

# Understanding the Public Health Implications of Household Pharmaceutical Waste in the US – Part Two



BY KEVIN T. BAIN

*The following article is the second part of a comprehensive two-part series exploring the public health and environmental impact of household pharmaceutical waste in the US.*

**E**nvironmental and health concerns are not the only public health implications of household pharmaceutical waste; costs are also an important factor. Whether it is consumers or other entities, someone has to pay for wasted pharmaceuticals. Any unconsumed or unused pharmaceutical is a wasted healthcare resource, and wasted healthcare resources add to the total costs of our healthcare system. Nearly a decade ago, experts estimated that more than \$1 billion worth of pharmaceuticals were wasted each year in the US. Pharmaceutical purchases in this country have increased markedly in recent years; waste has increased concurrent with this trend.

For example, researchers recently studied the cost of household pharmaceuticals wasted during hospice care. In a single hospice program, they found that the average cost of wasted drugs was between \$100 and \$200 per patient. If these data were extrapolated to the number of patients receiving services from all US hospice programs per year, it would mean that up to \$290 million (in 2005 dollars) of drugs are being discarded by hospice programs alone. Considering that hospice programs get paid approximately \$135 per patient per day for routine home care, which must cover payment for all of the patient's hospice-related drugs, and that this estimate includes a relatively small segment of the US population, these figures are quite staggering.

## Recommendations for Reducing Environmental Exposure to Household Pharmaceutical Waste

**T**here are opportunities to reduce environmental exposure to household pharmaceutical waste in every phase of the life cycle of pharmaceuticals: design; approval and regulation; production; use; and discharge and disposal. The top priority should be to reduce the amount of pharmaceutical waste generated, rather than dealing with the pharmaceutical waste once it has been generated. Reducing the amount of pharmaceutical waste generated starts at the beginning of the life cycle, where pharmaceuticals are designed. One potential solution to this problem is the use of "green chemistry," also known as sustainable chemistry. Green chemistry is the design and application of chemical products and processes that reduce or eliminate the use or generation of hazardous substances. Green chemistry offers great potential to help reduce the amount of pharmaceutical waste related to the design and production of pharmaceuticals. It also has the potential to enhance or improve the absorption, bioavailability or delivery of pharmaceuticals, which makes it possible to design pharmaceuticals with the same therapeutic effect that use less Active Pharmaceutical Ingredients (API). As a result of using less APIs in the design of pharmaceuticals, the amount of pharmaceutical waste generated both by production and by human excretion is decreased. Green chemistry can facilitate more rapid removal of pharmaceuticals upon release to the environment, which ultimately would decrease environmental persistence of pharmaceutical waste.

The pharmaceutical industry should incorporate green chemistry principles into its design and production processes. Providing incentives, possibly through the pharmaceutical approval process, to support the use of green chemistry should be examined by the federal government. I recommend an Environmental Assessment (EA) for all pharmaceuticals. Currently, the FDA is the federal agency responsible for regulating the approval of pharmaceuticals. While the FDA is required to conduct an EA for pharmaceuticals seeking approval, there are a number of exclusions to this requirement. The federal government should reevaluate and consider removing these exclusions, thereby requiring an EA for all pharmaceuticals before the FDA will approve them to be marketed.

We know that the environmental impact of pharmaceuticals can be lessened simply by reducing the amount of unconsumed or unused pharmaceuticals. In the US, most drugs are prescribed and dispensed in 30 or 90-day supplies, in part due to insurance requirements. If prescribers and pharmacies, respectively, could prescribe and dispense in shorter supplies, a great deal of pharmaceutical waste could be avoided. The federal government should fund research and pilot programs to identify new payment systems to encourage prescribing and dispensing in shorter supplies and to explore the use of new technologies, such as automated dispensing systems, that facilitate dispensing in shorter supplies.

Unfortunately, there is currently very little coordination between federal government agencies – the FDA, the EPA and the DEA – when it comes to handling pharmaceutical waste. The FDA recommends that consumers take advantage of community pharmaceutical take-back programs. Meanwhile, the EPA and the DEA have their own individual efforts underway to address the disposal of pharmaceuticals. The EPA addresses pharmaceutical waste disposal, while the DEA addresses the disposal of controlled substance waste. This patchwork approach has made some progress in handling pharmaceutical waste, but these agencies need to work together to establish more cohesive national guidelines that are environmentally friendly, practical and safe for the public and healthcare providers.

The establishment of more community pharmaceutical take-back programs would lead to significant reductions in the impact of pharmaceutical waste on the environment. Community pharmaceutical take-back programs are periodic or ongoing events that allow people to bring unconsumed or unused pharmaceuticals to an organized collection site, such as a local pharmacy or police station, for proper management and disposal. Currently, there are relatively few take-back programs in the US, primarily because very little funding is available for such programs. They are frequently short-lived, pilot programs funded by federal government grants. To begin to establish more community pharmaceutical take-back programs and to enable them to become permanent programs, the federal government should identify other funding sources for them, including requiring pharmaceutical companies to pay for these programs and levying other waste disposal taxes and fees. Additionally, the federal government must ensure that these programs are convenient to access and free for people who want to participate in them.

In the long term, perhaps the most important effort that can be made to reduce levels of pharmaceutical waste in the environment is educating

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the public and healthcare providers about disposal options. Currently, there is no national database or federal coordination to collect and disseminate information to the public or healthcare providers about safe pharmaceutical disposal practices and about community pharmaceutical take-back programs that are available for them to utilize. As a result, the public and healthcare providers may be unaware that these programs exist in their area. To begin to solve this problem, the federal government should establish a national clearinghouse to collect information about safe pharmaceutical disposal practices and community pharmaceutical take-back programs and they should provide technical assistance to state governments to disseminate this information to the public and healthcare providers.

In the short term, we must establish more environmentally friendly methods for handling pharmaceutical waste. Incineration has the potential to permanently destroy pharmaceutical waste while simultaneously preventing harm to the environment. It is necessary, however, for the incineration to be done with an incinerator that has been designed and approved for this purpose. Currently, few of these incinerators are available in the US, and those available can be costly. Providing incentives, possibly through the tax code, to begin to establish more of these incinerators and to expand their use is something that should be explored by the federal government. Although wastewater treatment plants remove some pharmaceuticals, most conventional plants do not effectively remove most pharmaceuticals from wastewater effluents and removal rates are highly variable. Advanced wastewater treatment techniques such as activated carbon, membrane bioreactors and filtration, and oxidation by chlorination or ozonation can increase pharmaceutical removal rates. Expanding the use of these techniques to more wastewater treatment plants in the US is something that should be explored by the federal government and the EPA.

## Conclusion

It is clear that trace concentrations of household pharmaceuticals, such as antibiotics, hormones and controlled substances, are finding their way into our nation's environment. In many cases, household pharmaceuticals enter the water when people excrete them or wash them away in the shower. In other cases, unconsumed or unused household pharmaceuticals are being flushed down the toilet or the drain and disposed of in the trash. Researchers suspect that the quantity of household pharmaceuticals entering our nation's water supply is increasing, particularly because per capita drug use in the US is on the rise. This has public health and environmental officials in

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On the one hand, there is no evidence that trace concentrations of household pharmaceuticals harm humans. On the other hand, researchers have found pharmaceuticals almost everywhere they have looked for them, and there is evidence that trace concentrations of household pharmaceuticals are harmful to aquatic life. This begs the question: should public health and environmental officials wait until scientists can make a still stronger case for a link between household pharmaceutical waste and harmful effects in humans? It would seem cavalier to dismiss the possibility of harm because of a paucity of evidence. Our nation's experience with the most egregious of chemicals (such as asbestos, lead and tobacco) demonstrates that it can be costly, in terms of human lives, health and dollars, to defer action until evidence of harm is overwhelming.

Although swift action is needed to mitigate the public health threat of household pharmaceutical waste, implementing the strategies recommended in this article will require major changes in attitudes, behavior and regulations. These changes will take time and some will likely be met with opposition. For example, the use of green chemistry would require a major change in the way pharmaceuticals are designed and brought to market through the regulatory approval process. Today, without the widespread use of green chemistry, it takes more than a decade (on average) to bring a new pharmaceutical to market in the US, costing the pharmaceutical company millions or billions of dollars.

The issue of who will pay for the use of green chemistry certainly needs to be addressed. Reducing the amount of unconsumed or unused household pharmaceuticals would require a major change in attitude and among prescribers, payers, pharmacies, and consumers. Consumers would need to access their prescribers and their pharmacies more frequently. In exchange, prescribers and pharmacies would need higher or more frequent reimbursement and dispensing fees, respectively, to support their more labor-intensive services. Payers would need to pass on these fees to consumers, resulting in increased premiums, co-payments, or both. Whether or not such a change is possible, even on a small scale, needs to be explored. In summary, no single strategy will fix the problem of household pharmaceutical waste overnight, yet taking no action is unacceptable.

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