

Leslie N. Wood
Senior Director
State Policy



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May 16, 2011

Chairman Charles R. Hoppin
State Water Board

Dear Chairman Hoppin:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) to address the upcoming State Water Board discussion regarding product stewardship and water quality on June 21, 2011. The agenda will include a discussion on pharmaceuticals. Unfortunately, PhRMA was not invited to provide a presentation at this meeting. This letter includes a few comments about PhRMA's positions on the issues of product stewardship with respect to pharmaceuticals in the environment and prescription drug abuse. We respectfully ask that if the Board decides to explore this issue further with respect to pharmaceuticals that PhRMA be invited to present information at a time mutually convenient for all concerned.

PhRMA recognizes the State's interest in patient safety with respect to unused medicine, drug abuse, and the environment. However, PhRMA believes it is important to address the issues of pharmaceuticals in the environment and drug take back programs individually. Specifically, drug take back programs do not address the issue of pharmaceuticals in the environment.

Product Stewardship

Pharmaceuticals do not fit into the well-established model for product stewardship. That model includes: (1) Do not generate the waste in the first place; (2) Reuse the material; (3) Recycle the material; and (4) Dispose of the material. The unique aspects of pharmaceuticals impact the choice of product stewardship approaches available as well as the ultimate disposal decision for unused medicines by patients. Unlike other take back programs (e.g., light bulbs, electronic equipment, batteries, and toner cartridges) that have end-of-life waste designed into the product, medicines are designed to be completely consumed by patients. Medicines are valuable, life-saving products that in order to be most beneficial should be taken through a full course as directed by a physician. Also, for patient safety reasons, the small percentage of residential medicine that does go unused cannot be recycled or reused. Thus, the most effective product stewardship approach should focus on understanding and addressing the root causes for patients not taking all of their medicine and disposing of any unavoidable unused medicine in the manner with the least overall environmental impact, the household trash.

Pharmaceutical Research and Manufacturers of America

For these reasons, PhRMA opposes mandates to fund drug take back programs for unused medicines because: (1) such programs do not reduce amounts of medicines in the environment and could increase drug abuse; (2) manufacturers currently are prohibited by federal law from taking controlled medicines from patients; (3) such programs could increase the cost of medicines; (4) consumers already have the environmentally sound option of quickly disposing of unused medicines in the household trash system; and (5) PhRMA already endorses several programs which address the disposal of unused medicine.

Scientific Research

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.

In addition, the amounts of pharmaceuticals in the environment are very small. On average, pharmaceuticals in the environment are present at 18 parts per trillion. A part per trillion is approximately one second for every 32,000 years or one penny for every \$10 billion. To put this into context, a recent story in the Erie Times News reported detecting ibuprofen at 2.5 parts per trillion. Based on the Erie data a person would have to drink Erie water for a lifetime lasting over 100,000 years to get the equivalent of a single 200 mg tablet. It is also important to note that the presence of chemicals in the environment does not necessarily equate to harm. However, PhRMA’s member companies are serious about studying this issue. They have committed to studying pharmaceuticals in the environment by using a scientific approach, and PhRMA has concluded that disposing of unused medicines in the household trash is safe and effective.

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. This research has been published in peer-reviewed journals and is available for review. The studies conducted to date, which include work on sensitive

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

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}

Regarding the disposal 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, with the recent detection of trace amounts of pharmaceuticals in the environment, PhRMA scientists studied whether household trash disposal would be an appropriate alternative to disposing of medicines.

PhRMA determined that both household trash disposal and incineration of unused medicines are environmentally acceptable ways to dispose of unused medicines. PhRMA presented a paper at the October 2008 Water Environment Federation Technical Exhibition and Conference, which 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 is most effective because it does not require the creation of a new, unnecessary infrastructure or the outlay of additional energy for special unused medicine collection.

PhRMA is not alone in its recommendations for disposal of unused medicines. In response to a growing concern about the improper disposal of unused or expired medications, the U.S. Fish and Wildlife Service, American Pharmacists Association (APhA), and PhRMA announced a joint effort called SMAR_XT Disposal™. It is a consumer outreach program designed to educate American consumers about the proper disposal of unused medicines through the current household trash disposal infrastructure. The SMAR_XT Disposal™ program's process for disposal ensures that there is no chance for unused medicines to be used again. At present, there are more than 100 national and local businesses and organizations that support the program. Furthermore, PhRMA and the pharmaceutical industry have rewritten all of its publications and guidelines to remove statements that suggested patients should flush unused medicines down their toilets.

Concerns about Diversion

PhRMA also believes that disposing of unused medicines in the household trash will prevent the diversion of unused medicines. Law enforcement and the federal Drug Enforcement

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.

Administration (DEA) play an important role in preventing diversion of drugs and potential abuse. DEA, FDA, and pharmaceutical manufacturers work together to create plans for preventing the diversion of drugs that are more greatly susceptible to abuse. However, drug take back programs could counteract such efforts by creating the potential for drug diversion. Disposing of medicines in household trash can ensure that unused medicines are not aggregated thereby increasing the opportunity for diversion—whereas, designated sites for drug take back could become sites for drug diversion. PhRMA supports the American Medicine Chest Challenge (AMCC) and the Drug Enforcement Administration’s drug “take back days” because both programs utilize law enforcement for the collection of unused medicines to ensure medicines are secure throughout the disposal process.

Differences between Canada and the United States

In the late 1990s, British Columbia (BC) mandated that drug manufacturers fund the collection of unused medicines. The program allows consumers to drop off unused medicines at pharmacies. Currently, a pharmacist in the United States cannot take back a controlled medicine per the Controlled Substances Act (CSA). For a program similar to BC’s to be allowed under current U.S. law, the pharmacist would have to identify the medicine being returned and only take back a non-controlled medicine. Such a task would increase costs by using pharmacist time to review each item being returned. Although federal legislation passed in 2010 to amend the CSA for the disposal of unused, controlled medicines, it is premature to design a program when the U.S. Attorney General has not yet issued regulations.

In 2007, ten years after the BC program mandated pharmaceutical manufacturer funding, the BC program conducted a survey on participation in the program. According to the survey, 60 percent of the people who responded that they recently disposed of unused medicine did so in the household trash, only 21 percent did so at the pharmacy. When asked about future behavior, 52 percent of respondents said they would dispose of unused medicine in the trash and 24 percent said they would do so at the pharmacy⁶. Additionally, BC noted in their 2008 report that expired medicines do not pose a serious threat to public health and the medicines returned under the program would not meet requirements for hazardous waste.

Health Care Costs

PhRMA member companies are concerned that a patchwork of mandated take back programs will have a significant impact on health care costs. Creating a new process for disposing of unused medicines would be a complex task that would require significant financial resources to secure medicines from diversion, transport medicines for disposal, and incinerate aggregated medicines in compliance with EPA and DEA regulations. It cannot be denied that a mandated program funded by pharmaceutical manufacturers would require significant funding

⁶ Vanasse, Ginette. “Medications Return Program: Pharmaceutical Annual Report, January 2007 to December 2007.” Submitted to the Director of Waste Management, Environmental Quality Branch on June 30, 2008).

which would be added to a manufacturer's cost of doing business. Therefore, it is reasonable to assume that for those who buy medicines (e.g., patients, insurers, union health funds, and MediCal) mandates to fund such programs could increase 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.

PhRMA believes that requiring drug take back programs is not an efficient use of resources—these programs do not “solve” potential environmental and drug abuse issues. Any resources are best allocated to educating patients on the proper disposal of unused and expired medicines.

We appreciate the opportunity to address our concerns and welcome an invitation to formally present to the Board at an informational hearing when mutually convenient.

Sincerely,

A handwritten signature in black ink that reads "Leslie N. Wood". The signature is written in a cursive style with a large, stylized initial "L".

Leslie N. Wood
Senior Director