

Statement



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PhRMA Statement on Take-Back Programs

Washington, D.C. (March 1, 2012) — Pharmaceutical Research and Manufacturers of America Senior Vice President Matthew Bennett issued the following statement today:

“PhRMA believes strongly that a secure and responsible disposal program must not create new avenues for diversion and must be coupled with a comprehensive consumer educational effort. All stakeholders must be involved in educating consumers on protection against diversion of controlled substances, appropriate use of medication and medication adherence, secure and responsible storage of prescription medicines, prompt and safe disposal of any unused medicines, and adequate recordkeeping and data collection efforts. America’s biopharmaceutical research companies have a long history of supporting partnerships like SMARxT Disposal, America’s Medicine Chest Challenge, and the DEA’s National Take Back Day which incorporate these principles and highlight consumer education about safe medication disposal.

“The creation of additional take back programs, aside from the DEA’s National Take Back Day and the American Medicine Chest Challenge, is unnecessary when the easiest, most acceptable way to rid the home of unused medicines is to dispose of them in household trash, per the FDA’s instructions.

“PhRMA partners with the U.S. Fish and Wildlife Service and the American Pharmacists Association on the SMARxT Disposal Program (www.smarxtdisposal.net). This program informs people how to safely dispose of medicines in the trash, to virtually eliminate any environmental risk posed from flushing medicines down the toilet. PhRMA recommends that all unused medicines, unless specified otherwise by the Food and Drug Administration, should be mixed with water, sealed in an opaque container safely secure from children, pets, and others, and discarded in household trash to be later incinerated or placed in a government approved solid waste landfill.

“Consumers may also take part in the DEA’s National Take Back Day as a way to safely dispose of medications in a way that prevents diversion or potential for abuse. PhRMA has long supported National Take Back Day, to be held on Saturday, April 28, 2011. This program allows patients to drop off expired, unused and unwanted prescription drugs – which will be collected and destroyed by local law enforcement

officials – at designated sites nationwide. The program is secure, free and anonymous, and those interested in learning more can go to www.dea.gov or www.nationaltakebackday.com to find available community resources and participating locations.

“PhRMA recently supported the American Medicine Chest Challenge (AMCC) (www.americanmedicinechest.com), a community-based public health initiative with law enforcement partnership designed to raise awareness about the dangers of prescription drug abuse. The AMCC provided a nationwide day of disposal of unused, unwanted and expired medicine held in communities across the country.

“Consumer education can have significant impact in helping to inform the public and reducing the overall rates of prescription drug abuse, and PhRMA has developed three simple messages as part of our educational effort on this important issue: First, people should take medication as prescribed by your physician or health care practitioner; Second, consumers should store medicines in a safe manner and should not share them; and finally, it’s important to promptly dispose of any unused medicines in safe manner, such as through household trash or an appropriate take back program, as mentioned.”

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated \$49.4 billion in 2010 in discovering and developing new medicines. Industry-wide research and investment reached a record \$67.4 billion in 2010.

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How to Dispose of Unused Medicines

Is your medicine cabinet filled with expired drugs or medications you no longer use? How should you dispose of them?

Most drugs can be thrown in the household trash, but consumers should take certain precautions before tossing them out, according to the Food and Drug Administration (FDA). A few drugs should be flushed down the toilet. And a growing number of community-based "take-back" programs offer another safe disposal alternative.

Guidelines for Drug Disposal

FDA worked with the White House Office of National Drug Control Policy (ONDCP) to develop the first consumer guidance for proper disposal of prescription drugs. Issued by ONDCP in February 2007, the federal guidelines are summarized here:

- Follow any specific disposal instructions on the drug label or patient information that accompanies the medication. Do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.
- If no instructions are given, throw the drugs in the household trash, but first:
 - Take them out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter. The medication will be less appealing to children and pets, and unrecognizable to people who may intentionally go through your trash.
 - Put them in a sealable bag, empty can, or other container to prevent the medication from leaking or breaking out of a garbage bag.



Take drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds ...



- Take advantage of community drug take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Call your city or county government's household trash and recycling service (see blue pages in phone book) to see if a take-back program is available in your community.

FDA's Director of Pharmacy Affairs, Ilisa Bernstein, Pharm.D., J.D., offers some additional tips:

- Before throwing out a medicine container, scratch out all identifying information on the prescription label to make it unreadable. This will help protect your identity and the privacy of your personal health information.
- Do not give medications to friends. Doctors prescribe drugs based on a person's specific symptoms and medical history. A drug that works for you could be dangerous for someone else.
- When in doubt about proper disposal, talk to your pharmacist.

Bernstein says the same disposal methods for prescription drugs could apply to over-the-counter drugs as well.

Why the Precautions?

Disposal instructions on the label are part of FDA's "risk mitigation" strategy, says Capt. Jim Hunter, R.Ph., M.P.H., Senior Program Manager on FDA's Controlled Substance Staff. When a drug contains instructions to flush it down the toilet, he says, it's because FDA, working with the manufacturer, has determined this method to be the most appropriate route of disposal that presents the least risk to safety.

About a dozen drugs, such as powerful narcotic pain relievers and other controlled substances, carry instructions for flushing to reduce the danger

of unintentional use or overdose and illegal abuse.

For example, the fentanyl patch, an adhesive patch that delivers a potent pain medicine through the skin, comes with instructions to flush used or leftover patches. Too much fentanyl can cause severe breathing problems and lead to death in babies, children, pets, and even adults, especially those who have not been prescribed the drug. "Even after a patch is used, a lot of the drug remains in the patch," says Hunter, "so you wouldn't want to throw something in the trash that contains a powerful and potentially dangerous narcotic that could harm others."

Environmental Concerns

Despite the safety reasons for flushing drugs, some people are questioning the practice because of concerns about trace levels of drug residues found in surface water, such as rivers and lakes, and in some community drinking water supplies. However, the main way drug residues enter water systems is by people taking medications and then naturally passing them through their bodies, says Raanan Bloom, Ph.D., an Environmental Assessment Expert in FDA's Center for Drug Evaluation and Research. "Most drugs are not completely absorbed or metabolized by the body, and enter the environment after passing through waste water treatment plants."


A company that wants FDA to approve its drug must submit an application package to the agency. FDA requires, as part of the application package, an assessment of how the drug's use would affect the environment. Some drug applications are excluded from the assessment requirement, says Bloom, based on previous agency actions.

"For those drugs for which environmental assessments have been required, there has been no indication of environmental effects due to flushing," says Bloom. In addition, according to the Environmental Pro-

tection Agency, scientists to date have found no evidence of adverse human health effects from pharmaceutical residues in the environment.

Nonetheless, FDA does not want to add drug residues into water systems unnecessarily, says Hunter. The agency is in the process of reviewing all drug labels with disposal directions to assure that the recommended methods for disposal are still appropriate.

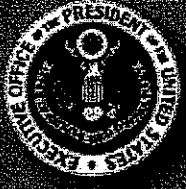
Another environmental concern lies with inhalers used by people who have asthma or other breathing problems, such as chronic obstructive pulmonary disease. Traditionally, many inhalers have contained chlorofluorocarbons (CFC's), a propellant that damages the protective ozone layer. The CFC inhalers are being phased out and replaced with more environmentally friendly inhalers.

Depending on the type of product and where you live, inhalers and aerosol products may be thrown into household trash or recyclables, or may be considered hazardous waste and require special handling. Read the handling instructions on the label, as some inhalers should not be punctured or thrown into a fire or incinerator. To ensure safe disposal, contact your local trash and recycling facility. 

This article appears on FDA's Consumer Health Information Web page (www.fda.gov/consumer), which features the latest on all FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

For More Information
SMARxT Disposal Campaign
www.smarxtdisposal.net

Albuterol Inhalers: Time to Transition
www.fda.gov/consumer/updates/albuterol053008.html



Proper Disposal of Prescription Drugs

Office of National Drug Control Policy 2009

Federal Guidelines:

- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the FDA's website.
- To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government's household trash and recycling service and ask if a drug take-back program is available in your community.
- If a drug take-back or collection program is not available:
 1. Take your prescription drugs out of their original containers.
 2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
 3. Put this mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
 4. Conceal or remove any personal information, including Rx number, on the empty containers by covering it with black permanent marker or duct tape, or by scratching it off.
 5. Place the sealed container with the mixture, and the empty drug containers, in the trash.

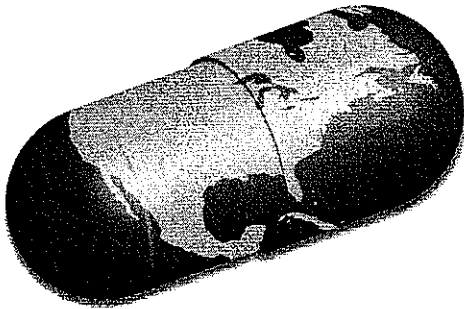
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Promoting Responsible Consumer Medication Disposal to Ensure Healthy Aquatic Ecosystems



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Protecting the environment is everyone's responsibility.

DO NOT FLUSH unused medications and DO NOT POUR them down a sink or drain.

Follow these simple steps to help safeguard lives and protect the environment:

-  Pour medication into a sealable plastic bag. If medication is a solid (pill, liquid capsule, etc.), add water to dissolve it.
-  Add kitty litter, sawdust, coffee grounds (or any material that mixes with the medication and makes it less appealing for pets and children to eat) to the plastic bag.
-  Seal the plastic bag and dispose of it in the trash.
-  For more information, consult your pharmacist or visit our web site at:

smarxtdisposal.net



American Pharmacists Association
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