



# KEEPING DRUG DISPOSAL SECURE

Senate hearing highlights confusion over what to do with leftover medicines, barriers to **DRUG TAKE-BACK PROGRAMS**

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**DOZENS OF STATES** and local communities across the U.S. have sponsored drug take-back programs to help keep unused pharmaceuticals out of the nation's waters and out of the hands of drug abusers. But about 10% of prescriptions dispensed in the U.S. contain controlled substances such as painkillers, which cannot be collected legally by most take-back programs under current Drug Enforcement Administration (DEA) regulations.

Lawmakers, particularly those from rural areas where prescription drug abuse is high, are urging DEA to loosen up its restrictions and allow take-back programs to collect all unwanted drugs for disposal. They are also calling for a single federal guideline to help consumers know what to do with unwanted medications.

Various federal entities, including the White House Office of National Drug Control Policy, the Food & Drug Administration, the Fish & Wildlife Service, and the Environmental Protection Agency, have offered guidelines for consumers on how to properly dispose of unused medicines. However, as pointed out at a June 30 hearing of the Senate Special Committee on Aging, they have provided conflicting information.

FDA and the White House, for example,

recommend mixing most unwanted drugs with coffee grounds or kitty litter to make them undesirable, placing the mixture in a sealed container, and throwing it out with the household trash. But at the same time, they suggest that narcotic pain relievers and other drugs that can cause life-threatening effects, such as breathing difficulties or heart problems, be flushed down the toilet to prevent accidental ingestion. EPA and the Fish & Wildlife Service, on the other hand, are opposed to flushing any pharmaceuticals because of concerns about the impacts on fish and the environment.

"We need to provide Americans with better information about what to do with their leftover medications," Sen. Herb Kohl (D-Wis.), chairman of the committee, emphasized at the hearing. "Contradicting guidelines put forth by the DEA, FDA, EPA, and U.S. Fish & Wildlife Service need to be reconciled," he said.

Kohl also urged DEA to update its regulations to allow drug take-back programs to collect all unwanted prescription drugs. "While we understand there is a risk that drugs can fall into the wrong hands on their way to a drug disposal collection point, the fact is that the risk of that happening in the home is even greater," he noted.

**DISPOSAL DILEMMA**  
Consumers are confused about how to get rid of unwanted household medications.

Officials from DEA and the White House, however, told lawmakers that changes have to be made to the Controlled Substances Act to allow

prescription drugs that contain controlled substances to be legally collected by take-back programs.

"DEA's hands are tied right now," stressed Joseph T. Rannazzisi, deputy assistant administrator in DEA's Office of Diversion Control. "We cannot promulgate a regulation because the statute is prohibiting us from doing so."

Under the Controlled Substances Act, an individual who is prescribed a controlled substance cannot transfer that substance to a pharmacist or another non-law enforcement person for any reason, including for disposal purposes, explained the White House "drug czar," R. Gil Kerlikowske.

"Consumers, therefore, often retain unused controlled substances in their homes, which can lead to diversion and abuse," he said.

Legislation has been introduced in Congress that would give DEA more regulatory flexibility with respect to drug disposal. For example, the Secure & Responsible Drug Disposal Act was introduced in the spring of 2009 (H.R. 1359; S. 1292) and again this past May (S. 3397). The legislation would allow DEA to issue regulations regarding the collection of controlled substances for disposal. But so far, the bills have seen no movement in Congress.

**THROUGHOUT** the hearing, witnesses reiterated the need to amend the Controlled Substances Act because of the growing problem of prescription drug abuse. "From 1997 to 2007, there was a 400% increase in treatment admissions for individuals primarily abusing prescription painkillers," Kerlikowske pointed out.

Bruce Behringer, associate vice president of the Office of Rural & Community Health at East Tennessee State University, provided lawmakers with a snapshot of the prescription drug abuse problem in rural Appalachia. He also emphasized the need for better prescription drug monitoring.

"There is no central national database that reliably exposes the depth and breadth of the prescription medication abuse problem in Tennessee or in the U.S.," Behringer noted. "The most reliable place-based and population data may be its unfortunate

end points—mortality and arrest records.”

Behringer urged lawmakers to require physicians and pharmacies to use registries to better track prescriptions. “All public- and private-sector health care providers should use databases prior to prescribing or dispensing controlled substances,” he stressed. “Although states have developed prescription monitoring programs, they are underused.”

**LAWMAKERS** at the hearing also heard about a unique approach taken by the State of Maine to circumvent the problem related to the transfer of controlled substances. In partnership with the Maine DEA and the U.S. Postal Service, Maine has established the Safe Medicine Disposal for ME program. Consumers mail back their unused drugs, including controlled substances, in return envelopes provided at local pharmacies and other locations. The mailers are addressed to the Maine DEA, where the drugs are incinerated.

Maine’s pilot program was implemented in 2007 with a grant from EPA, according to testimony by Stevan Gressitt, founding di-

rector of the Maine Institute for Safe Medicine at the University of New England. The Maine legislature further funded the initiative, but that funding is now running out, Gressitt told lawmakers.

A pilot program was also conducted in two rural counties in Wisconsin, Mary L. Hendrickson, director of Quality & Regulatory Affairs at Genco Pharmaceutical Services (formerly Capital Returns), testified. GPS is a reverse pharmaceutical distributor—it receives unused, expired, or recalled pharmaceutical products, including controlled substances, from pharmacies and drug wholesalers. The company then returns the drugs to pharmaceutical companies or incinerates them. In some cases, it even captures energy from the incineration process, Hendrickson noted.

GPS wants to begin collecting unwanted consumer drugs. It sponsored the Wisconsin pilot program to determine how often consumers would use a drug mail-back program. “GPS has received requests from our customers, including both large pharmacy chains and pharmaceutical manufacturers, to provide a consumer take-back

solution. Regrettably, we have not been able to develop this business opportunity due to the Controlled Substances Act,” Hendrickson testified.

In the Wisconsin pilot program, customers were specifically told not to mail back any controlled substances. “While we did our best to educate individuals on the definition of a controlled substance, including why we could not accept these products, we found that consumers did not fully understand and incorrectly sent us controlled substances,” Hendrickson said.

Both the Maine and Wisconsin pilot programs demonstrated that the demand for a consumer drug take-back program is high, particularly in rural areas. But Hendrickson told lawmakers that GPS decided not to continue its program when it became evident that “individuals will return controlled substances even when educated not to return these products.”

One way to fix the problem is to change the law, Hendrickson stressed. “The Controlled Substances Act needs to be amended to allow take-back of controlled substances from non-DEA registrants.” ■

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