tracking of buckets that store the medicines. Requiring pills to be counted will not significantly reduce risks of diversion, but it will increase the time, labor and expense of a medicine return program to such a degree that very few organizations will want to participate.

We look forward to continuing to work with you to develop policy that allows for the secure return and safe disposal of unwanted medicines from households. Thank you for the smart and caring leadership you are providing on this important issue.

Sincerely,

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