

June 3, 2016

Mr. Gary M. Goldbaum, MD, MPH
Snohomish County Health Officer
3020 Rucker Avenue, #300
Everett, WA 98201-3971
cc: Members, Snohomish County Board of Health

Dear Dr. Goldbaum,

The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully submits comments in opposition to the Snohomish County Board of Health Draft Pharmaceutical Stewardship proposal that would mandate prescription drug manufacturers to create, implement, and fund a drug take-back program. This proposal is unlikely to solve any perceived public health issue and will likely never be implemented as envisioned.

The biopharmaceutical industry is committed to working with the entire drug supply chain to help address issues associated with secure disposal, adhering to prescription medicines and prescription drug abuse. PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures. Innovative medicines, such as those developed by PhRMA's members, account for approximately 10 to 15% of the prescription medicines filled in Snohomish County – the rest are generic medicines.

We appreciate the County's interest in reducing prescription drug abuse and the trace amounts of pharmaceuticals in the environment but this proposal will not solve those issues. Specifically, the vast majority of pharmaceutical traces in the environment are from patients digesting and excreting their medicines. Further, community collection sites could become targets for diversion, increasing, rather than decreasing, the issue of prescription drug abuse. As an alternative, we support efforts to educate consumers on how to take medicines as prescribed, securely store medicines, and safely and effectively dispose of unused medicines in the home through our "MyOldMeds" campaign which will be launched in Washington in the coming weeks.

PhRMA opposes drug take-back mandates which would require pharmaceutical manufacturers to fund and administer a new program to specially collect and dispose of unused pharmaceutical products. There are a myriad complications associated with the disposal of unused medicines outside of the otherwise broadly recommended household trash method. These complexities play a significant role in the establishment of such a product take-back program and have resulted in a severely limited program in Alameda County, California – not to mention a substantial and unnecessary price tag borne by all participants in the healthcare economy. In King County, Washington, one of the stewardship organizations, ReturnMeds, is withdrawing its participation as an approved stewardship plan under King County's Regulations because of the complexities of the program.

Our opposition is hinged on the fact that these programs will not work, again as seen in Alameda, and will not address environmental concerns or drug abuse. While we remain opposed to the proposal as drafted, we appreciate the inclusion of preemption language should a state or federal take-back program be created.

Our main areas of concern with the proposal as drafted are incorporated below:

Alameda: A Fundamentally Flawed Program

The proposal is very similar to Alameda County's unsuccessful drug take back program. As seen in Alameda, the proposed drug take-back program will be severely limited because of the rigorous safety standards necessary to comply with the regulations issued by the U.S. Drug Enforcement Administration (DEA) for drug disposal. In fact, kiosk collection in Alameda has yet to commence. Per the DEA regulations, any kiosk-based take-back program that will or could reasonably be expected to collect controlled substances will need to be located at only a handful of regulated sites. Specifically, law enforcement offices, pharmacies, certain hospitals with pharmacies, long-term care facilities, and pharmaceutical manufacturers (but regulations only allow manufacturers to collect at their physical DEA registered locations). Interestingly, representatives from the pharmacy community have consistently indicated a disinterest in hosting kiosks due to the attendant compliance obligations and diversion risks.

This difficulty in securing community-wide kiosk locations is obvious in Alameda. And for good reason: kiosks are necessarily a collection point – a very visible one – for prescription medications. Unfortunately, this also makes them a target for diversion, so we understand why pharmacies do not want to take on this liability. This is why recommendations for in-home disposal, as is widely accepted throughout the healthcare system, are so attractive. In-home disposal has the dual advantage of not amassing a publicly accessible collection of prescription medicines, but it also makes the entire process intuitive and accessible to the widest range of consumers. Moreover, such a disposal method avoids the regulatory complexities of a program that must comply with multiple state and federal regulations.

DEA Regulations

The proposal completely fails to recognize the complexities of the DEA regulations for disposal of controlled substances. Take-back programs, whether industry funded or not, are regulated by the DEA if they collect, or may reasonably be expected to collect, controlled substances. In programs that contain consumer-facing collection, it is a virtual certainty that consumers will deposit controlled substances, thus triggering the oversight of the DEA. And, to be sure, even if there is an explicit warning to not deposit controlled substances, the DEA regulations apply even if these products are *inadvertently* returned.¹ Since no collection program will be able to be monitored at all times, any realistic program will need to operate in compliance with DEA regulations to ensure complete protection from inadvertent controlled substance liabilities.

Like the program in Alameda, simply shifting the funding and coordination activities of such a take-back program on to industry does not mitigate the responsibilities for compliance of the local pharmacies and law enforcement agencies that might serve as hosts for these kiosks. In fact, the DEA rules prohibit the mitigation of a pharmacy's regulatory burden by having a distributor or other entity maintain the collection receptacle at the subject pharmacy for them; thus the opposition to hosting kiosks by the pharmacy community during the stakeholder meetings in California.

Mail-back Programs: Increased Risk of Diversion

The proposal requires a mail-back option for all residents to return unused medicines. PhRMA has serious concerns about the high likelihood of diversion that could occur with drug mail-back programs. Further, such a program is unquestionably the costliest and least efficient alternative.

Currently, there are mechanisms in place to secure medicines in the supply chain moving from manufacturers to the patient, but a reverse system to secure medicines from the patients back through the mail does not exist. For

¹ See 79 Fed. Reg. 5320, 5329 (Sept. 9, 2014) ("[A]ll [DEA] regulations and laws relevant to controlled substances will apply if controlled substances are collected, even if inadvertently.").

example, mail-back programs do not have a completely secure way to track medicines sent from the patient to a DEA-compliant facility for destruction. It is reasonable to expect that drug take-back mailers would be targets for those wishing to divert medicines for misuse and abuse. Additionally, DEA requires on-site and immediate destruction of mailed-back packages. Presently, our research has not identified such a certified facility in the US.

Finally, this proposed program ignores the real goal underlying the idea of take-back: minimizing the possibilities that unused medicines meet an undesirable end. Nothing suggests that consumers will actually use such programs, and, in fact, much evidence cuts in the opposite direction.

An Alternative for Safe and Secure Disposal of Unused Medicines: In-Home Secure Disposal

Instead of implementing a flawed, unsuccessful program, we urge the County to consider meaningful, measurable and comprehensive mechanisms to educate consumers on how to safeguard medicines in the home, how to ensure patients are taking their medicines as prescribed – thereby significantly mitigating unused medicines in the first place – and how to safely and securely dispose of their truly unused medicines in the household trash. PhRMA will be launching the “MyOldMeds”(<http://myoldmeds.com>), campaign in Washington in the coming weeks.

The comprehensive, innovative education program is a multiyear, multichannel, multilingual campaign that is customized for the County’s diverse citizenry. The goal of this program is to increase awareness and understanding of the importance of taking all medicines as prescribed and directed, how to safely store your medicines and sharps in your home, and the process for disposing of medicines and sharps properly, either in the home or through existing collection points.

Research demonstrates that household trash disposal is effective for disposing of unused medicines. For many, in-home medicine disposal offers a simple, convenient way to dispose of unwanted, unneeded or expired medication. Because all households already participate in the collection of household trash, in-home drug disposal is a safe and preferred way of disposing of unused medicine.

In-home medicine disposal offers many benefits. It removes the medicines from the home immediately so that the medicine is not available for misuse or abuse and it does not create any additional environmental impact or cost. It also gives community residents the ability to handle medicine disposal discretely and independently, and protects medical privacy when done properly.

In-home disposal effectively manages any potential environmental issues given that household waste in the U.S. is either incinerated or disposed of in capped, double-lined landfills equipped with leachate collection and treatment systems. Either technology effectively isolates waste from the physical environment. In-home disposal also avoids the environmental carbon footprint and costs of trips to a collection site and of separately shipping the collected pharmaceuticals for destruction.

PhRMA believes that Snohomish County should focus on educating patients on how to securely dispose of unused pharmaceutical products. The “MyOldMeds” Program which we have successfully launched in New York, Louisiana and Massachusetts instructs patients on how to safely dispose of medicines in the home using the following easy steps:

- Step 1: Pour medication into a sealable plastic bag. If the medication is in solid form (pill, liquid capsule, etc.), add water to dissolve it.
- Step 2: Add kitty litter, sawdust, coffee grounds or another mixing material to the plastic bag to make the solution less appealing for pets and children.
- Step 3: Seal the plastic bag and put it in the trash.

- Step 4: Remove and destroy all identifying personal information (for example, the prescription label) from the medication containers before recycling them or throwing them away. This helps to ensure medical privacy.

Based on the success of the launched programs in New York, Louisiana and Massachusetts, we know that educating consumers on safely storing and disposing of medicines in their own home works. The industry looks forward to expanding on those efforts in Washington and is committed to working with the County on such efforts.

In conclusion, the drug-take back mandates will not be easily or effectively implemented, as seen in Alameda, and will not have any meaningful impact on environmental or drug abuse concerns. We recommend that the County focus their efforts on promoting adherence to medication treatment regimens and educating constituents about the safe disposal of unused medicines instead of implementing a program which is doomed to fail. We look forward to further collaboration and engagement with you, including partnering with you on effective communication efforts like the "MyOldMeds" campaign.

Sincerely,



Kim Martin
Senior Director
State Advocacy, PhRMA