



Fax Transmittal

From the desk of:

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To: Supervisor Nathan Miley

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Marjorie E. Powell
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March 5, 2012

Honorable Nathan A. Miley
President
Alameda County Board of Supervisors
1221 Oak Street, Suite 536
Oakland, CA 94612-4305

Re: Opposition to the Alameda County Safe Medication Disposal Ordinance

Dear Supervisor Miley:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) to express our opposition to the proposed Alameda County Safe Medication Disposal Ordinance. Secure disposal is an exceedingly complex issue and the ordinance as drafted is impractical and will have numerous unintended consequences, including possibly increasing health care costs, risking access to medicine, and unintentionally increasing the diversion of medicines. Additionally, several safe and secure ways already exist to dispose of unused medicines.

1. Given the Drug Enforcement Administration (DEA) is already drafting federal rules per the federal *Secure and Responsible Drug Disposal Act of 2010* for the secure disposal of controlled medicines, it is premature to consider funding non-law enforcement drug collection programs. DEA guidance could drastically change the collection of unused medicines.

PhRMA is concerned that drug take back programs without law enforcement could undermine efforts to secure medicines by creating a greater potential for drug diversion through theft or misappropriation of collected medicines—designated sites for drug take back could become sites for drug diversion. Also, if passed now, Alameda County law may not conform with upcoming federal regulations and may require a complete overhaul when the DEA regulations go into effect. Mandating a non-law enforcement drug collection program at this time could waste valuable resources.

2. Drug take back programs do not address the issue of pharmaceuticals in the environment.

Scientists generally agree that the majority of the trace amounts of pharmaceuticals in the environment (approximately 90 percent) are from human use and metabolite of medicines—not from the improper disposal of medicines. For example, Dr. Raanan Bloom, an Environmental Assessment Expert in FDA's Center for Drug Evaluation and Research, has said, "...the main way drug residues enter water systems is by people taking medications and then naturally passing them through their bodies...Most drugs are not completely absorbed or metabolized by the body, and enter the environment after passing through waste water treatment plants."¹ Given this, drug take back programs are not expected to reduce residual amounts of pharmaceuticals in the environment.

¹ FDA Consumer Health Information. "How to Dispose of Unused Medicines."
www.fda.gov/consumer/updates/drug_disposal062308.html

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PhRMA member companies have conducted research that evaluated whether detectable levels of pharmaceuticals in the environment pose a risk to human health, evaluated methods for the effective disposal of human medicines, and they continue to study the potential effects of human pharmaceuticals and their metabolites in surface waters on aquatic life. Additionally, many technical experts have contributed to the on-going scientific research in the area of pharmaceuticals in water. The studies conducted to date, published in peer-reviewed journals, which include work on sensitive subpopulations, suggest that it is highly unlikely that the very small quantities of pharmaceuticals detected in the environment would be harmful to human health.^{2,3,4,5}

3. Research demonstrates that household trash disposal is effective for disposing of unused medicines.

Past guidance advised patients to flush unused medicines to ensure that unused medicines were quickly disposed of to prevent accidental poisonings, misuse, and abuse of medicines. However, PhRMA member company research concludes that household trash disposal and take back for incineration are equally effective at removing the unused medicine contribution to pharmaceuticals in water. A paper presented at the October 2008 Water Environment Federation Technical Exhibition and Conference found that if all unused medicines were placed in household trash and disposed of in municipal landfills, less than 0.1% of the total amount of medicine found in the environment would be contributed from landfills — the rest would be from patient use of medicine. Using current household trash disposal methods for unused medicines does not require the creation of a new, unnecessary infrastructure or the outlay of additional energy for special unused medicine collection.

In fact, PhRMA members used the 2010 Maine Landfill Leachate data to validate our calculations predicting the fate of pharmaceuticals in municipal solid waste (MSW) landfills. We compared the leachate concentration predicted by our model to Maine's measured concentrations and found that the Maine data completely supports our conclusion that MSW landfills are a very effective and environmentally acceptable disposal method for the patient.

4. Creating a new process for disposing of unused medicines is a complex task; it will require significant financial resources to secure medicines from diversion, transport medicines for disposal, and incinerate aggregated medicines in compliance with federal and state EPA and DEA laws and regulations.

Although the ordinance says there can be no charge for disposal at the point of sale, significant costs will be incurred which are likely to be added to the cost of drug distribution. Therefore, it is reasonable to assume that for those who buy medicines (e.g., patients and insurers, including MediCal), this legislation (perhaps unintentionally) increases the cost of medicines. These costs can be avoided if patients dispose of medicines in the household trash, which can be done in compliance with federal laws and is environmentally responsible.

² Christensen, F.M. *Pharmaceuticals in the environment – A Human Risk?*, Reg. Toxicol. & Pharmacol., 28, 212-221. (1998)

³ Schwab, et al. *Human pharmaceuticals in US surface waters: A human health risk assessment*. Regulatory Toxicology and Pharmacology, Volume 42, Issue 3, Pages 296-312 (August, 2005)

⁴ Webb, et al. *Indirect human exposure to pharmaceuticals via drinking water*, Toxicology Letters, 142, 157-167. (2003)

⁵ Mons, M.N., (2003) *Pharmaceuticals and drinking water supply in the Netherlands*, Kiwa N.V. Water Research.

5. Several programs already in place are accomplishing the same goal of removing unused medicines from the home.

SMARxT DISPOSAL™ (www.SMARxTdisposal.net) is a cooperative program developed by the U.S. Fish and Wildlife Service, the American Pharmacists Association, and PhRMA, that provides guidance to consumers on the proper disposal of unused prescription and over-the-counter medications. SMARxT DISPOSAL™ also raises awareness about the potential environmental impacts from improperly disposed medications. This national campaign unites diverse interests from the health care profession, pharmaceutical manufacturers, and conservation community and provides simple steps for patients to mix their unused medicines with an undesirable substance to avoid diversion and throw them away in the trash, in contrast to flushing them or pouring them down the sink.

In addition to SMARxT Disposal, PhRMA has been supportive of drug take back programs that operate with law enforcement. Specifically, PhRMA supports the DEA's Drug Take Back Initiative which will next collect medicines on April 28, 2012. Also, American Medicine Chest Challenge combines necessary law enforcement oversight with educational and grassroots community advocacy to create a voluntary program that is expected to help prevent prescription medicine diversion. Partner groups include PhRMA, Partnership for a Drug-Free America, American College of Emergency Physicians, National Association of Chain Drug Stores, and Consumer Healthcare Products Association. AMCC's next collection day is November 10, 2012.

Preserving access to needed treatments is of paramount importance as the State implements national health reform. Given that drug take back programs do not address the issue of pharmaceuticals in the environment, and the fact that several ways already exist for patients to dispose of their unused medicines, PhRMA urges the Alameda Board of Supervisors to reject the Safe Medication Disposal Ordinance.

Sincerely,



Marjorie Powell

cc. Honorable Scott Hagerty
Honorable Nadia Lockyer
Honorable Wilma Chan
Honorable Keith Carson