

## Introduction

The fate of unused medicines is a rapidly emerging concern that spans a broad range of issues including human and environmental health, water quality, solid waste management, law enforcement, and the health care industry. Substances of concern include both prescription and non-prescription medicines, and this category is sometimes expanded to include cleansing agents, cosmetics, nutritional supplements, and skin care products. A common term used for this suite of compounds is pharmaceuticals and personal care products (PPCPs). There are thousands of products that fall into this classification; all of these substances are specifically designed to interact with biological processes and are widely used around the world. They can enter the environment when people dispose of medicines via trash or toilet, or after use when they are excreted in their original or metabolized form or rinsed off the skin in the case of topical applications (Daughton and Ternes 1999).

### *The Issue*

Medicines are produced and prescribed in increasing volumes every year. In the United States, sales of over-the-counter medicines have increased by 60% since the 1990s<sup>1</sup>. In 2008, total sales for prescription medicines in the United States reached \$291.5 billion, a 1.4 percent increase from 2007 (Ruiz 2009). With these increases comes concern about the fate and effects of these compounds in the environment. Recent studies have identified a wide range of pharmaceutical chemicals in rivers, streams, and groundwater nationwide (Kolpin *et al.* 2002, Barnes *et al.* 2008), and it has also been shown that some of these compounds are potentially harmful to aquatic organisms, affecting reproduction and development even at very low concentrations in some cases (cited in Daughton and Ternes 1999). The fate of pharmaceutical chemicals in sewage sludge is also of concern (Kolpin *et al.* 2002), as sludge from wastewater treatment is often applied to agricultural land as a fertilizer. The long-term impacts of medicine disposal on our health and the health of the environment are not fully known. However, unless action is taken, the quantity of these chemicals reaching our waterways will continue to increase as pharmaceutical usage increases. Thus, Illinois-Indiana Sea Grant recommends a precautionary approach to this issue.

So what can be done? The issues surrounding medicine disposal are complex. Improper disposal of unwanted medicines can pose a risk to children and pets. For example, medicines placed in the trash without taking precautions to secure the container, make the medication unpalatable, or disguise the content are potentially accessible to children and pets, sometimes resulting in unintentional poisonings. Medicines disposed with their original labels intact can result in identity theft and medicine theft. This is an especially important issue for the elderly, who are the biggest consumers of prescribed medicines.

In early 2007, the Office of National Drug Control Policy issued guidelines for proper disposal of prescription drugs, following on the heels of several states providing advice to their citizens. This guidance was most recently updated in October 2009 and is available at [http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip\\_disposal.pdf](http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf). The three main components of the national guidelines are:

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<sup>1</sup> Pistell, Anne. Maine Department of Environmental Protection. Presentation at Northeast Water Science Forum, August 9, 2007.

1. Don't flush medications down the toilet unless the label specifically instructs you to do so and instead,
2. Take advantage of community take-back programs or other programs that collect medicines at a central location for proper disposal. If a take-back or collection program is not available, then
3. Remove labeling from packaging and dissolve solid medications, mix with unpalatable items (kitty litter, coffee grounds, etc.) and seal in a bag before placing in the trash.

Several states have adapted these suggested guidelines and issued state-specific advice to ensure compliance with specific state hazardous waste and household waste regulations. Options such as mixing with plaster, crushing the pills, and locking up medication if it can be done safely until the next community collection have also been suggested. Several state guidelines provide information about how to determine if there are local collection programs in a state or community.

Disposal to trash is considered to be an interim solution because medicines placed in landfills are likely to slow the transport of the chemicals to waterways or sludge, but landfill leachate ultimately reaches wastewater treatment plants and local streams and rivers (Barnes *et al.* 2004). Illinois-Indiana Sea Grant believes that currently, the best disposal solution is incineration of medications in a regulated incinerator. There is, however, a very long list of hurdles to overcome before a national disposal plan can be implemented that is protective of humans, wildlife and pets and their shared environment. These hurdles include identifying safe and convenient medicine collection pathways and determining who will pay for this service, minimizing the need for disposal through smarter prescribing and smarter consumer choices to save healthcare dollars and resources.

The Illinois-Indiana Sea Grant resource kit, "Disposal of Unwanted Medicines: A Resource for Action in Your Community" was created to help communities design, establish and implement safe and legal unwanted medicines collection programs. One component of a successful program is identifying the best way to engage the community and let them know when the collection will occur and what can be brought to the event. Included in the kit are several examples of pamphlets, fact sheets and education materials that have been developed by communities and states as they wrestle with this complicated issue. The recommendations and advice vary because jurisdictions are finding different ways to deal with the fact that only interim solutions are available currently. These outreach materials can be adapted and used by other communities to save time and funds.

The good news about this issue is that it touches upon so many different aspects of our lives that there is no end of partners to join with to educate and reach out to the public. This issue impacts the elderly through medicine and identity theft issues, accidental poisoning, and health care costs. It matters to the police because prescription drug abuse by teenagers is on the rise. In 2008, 15.4 percent of 12th-graders reported using a prescription drug nonmedically within the past year (Johnston *et al.* 2009). Concerns for the safety of children and pets also can drive behavioral change. Furthermore, medications that go unused are a significant waste of health

care dollars. And for all of us, our health depends on the health of our environment, including rivers and streams and the creatures that live in them.

## **1. Background**

### **1.1 Disposal of Unwanted Medicines**

For many reasons, medicines are not always entirely used and therefore remain and may eventually expire in the hands of consumers or health care facilities. Some reasons for this include:

- Improvement of the patient's medical condition
- Patient or doctor decides to discontinue use of the medication due to side effects or lack of therapeutic effect
- Patient death
- Packaging contains more medication than the patient needs, e.g. with over-the-counter or prescription medicines bought in bulk

Disposal of unwanted medicines is an issue both for households and healthcare business such as hospitals, hospices, rehab centers, assisted living facilities, clinics, and pharmacies. Health care businesses disposal practices are regulated at the state and federal level. Some medications are classified as hazardous waste because they contain or are preserved with hazardous chemicals (mercury, preservatives, radioactive components) and therefore most states have specific regulations surrounding pharmaceutical disposal. The medicines that are disposed of by individual households are generally unregulated. The U.S. Environmental Protection Agency is currently considering including pharmaceuticals in the federal Universal Waste Rule set forth in 40 CFR part 273 which, if adopted by individual states, would allow for simpler easier management of household medicine waste. This document focuses on the medicines that are disposed of by individual households. We have provided a short section on the disposal practices of medical facilities because their practices may provide insight for community programs on different ways to approach the collection of unwanted medicines.

#### **1.1.1 Disposal by Individuals**

A 1996 survey (Kuspis and Krenzeloek 1996) examined the expired medicine disposal habits in 100 pharmacies and 500 patients (Figure 1). The survey found:

##### Pharmacies:

- **97%** had established policies regarding the disposal of undispensed, expired medicines
- However, only **5%** had consistent recommendations for customers on medicine disposal

##### Patients:

- **54.0%** disposed of medicines in the trash
- **35.4%** flushed medicines down the toilet or sink
- **7.2%** did not dispose of medicines
- **2.0%** used all medicines prior to expiration
- **1.4%** returned medicines to the pharmacy

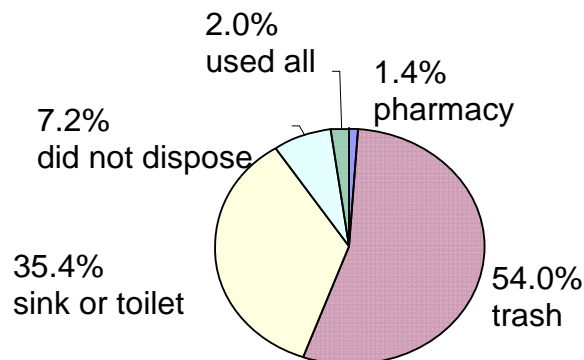


Figure 1: Patient disposal methods of unused medicines (from Kuspis and Krenzolek 1996)

### 1.1.2 Disposal by Health Care Centers and Pharmacies

Disposal of medicines by health care centers and pharmacies is regulated by states. For instance, Minnesota instructs its hospitals and other health care facilities to obtain approval from the local wastewater treatment plant before discharging any medicines to the sewer system.<sup>2</sup> Michigan regulates some types of hospital waste as hazardous waste, which requires incineration as the final treatment and does not permit sewerage or landfilling.<sup>3</sup>

Large-scale generators of pharmaceutical waste may have market options for disposal of their unused drugs. Pharmacies and health care centers can contract with reverse distribution companies to remove their undispensed expired medicines. Reverse distributors sort the drugs; some are sent for disposal and others are returned to the manufacturers who give purchase credits for certain types of medicines. Reverse distributors do not process pharmaceutical products for reuse. While manufacturers may ultimately process returned medicines for reuse, most medicines returned to manufacturers are sent off-site for disposal by regulated incineration.<sup>4</sup>

Reverse distributors do not have hazardous or medical waste management or transfer station permits. Instead, they are treated as hazardous waste *generators* under the law. This is because unwanted medicines that are sent to reverse distributors may have financial value—a value that is only determined by the sorting process at the reverse distributor. Medicines sent to reverse distributors (and from reverse distributors to manufacturers) are treated as “products in commerce” because of this financial value, and thus are not subject to hazardous waste transportation and permitting requirements. The reverse distribution system is only available to consumers in the case of manufacturer or FDA recall of a suspected defective product.

<sup>2</sup> Minnesota Pollution Control Agency, “Evaluating Pharmaceutical Wastes.” August 2004. <http://www.pca.state.mn.us/publications/w-hw4-45a.pdf>

<sup>3</sup> Michigan Department of Environmental Quality, “Waste Management Guidance: Hospital Pharmacies.” December 1997. <http://www.deq.state.mi.us/documents/deq-wmd-hwp-hospital.pdf>

<sup>4</sup> Charlotte Smith, quoted in Moran, K. 2004. “Household Pharmaceutical Waste: Regulatory and Management Issues.” <http://www.tdcenvironmental.com/HouseholdPharmWasteMgtIssuesFinal.pdf>

In most of the U.S. there is no structured system for consumers to dispose of partially used or unused medicines. Locally organized, one-time collection events have provided an interim solution to the problem, but many people are calling for a disposal system that would be continuously available, such as a mail-back scheme or ongoing collections through pharmacies. See Section 2 of this resource kit for examples of large- and small-scale collection programs.

## **1.2 Risks of Unsafe Medicine Storage and Disposal**

1. **Accidental poisoning:** Medicines are the most common poison exposure category in the United States, and unsecured storage or disposal via the trash is a significant source of accidental poisoning. In the United States, approximately 30 children under five years of age die as the result of unintentional poisoning annually (U.S. Consumer Product Safety Commission 2005). Furthermore, data from the National Electronic Injury Surveillance System also indicate that in 2003, an estimated 78,000 children under age five were treated for poisonings in U.S. hospital emergency rooms (U.S. Consumer Product Safety Commission 2005). Medicines account for 45% of these hospitalizations, and of these medicines, aspirin and other painkillers accounted for the most hospitalizations (11.8%) (Centers for Disease Control and Prevention 2005).

Additionally, as the biggest consumers of prescription medicines, it is possible for senior citizens to misuse and self-prescribe medicines, using out-of-date medicines from past ailments to treat new, undiagnosed symptoms. Having a large number of medicines in the home can contribute to confusion over proper dosages and which pills to take when.

2. **Diversion and drug abuse:** Medicines are sometimes misappropriated for consumption or sale by family members and friends, workers in homes, and by burglars. Storing numerous medicines in the home or throwing excess medicines in the trash without first securing them can lead to this type of misuse. The National Survey on Drug Use and Health found in a nationwide study that 12% of young adults (ages 18-25) used prescription pain relievers non-medically in 2005 (Office of Applied Studies, Substance Abuse and Mental Health Services Administration 2006). Of these users, 67% obtained them from a friend or relative, as compared to 14% who had the medicines prescribed to them by a doctor. The 2006 “Monitoring the Future” survey conducted by the University of Michigan reported that although illegal drug use by American teens dropped more than 23% from 2001-2006, their abuse of medicines, both over-the-counter and prescription, was rising (Johnston et al. 2007).

3. **Economic waste:** Medicines thrown in the trash or flushed down the drain represent wasted health care dollars. Studies identifying the types and quantities of medicines that go unused could lead to better-informed prescription practices and better advice to patients on how to properly take prescriptions.

4. **Improper medicine donations:** In response to humanitarian crises, large quantities of medicines are sometimes donated internationally. If the donations do not match the need, or if the donated medicines are expired or otherwise unusable, significant disposal problems can arise overseas, as the receiving areas may have impaired waste treatment systems. Because there have been several cases where unusable medicines have been donated, in most cases with the best intentions, to international relief organizations during crises, the World Health Organization discourages donation of unwanted medicines from collection events (World Health Organization 1999). This

is especially important as environmental safeguards for proper disposal of unusual medicines may not be available in these countries.

5. Environmental impact: Waste discharged through sewage systems can contaminate water resources in the surrounding environment. Pharmaceutical chemicals in waterways pose a potential for deleterious effects on wildlife. Wastewater treatment plants (WWTPs) are not designed to treat chemicals in medicines. Therefore, when flushed down the toilet or sink, some pharmaceutical chemicals pass through the WWTP altered or unaltered and can enter rivers, lakes, living organisms, and groundwater (Daughton and Ternes 1999). Additionally, some of these chemicals remain in the sewage treatment plant's sludge, which is frequently applied to agricultural land as a fertilizer (Daughton and Ternes 1999).

Two examples of compounds in medicines that have been shown to impact aquatic life:

- Estrogens (and estrogen-mimicking compounds) are a group of steroid compounds that function as the primary female sex hormone. Even at low levels, estrogens can have a feminization effect on male fish, and therefore may decrease the reproductive capacity of affected species. (e.g. Nash et al. 2004)
- Antidepressants are designed to control or alter behaviors by inhibiting the uptake of key neurotransmitters such as serotonin, norepinephrine, and dopamine. Once released into the environment, they can have similar or unforeseen effects on aquatic species and have been demonstrated to affect the spawning behavior of shellfish (Fong 2001) and delay fish and frog development (Holmes 2003). They also have been observed to result in slower heart rates for the water flea *Daphnia*, which could indicate broader physiological effects<sup>5</sup>.

Some pharmaceutical chemicals (e.g. anti-epileptics) persist in the environment; others are “pseudo-persistent”—they break down but are continually replaced because of widespread use. The concentrations of individual pharmaceutical chemicals detected in the influent of sewage treatment plants are typically in the range of a few parts per billion, while concentrations in treated effluent are usually lower, in the range of several hundred parts per trillion up to several parts per billion, depending on the chemical. As the effluent is diluted when it discharges into a river, the concentrations in waterways tend to range from undetectable to a few hundred parts per trillion. In sewage sludge, concentrations are sometimes much higher as the sludge is compacted.

Researchers have found that chronic exposure to low levels of pharmaceutical chemicals—within the same range of concentrations as has been observed in some waterways—can have significant effects on aquatic animals including fish (Palace *et al.* 2002, 2006) and lobsters.<sup>6</sup> At present, the greatest concern regarding pharmaceutical chemicals in the environment is their potential effects on small aquatic organisms. This is mainly because these organisms have short generation times, hence multiple generations are easily exposed. Because of this, there is a greater likelihood that effects will not be restricted to individual organisms but instead will accumulate over time to result in population-level effects.

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<sup>5</sup> Rebecca Klaper. “Effects of Pharmaceuticals on Non-Target Organisms.” Presentation at State of the Lakes Ecosystem Conference, Milwaukee, WI, November 2, 2006.

<sup>6</sup> Spanne, Autumn. “Human hormones hurt lobsters.” *The Standard-Times*. Jan. 14, 2007.  
<http://www.southcoasttoday.com/daily/01-07/01-14-07/01perspective.htm>

Pharmaceutical chemicals identified in the environment are generally present in concentrations several orders of magnitude lower than the concentrations known to exert effects on humans. This makes direct human toxicity seem unlikely but does not rule out the possibility of subtler long-term effects that are harder to detect and the exposure is to a vast mixture of compounds that we are unable to measure (Sherer 2006). Some scientists believe that low-level exposures to numerous drugs with the same or similar methods of action may add up to larger effects on aquatic organisms, that certain combinations of medicines may act synergistically to produce disproportionately large effects, or that other unpredictable interactions between chemicals may occur. It is possible that there were other substances of potential concern in the water that were unobserved in these studies simply because researchers did not sample for them, or because there are currently no analytical techniques capable of identifying them. Much research remains to be done in this area.

### **1.3 Where are Pharmaceutical Chemicals Present in the Environment?**

A recent United States Geological Survey (USGS) study analyzed 139 streams in 30 states and found 82 different organic wastewater contaminants, including pharmaceuticals and pesticides (Kolpin *et al.* 2002). Eighty percent of the streams they sampled had at least one organic wastewater contaminant. Furthermore, 75% of the streams tested had more than one contaminant present, 50% had seven or more, and 24% had 10 or more. However, these results are not necessarily representative of *all* waterways because sample collection was targeted to areas where these compounds were expected, namely downstream from urban areas and areas of livestock production. Since this study, further research has found pharmaceutical chemicals in ponds<sup>7</sup> and rivers<sup>8</sup> in many states and more studies are currently ongoing.

It is possible that there were other substances of potential concern in the water that were unobserved in these studies simply because researchers did not sample for them, or because there are currently no analytical techniques capable of identifying them (see Daughton 2003).

### **1.4 What are these Pharmaceutical Chemicals?**

Types of human and animal pharmaceutical chemicals that have been identified in water bodies include (from Daughton and Ternes 1999):

- Hormones
- Antibiotics
- Blood lipid regulators
- Analgesics and anti-inflammatories
- Beta-blockers
- Antidepressants
- Antiepileptics
- Antineoplastics (used in chemotherapy)
- Tranquilizers
- Retinoids

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<sup>7</sup> Standley, L. Presentation “Contamination of Surface Ponds on Cape Cod, MA, by EDCs and Pharmaceuticals from Septic-Contaminated Groundwater” at Northeast Water Science Forum, August 8, 2007.

<sup>8</sup> Furlong, E., P. Phillips, USGS; Lloyd Wilson, NYS DOH. Presentations at Northeast Water Science Forum, August 8, 2007.

- X-ray contrast media

The degree to which these and other medicines are destroyed at wastewater treatment plants can vary greatly depending on both the type of medicine and the treatment method used. Various treatment techniques can alter some medicines into different forms that may be more or less toxic; even chemicals that have been converted into non-toxic forms can sometimes revert to more dangerous forms in the environment.

### **1.5 How do Pharmaceutical Chemicals Enter the Environment?**

Residential, commercial, and agricultural pharmaceutical chemicals follow two primary pathways to wastewater treatment systems (Figure 2):

- **Metabolic excretion:** Many pharmaceutical chemicals are biotransformed in the body. Biodegradation alters the chemical structure of their active molecules, which, in turn, often results in a change in their physical and chemical properties. Metabolism is frequently incomplete, and excretion rates range from 0 to 100%.<sup>9, 10</sup> This means that sometimes a significant fraction of the medicine is not absorbed into the patient's body and instead is excreted. In some cases, metabolic processes alter the medicine, creating a different chemical that may be more or less toxic than the parent compound and may revert back to the parent form in the sewage treatment plant or in the environment.
- **Direct disposal:** Disposing of unwanted or expired medicines can be a challenge for households. In the U.S., few formal guidelines are available for individual consumers on medicine disposal, and, consequently, most of their unused medicines enter septic tanks, sewers, or landfills.

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<sup>9</sup> Kummerer, K. *Pharmaceuticals in the Environment: Sources, Fate, Effects and Risks*. Springer. 2<sup>nd</sup> Edition. 2004.

<sup>10</sup> Bound, Jonathon, and Nikolaos Voulvoulis. "Household Disposal of Pharmaceuticals as a Pathway for Aquatic Contamination in the United Kingdom." *Environmental Health Perspectives*. 113.12 (2005):1705-1711.

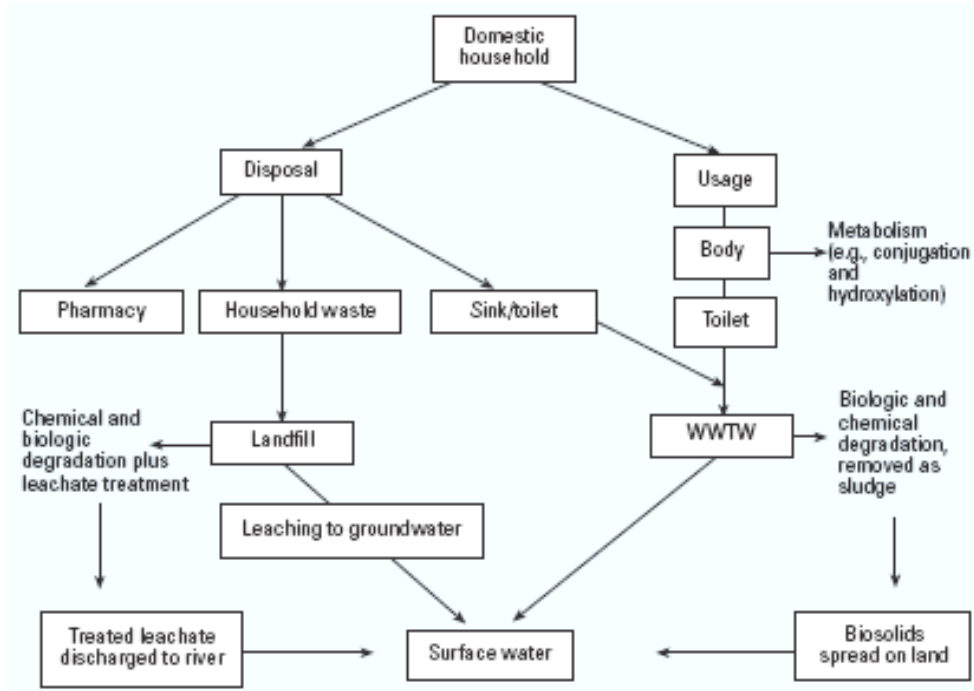


Figure 2. Pathways of drugs from households to the environment from Bound and Voulvoulis 2005

Once they have been discarded or excreted, pharmaceutical chemicals enter surface waters and groundwater through several pathways (Figure 3):

- Effluent from plants that treat household, industrial, and hospital wastewater
- Septic systems
- Runoff and/or groundwater from uncontrolled landfills or landfill leachate sent to waste water treatment plants
- Controlled industrial discharges
- Commercial animal feeding operations and aquaculture
- Surface application of manure and biosolids

# Origins and Fate of PPCPs<sup>†</sup> in the Environment

<sup>†</sup>Pharmaceuticals and Personal Care Products



U.S. Environmental Protection Agency  
Office of Research and Development  
National Exposure Research Laboratory  
Environmental Sciences Division  
Environmental Chemistry Branch

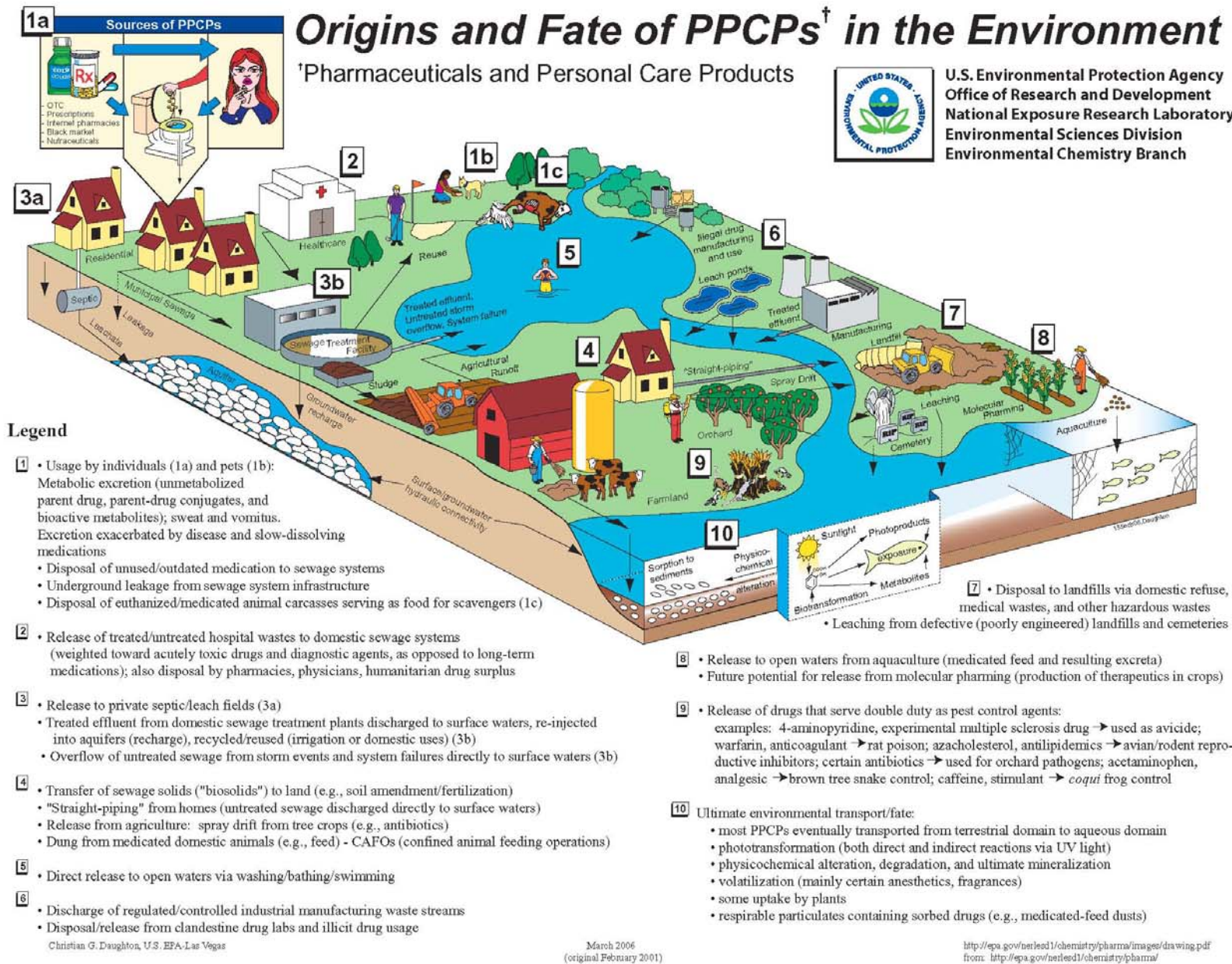


Figure 3. From U.S. EPA's website <http://www.epa.gov/ppcp/pdf/drawing.pdf>

In general, wastewater treatment plants were not designed to remove dissolved medicines from water. They were designed to remove solids, organic materials, and some nutrients such as phosphorus and nitrogen. At wastewater treatment plants, water goes through one, two or three stages of treatment, depending on the sophistication of the plant and the needs of the community served.

Primary treatment removes solids, which are either applied to land as fertilizer or sent to a landfill. The treated water still can contain dissolved and colloid organics and bacteria. If the

plant does no more than primary treatment, then the water is chlorinated to kill the remaining bacteria and discharged.

During secondary treatment, organic materials and nutrients are removed with the aid of bacteria in aerated tanks. After the bacteria are added, the wastewater flows to settling tanks where the bacteria settle out.

Various types of tertiary treatment are possible, depending on the composition of the wastewater. Typically, tertiary treatment uses chemicals to remove phosphorous and nitrogen from the water, but may also include filter beds and other types of treatment. Chlorine added to the water kills any remaining bacteria, and the water is discharged.<sup>11</sup>

Septic systems represent another source of unwanted medicines to groundwater and ponds, as they are also not equipped to break down pharmaceutical chemicals. Researchers have discovered some estrogenic chemicals in groundwater down-gradient of residential septic systems,<sup>12</sup> and new research indicates higher levels of these chemicals in ponds near areas of higher residential density.<sup>7</sup>

Stockyards and feedlots where animals are treated with steroids, hormones, antibiotics, and other veterinary pharmaceuticals are also significant sources of pharmaceutical chemicals to the environment. The chemicals are excreted by the animals directly onto the land, are dispersed via manure spreading, and are discharged into streams by runoff. Any of these routes may result in impacts to surface and groundwater.<sup>13</sup>

## 1.6 Conclusion

The release of pharmaceutical chemicals into the environment after they are excreted by humans and animals is inevitable without sweeping changes to wastewater treatment systems or to medicine manufacture and design. A wide array of changes in each of the many aspects of pharmaceutical manufacturing, distribution, prescribing, consumption, and disposal has been proposed for reducing the introduction of pharmaceuticals to the environment (Daughton 2003). In the U.S., both the EPA and FDA regulate waste pharmaceuticals and other byproducts that result from medicine manufacture.

There is currently insufficient information to determine the relative quantities of medicines reaching the environment from each of the various sources. But one area of this complex issue that is amenable to immediate change is in the disposal of unwanted medicines by consumers. This resource toolkit discusses several ways to address the issue of unwanted and/or expired medicine disposal from households.

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<sup>11</sup> How Sewer and Septic Systems Work, by Marshall Brain, <http://people.howstuffworks.com/sewer3.htm>

<sup>12</sup> Swartz, C. et al. "Steroid Estrogens, Nonylphenol Ethoxylate Metabolites, and Other Wastewater Contaminants in Groundwater Affected by a Residential Septic System on Cape Cod, MA." *Environmental Science and Technology*. Volume 40, number 16, pp. 4894 -4902. Published online July 18 2006.

<sup>13</sup> Boxall, L.A. et al. 2004. "Veterinary Medicines in the Environment." *Rev Environ Contam Toxicol*. 180:1-91. See also Society of Environmental Toxicology and Chemistry (SETAC). *Veterinary Medicines in the Environment*. Crane, M.; Barrett, K.; Boxall, A.; Eds., SETAC Press: Pensacola, FL, 2007. (in preparation).

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