Proper Disposal of Expired or Unwanted Drugs

The new federal prescription drug disposal guidelines recommend mixing unwanted drugs with unpalatable substances and placing in a non-descript container before discarding in the trash, unless the prescribing information specifically states the drug is to be flushed down the toilet or sink. The current federal prescription drug disposal guidelines state specifically that the following drugs should be flushed down the toilet instead of being disposed of in the trash: Actiq (fentanyl citrate), Daytrana transdermal patch (methylphenidate), Duragesic transdermal systems (fentanyl), OxyContin (oxycodone), Avinza (morphine sulfate), Baraclude (entecavir), Reyataz (atazanavir sulfate), Tequin (gatifloxacin), Zerit for oral solution (stavudine), meperidine, Percocet (oxycodone and acetaminophen), Xyrem (sodium oxybate), and Fentora (fentanyl buccal tablet).30 For a copy of the new federal disposal guidelines, go to http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf. Specific disposal instructions for these drugs along with a list of additional agents that should be disposed of in the sewer system per the prescribing information is provided in the chart below.

Drugs with specific disposal instructions: a,b,c,d,e

<table>
<thead>
<tr>
<th>Drug</th>
<th>Special Disposal Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Actiq</strong></td>
<td>• Do not flush entire unused units, handles, or blister packages down the toilet.</td>
</tr>
<tr>
<td>(oral transmucosal</td>
<td>• If there is any medicine remaining after the dose, place the handle under hot running water</td>
</tr>
<tr>
<td>fentanyl citrate)</td>
<td>until the medicine is gone and throw the handle away out of reach of children and pets.</td>
</tr>
<tr>
<td></td>
<td>• For unopened/unused Actiq units:</td>
</tr>
<tr>
<td></td>
<td>1. Remove one Actiq unit from its blister package and hold the Actiq by its handle over the</td>
</tr>
<tr>
<td></td>
<td>toilet bowl.</td>
</tr>
<tr>
<td></td>
<td>2. Use wire-cutting pliers to cut the medicine end off so that it falls into the toilet.</td>
</tr>
<tr>
<td></td>
<td>3. Throw away the handle in a place out of reach of children and pets.</td>
</tr>
<tr>
<td></td>
<td>4. Repeat steps 2 to 3 for each Actiq unit.</td>
</tr>
<tr>
<td></td>
<td>5. Flush the toilet twice after 5 Actiq units have been cut. Do not flush more than 5 Actiq</td>
</tr>
<tr>
<td></td>
<td>units at a time.</td>
</tr>
<tr>
<td><strong>AndroGel</strong></td>
<td>• Unused gel should be disposed of by thoroughly rinsing down the sink or throw in the trash</td>
</tr>
<tr>
<td>(testosterone gel)</td>
<td>in a manner to avoid accidental exposure or ingestion by household members or pets.</td>
</tr>
<tr>
<td><strong>Avinza</strong></td>
<td>• Flush capsules down the toilet.</td>
</tr>
<tr>
<td>(morphine sulfate</td>
<td></td>
</tr>
<tr>
<td>extended-release)</td>
<td></td>
</tr>
</tbody>
</table>

More...
<table>
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<tbody>
<tr>
<td><em>Baraclude</em>&lt;sup&gt;4&lt;/sup&gt; (entecavir)</td>
<td>• Flush tablets down the toilet or pour the oral solution down the sink.</td>
</tr>
<tr>
<td><em>Daytrana</em>&lt;sup&gt;5&lt;/sup&gt; (methylphenidate)</td>
<td>• Fold the patch in half so that the adhesive side adheres to itself and flush down the toilet or dispose of in an appropriate lidded container.</td>
</tr>
<tr>
<td><em>Demerol</em>&lt;sup&gt;6&lt;/sup&gt; (meperidine)</td>
<td>• Flush tablets/syrup down the toilet.</td>
</tr>
</tbody>
</table>
| *Diastat AcuDial*<sup>7</sup> (diazepam rectal gel) | • Any diazepam rectal gel remaining in the *AcuDial* applicator after use should be disposed of before the applicator is discarded.  
• With the applicator tip pointed over the sink or toilet, the plunger should be pulled back then gently depressed until it stops to force gel from the applicator tip into the sink or toilet.  
• Flush the toilet or rinse the sink with water until gel is no longer visible. |
| *Dilaudid*/Dilaudid-HP<sup>9</sup> (hydromorphone) | • Flush tablets or oral liquid down the toilet.                                                   |
| *Dolophine*<sup>10</sup> (methadone) | • Flush tablets down the toilet.                                                                |
| *Duragesic*<sup>11</sup> (fentanyl) | • Fold sticky sides of the patch together and flush down the toilet.                           |
| *Estrogel*<sup>12</sup> (estradiol gel) | • Unused gel should be disposed of by thoroughly rinsing down the sink or throw in the trash in a manner to avoid accidental exposure or ingestion by household members or pets. |
| *Fentora*<sup>13</sup> (fentanyl buccal tablets) | • Contact Cephalon at 1-800-896-5855 or flush unneeded tablets down the toilet.  
• Do not flush blister packages or cartons down the toilet. |
| *Ionsys*<sup>14</sup> (transdermal fentanyl) | • Handle *Ionsys* by the side or the top housing only since contact with hydrogel in *Ionsys* can be harmful to humans and animals.  
• Disposal should be in accordance with state or federal regulations.  
• Wear gloves to dispose of a used *Ionsys* unit:  
  1. Pull the red tab to separate bottom and top housing.  
  2. Fold the hydrogel-containing bottom housing in half with sticky side facing in.  
  3. Dispose of the bottom housing containing fentanyl by flushing down the toilet with another healthcare professional as a witness.  
  4. Dispose of the top housing containing electronics according to hospital procedures for battery-containing waste.  
  5. If hydrogel accidentally contacts the skin, rinse with water thoroughly. Do not use soap. |
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<tbody>
<tr>
<td>Opana/Opana ER (oxymorphone)</td>
<td>• Flush tablets down the toilet.</td>
</tr>
<tr>
<td>OxyContin (oxycodone)</td>
<td>• Flush tablets down the toilet.</td>
</tr>
<tr>
<td>Percocet (oxycodone)</td>
<td>• Flush tablets down the toilet.</td>
</tr>
<tr>
<td>Reyataz (atazanavir)</td>
<td>• Flush capsules down the toilet or pour down the sink.</td>
</tr>
<tr>
<td>Suboxone (buprenorphine/naloxone)</td>
<td>• Flush tablets down the toilet.</td>
</tr>
<tr>
<td>Subutex (buprenorphine)</td>
<td>• Flush tablets down the toilet.</td>
</tr>
</tbody>
</table>
| Tequin (gatifloxacin)      | • Flush tablets down the toilet.  
  • Note that this product is no longer manufactured in the U.S. and Canada. |
| Tyzeka (telbivudine)       | • Flush tablets down the toilet. |
| Videx/Videx EC (didanosine) | • Flush tablets or capsules down the toilet or pour oral liquid down the sink. |
| Xyrem (sodium oxybate)     | • Handle according to state and federal regulations.  
  • Flush solution down the toilet or pour down the sink. |
| Zerit/Zerit XR (stavudine) | • Flush capsules down the toilet or pour oral solution down the sink.  
  (Please note Zerit XR has been discontinued) |

a. This list is not all-inclusive.
b. Patients should follow specific drug disposal instructions found in the patient information from the manufacturer.
c. Many Schedule II drugs have special instructions to flush the drug down the toilet or pour down the sink.
d. Unless listed above, most topical patches, including hormone patches, are to be folded in half so that the sticky side sticks to itself and discard in the trash in a manner to prevent accidental ingestion by children or pets.
e. Estring, Femring, and Nuvaring are to be disposed of in the trash. For Femring, wrap the used ring in tissue paper before throwing in the trash. For Nuvaring, wrap the used ring in the foil pouch it came with before throwing in the trash.
Proper Disposal of Expired or Unwanted Drugs

Background
Pharmaceuticals and personal care products as trace environmental pollutants have been a concern since the 1980s. Drugs may enter the environment inadvertently by excretion and washing or purposefully by disposal into sewage or trash. In addition to environmental concerns, prescription drug abuse is also on the rise.

According to federal data, prescription drug abuse is second only to marijuana use by 12- to 17- year olds. To limit inappropriate access to prescription medications and environmental pollution, the White House Office of National Drug Control Policy (ONDCP), the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) jointly published new guidelines for proper disposal of prescription drugs in February of 2007. At the same time, the American Pharmacists Association (APhA) also published similar guidelines on proper drug disposal. While the focus of these guidelines is consumer pharmaceutical waste, improper disposal of pharmaceutical waste from healthcare facilities is also a concern.

Proper Disposal - Consumers
The new federal prescription drug disposal guidelines urge consumers to:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mix the prescription drugs with an undesirable substance, like used coffee grounds or kitty litter. Putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Throw these containers in the trash.
- Flush prescription drugs down the toilet only if the accompanying patient information specifically instructs doing so.
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The APhA guidance on proper medication disposal recommends crushing solid medications or dissolving medications (solid or liquid) in water and mixing with kitty litter or another unpalatable substance before placing in a sealed plastic bag for disposal. APhA also recommends removing and destroying all personal information (e.g., prescription label) from the medication container before throwing the container in the trash.

Some environmental experts disagree with these recommendations, advising consumers instead to dispose of unwanted medications in their original prescription containers with any identifying information removed, and to not flush any medications, even if the patient information instructs otherwise. For now, healthcare providers should recommend patients follow the new ONDCP guidelines. These are the only existing federal patient guidelines and seek to balance environmental and drug diversion concerns.

At this time, pharmaceutical take-back programs are limited in the U.S. Local efforts to provide take-back programs to encourage proper disposal of unwanted medications are underway in many states. In Maine, a state take-back program has been in place for over a year. In addition, a registry of unused medicine has been maintained to track, sort, and quantify the medications recovered in these efforts. Washington state also recently implemented a pilot pharmaceutical take-back program. The Washington program is modeled after one in British Columbia, Canada, established by pharmaceutical companies in 1996.

The Northeast Recycling Council hosted a series of pilot medication collection programs in pharmacies and developed a guidance document summarizing legal and safety issues involved with these programs. This document includes instructions for setting up a collection event including staffing issues, data management,
packing medications for disposal, sample press release and fliers, law enforcement requirements, controlled substances and privacy law summaries and much more information. It is available at: http://www.nerc.org/adobe/setting.up.draftFINAL.pdf. Users of this document should keep in mind that some disposal instructions are not consistent with ONDCP guidelines and that any legal and safety information should be verified with the appropriate state and federal regulatory bodies if in question.

Proper Disposal - Healthcare Facilities

Healthcare facilities such as hospitals, skilled nursing facilities, and clinics are the largest bulk users of medications. Although most hospital facilities utilize pharmaceutical returns/disposal services to discard non-reusable or expired medications, many dispose of unused contents of syringes and IV bags into drains. States such as California and Washington prohibit disposal of virtually any drugs down the sewage system. It is recommended to consult local wastewater treatment plants to determine what pharmaceutical wastes are appropriate to dispose of down the sewer system in healthcare facilities.

In general, wastes that are acceptable for sewage disposal include IV bags containing saline solution, lactate, nutrients such as glucose, added salts such as potassium, vitamins, and/or other electrolytes. Avoid disposing of other IV solutions containing antibiotics, painkillers, chemotherapeutic agents, controlled substances, or other pharmaceutical wastes down the sewage system. It’s recommended to dispose of excess medication (solid and liquid, including injectables) into a pharmaceutical waste container.


In long-term care settings, some states allow unopened drugs (except for controlled substances) in sealed containers to be returned to the dispensing pharmacy for disposal unless prohibited by federal or state laws. In some states, nursing homes that can prove unused medications have been handled properly can potentially reuse them. The medication has to go back through a pharmacy that then has to ensure the integrity of the drug. To reduce pharmaceutical waste, some states, including California, Oklahoma, Louisiana, and Ohio, allow unused drugs from nursing homes, wholesalers, and manufacturers to be distributed to the poor or uninsured.

In clinic settings, sewage disposal of expired drug samples should be avoided. It is recommended to check expiration dates prior to accepting drug samples. Typically manufacturers do not accept drug sample returns. Consider using a pharmaceutical waste management service (e.g., EXP Pharmaceutical Services Corp., etc) to properly dispose of expired drug samples.

Expiration Date vs. Beyond Use Date

Patients often wonder whether to dispose of expired medications or keep them on hand for future use. The question of whether it is safe to take expired medications often comes up. Expiration dates on prescription drugs in their original packaging are set by the manufacturer based on stability testing results. Most pharmaceutical manufacturers choose two to three years after the date of manufacture as the expiration date. The expiration date assigned to a medication by the manufacturer is not the date after which it has “gone bad.” It is the date after which the manufacturer cannot guarantee that the product meets FDA standards.

The FDA requires that a product pass “stability” tests. These tests analyze the ability of the drug to meet the FDA standards of maintaining identity, strength, quality, and purity for the duration of a chosen expiration period. For example, if a drug manufacturer chooses the expiration date of a given drug to be three years, then the drug must be tested during this period and at the end of three years, to affirm that the drug meets the standards. These determinations must be made using the packaging that the drug is to be marketed in and under the storage conditions that are appropriate for the product. Usually, maintenance of at least 90% potency is acceptable.

A “beyond-use” date is different from an expiration date set by the drug manufacturer.
When filling a prescription, the pharmacist generally removes a drug product from the manufacturer’s bulk container and places the drug product in a different container for dispensing. In 1985, the United States Pharmacopeia (USP) began recommending that pharmacists set beyond-use dates at no more than one year if they are dispensing drugs in a container other than the original one. In 1997, it became a USP requirement that, unless otherwise specified in compendium standards, the beyond-use date on a dispensed medication should be no later than the expiration date on the manufacturer’s container or one year from the dispensing date, whichever is earlier. Many states have now passed legislation that dictates this standard be followed.

**Potency of Expired Drugs**

The U.S. Air Force began stability testing of stockpiles of prescription medications in 1985. The testing was begun after officials of the Government Accounting Office (GAO) estimated that the military would have to start spending approximately 100 million dollars per year to replace outdated prescription drugs beginning in the 1990s. The program is referred to by the Department of Defense (DoD) as the “Shelf Life Extension Program” (SLEP). In the first year of the testing program, the FDA tested 58 different prescription drugs, representing 157 different manufacturing lots. Some of the original drugs tested were penicillin, lidocaine, and lactated ringers.

After this initial round of testing was complete, the FDA extended the expiration dates for 80% of the expired lots tested by an average period of 33 months. In 1992, seven years after testing began, the expired lots were retested, and more than 50% met testing standards (i.e., remained useable). In the year 2000, at least one of those batches remained stable, fifteen years after its original expiration date. Some specific drugs that have been incorporated into this testing program include: pralidoxime, chloroquine, diazepam, ciprofloxacin, atropine, sodium chloride for injection, and cimetidine. The original expiration date of ciprofloxacin tablets that were added to the testing program was 1993, and this expiration date was extended to 2001. By 2000, 312 drug products had been evaluated by the SLEP program. It is important to note that the military stored these drugs under optimal conditions, either in carefully monitored controlled room temperature warehouses or refrigerated when appropriate. Although the SLEP data suggest that many drug products can be extended past the expiration date, it is important to point out that the additional stability period is highly variable. Due to the lot-to-lot variability, the stability and quality of extended drug products can only be assured by continual testing and systematic evaluation of each lot.

How a medication is stored affects its long-term stability. Exposure to light, air, humidity, and temperature extremes can affect the degradation rate of a drug. The expiration date assigned by the manufacturer assumes that the medication will be stored properly in the closed container it was dispensed in at the appropriate temperature. In reality, many patients store medications in less than ideal environments: warm, humid areas (bathroom cabinet), windowsills (lighted areas), various locations in the interior of automobiles (hot), etc. Therefore, it is unclear whether findings from SLEP would be applicable to the civilian environment.

**Safety of Expired Drugs**

Most drugs simply lose potency and are not toxic after the expiration date. Human toxicity related to taking expired drugs has only been linked to degraded tetracycline. There have been rare reports of renal tubular dysfunction or Fanconi-like syndrome associated with ingestion of outdated tetracycline. The majority of the cases were reported in the 1960s. Degradation products of tetracycline (i.e., anhydrotetracycline and epi-anhydrotetracycline) accumulate within mitochondria of renal cells and interfere with oxidative phosphorylation and can potentially cause nausea, vomiting, lethargy, polydipsia, polyuria, glycosuria, aminoaciduria, phosphaturia, proteinuria, acidosis, and hypokalemia. There is at least one case of lactic acidosis, in addition to Fanconi syndrome, reported in a patient who took outdated tetracycline. Tetracycline products have since been reformulated and the stability of tetracycline appears to have been improved. Current tetracycline products do not seem to cause this problem.

Except for a handful of drugs, most drugs are probably as durable as those tested under the Shelf-Life Extension Program. Liquid
formulations tend not be as stable as solid dosage forms. Some liquids containing sugar or other flavoring additives can grow mold or other contaminants if left too long. Injectable liquids (e.g., EpiPen, Twinject, etc) should be visually inspected periodically and be replaced if discolorations or particulates are evident. Antibiotic suspensions prepared from powders are relatively unstable and should be properly discarded once expired. Eye drops come in sterile formulations and once expired, the potency of preservative cannot be guaranteed even though the drug may still be active. Other drugs that tend to degrade quickly include nitroglycerin and insulin and should not be used beyond expiration date. Advise patients that drugs with narrow therapeutic index (e.g., warfarin, digoxin, phenytoin, carbamazepine, levothyroxine, etc) may not produce adequate therapeutic response even with a small loss of potency.

Conclusion
Many medications are found to be stable beyond expiration date when stored under ideal conditions. However, the stability of medications cannot be guaranteed once the medication has been dispensed to the patient. Counsel patients to store medications in their original containers in a cool dry place (e.g., linen closet, etc) to prevent rapid degradation and to keep out of reach of children. Advise against storing medicines in bathroom cabinets. Showers and baths create heat and humidity that can cause some drugs to degraded rapidly. Recommend cleaning out medicine cabinets at least once a year to properly discard and replace outdated products, damaged containers, and old supplies. Advise patients to check with local hazardous waste management or pharmacies for pharmaceutical take-back programs or to dispose of unwanted medications by following the new federal drug disposal guidelines.

Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and Internet links in this article were current as of the date of publication.

Project Leader in preparation of this Detail-Document: Wan-Chih Tom, Pharm.D.

References

More . .


_Cite this Detail-Document as follows: Proper disposal of expired or unwanted drugs. Pharmacist’s Letter/Prescriber’s Letter 2007;23(4):230401._

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Federal Guidelines:

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- Flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so (see box).

- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

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- Baraclude Tablets (entecavir)
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Note: Patients should always refer to printed material accompanying their medication for specific instructions.
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