



Input on Federal Legislation to Amend Statutes Related to Safe Drug Disposal Product Stewardship Institute Regulations Workgroup September 14, 2009

This document provides recommendations on the amendment of federal statutes related to the collection and disposal of unwanted medications and issuing clear guidance to the public not to flush leftover drugs. It is intended for the consideration of federal agencies and Congressional offices and committees, and has been endorsed by the agencies, companies, and organizations listed on page 4. Changes to the Controlled Substances Act and Food, Drug, and Cosmetic Act, as described in these comments, would provide a critical first step towards achieving secure, convenient, cost-effective, and on-going drug take-back around the country. Additional issues, such as the need for sustainable funding of such programs, will also need to be addressed to ensure effective drug take-back programs are available in all communities.

The [Product Stewardship Institute](#) is facilitating a multi-party National Dialogue on Waste Pharmaceuticals. Within this effort, a Regulations Workgroup has convened for the purpose of developing options to resolve regulatory barriers that prevent clear and consistent messaging on drug disposal and hinder the sustainable collection and disposal of waste pharmaceuticals from residential and other similar sources.

Comments Related to the Controlled Substances Act:

- **The broadest possible range of people should be able to access new options created for the secure collection of controlled substances, including: patients, family members or friends who act as caregivers, hospice workers, long term care facilities, boarding homes for the elderly, school nurses, and veterinarians.**

In our experience, many of the patients using controlled substances are elderly or very ill and their mobility is limited. They may also have a range of people caring for them, whether a family member (who may or may not live with them), hospice worker, or other healthcare professional. They may or may not be in a facility of some sort, and those facilities may be regulated very differently in different states. Caretakers -- whether family members, friends, or professionals, and whether in a facility or a patient's home -- are often left with the responsibility of disposing of medications when a person passes away or their treatment changes.

- **Multiple collection and disposal options should be available to those designing and implementing drug take-back programs. These should include, at minimum: individual mail-back, collection at retail pharmacies, community take-back events, and, for long-term care facilities, the ability to mail-back or have scheduled pick-ups of sealed containers.**

Capturing the largest possible quantity of leftover medications requires that convenient, secure collection opportunities are available (to the range of individuals described above) when drugs are discarded due to a change of treatment or patient status. Diversity in the patient and caretaker population, as well as the

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multiplicity of settings necessitates the availability of multiple collection options. Drug take-back programs are also managed by different agencies or coalitions at the local and state level. These groups may prefer different types of programs due to factors such as cost, convenience, rural vs. urban settings, the willingness of key players such as retail pharmacies to participate in collection, and/or applicable local or state laws.

- **Collection efforts should be able to accommodate all pharmaceutical drugs (both controlled substances and other drugs).**

The Controlled Substances Act or other federal legislation should not preclude take-back programs from including both controlled and non-controlled drugs. The general public is not able to distinguish between these categories, and it is likely most efficient to collect all types of drugs together under the same security protocols.

- **Collection and disposal options should not *require* law enforcement for normal operations.**

While it is important that the handling of controlled substances be conducted within a secure structure with sufficient oversight to prevent diversion, this does not inherently require the participation of law enforcement personnel in the receipt of discarded pharmaceuticals, including controlled substances, particularly if collection and transport is conducted using the option of sealed packages or containers. Law enforcement involvement makes drug take-back more expensive and may detract from other local law enforcement priorities. Law enforcement agencies should have the option of implementing drug take-back programs according to their local priorities, but the Controlled Substances Act should not require them to participate in the collection or disposal.

- **New methods for collection of controlled substances should be readily accessible to new and existing drug take-back programs at the community, local, state, and national levels, without a federal requirement for additional enabling legislation at the state or local levels.**

Regulations resulting from a change to the Controlled Substances Act should be developed as quickly as the appropriate public review and consideration of stakeholder comment will allow. States should not be required to pass legislation for entities in that state to implement drug take-back programs that can accept controlled substances. Any collection and disposal program must comply with the rules and regulations of existing state authorities with jurisdiction over waste and/or controlled substances and prescription drugs. It should be as simple as possible to begin implementing programs under the new regulations, and all requirements must be clearly communicated via the Drug Enforcement Administration (DEA) or other federal entity.

Because diversion from collection programs is a concern, we understand that the DEA or DEA-designated authorities in states and localities may request notification of collection program implementation. This notification procedure should be clear and simple to complete.

- **Federal law should not mandate that drugs collected for disposal be inventoried.**

Some take-back programs may choose to inventory drugs they collect in order to better understand the types of drugs that end up as waste or to characterize the benefits they provide (such as the environmental benefits of capturing antibiotics or endocrine disruptors, or the safety benefits of capturing narcotics that are commonly abused). However, the Controlled Substances Act should not require the inventorying of drugs collected for the purpose of disposal. Inventorying drugs also adds to the cost of drug take-back programs, and, unless conducted under certain conditions, could create opportunities for illegal diversion due to this additional handling of the collected substances. Drug take-back programs can ensure that waste medicines are not diverted following non-inventoried collection by practicing secure protocols for handling collected medicines, including: careful oversight of staff handling waste medicines, using tamper resistant and evident seals on boxes for disposal, recording weights of boxes, and securely tracking boxes from collection through final destruction.

- **New regulations developed under an amended Controlled Substances Act should be developed in consultation with the Environmental Protection Agency (EPA). No statute related to drug disposal should preempt state and local governments' right to apply more stringent requirements regarding the ultimate disposal of collected pharmaceuticals.**

Environmental concerns are one factor driving the growth in drug take-back efforts across the country. State and local governments implementing drug take-back programs should be able to design programs that adhere to the strictest possible environmental standards for the ultimate disposal of collected pharmaceuticals applicable in their own jurisdiction. In developing regulations under an amended Controlled Substances Act, the DEA should consult with the EPA to ensure the regulations are consistent with the goals and requirements of the Federal Clean Water Act, Resource Conservation and Recovery Act, and Solid Waste Disposal Act. These federal statutes allow state and local governments to impose more stringent requirements as they choose.

Comments Related to the Food, Drug, and Cosmetic Act:

- **The Food and Drug Administration (FDA) should eliminate the flushing recommendation from existing drug labels and not allow future drug labels to include the recommendation that leftover drugs be flushed.**

Several state and local governments have developed guidance for consumers specifying that leftover drugs should never be flushed. The Office of National Drug Control Policy has also developed federal recommendations for consumers which states that drugs should not be flushed unless noted on the FDA website. Because some drug labels, or "product inserts" (approved by FDA at the time a drug is approved for market) include the recommendation that leftover drugs be flushed, the federal government is unable to issue a clear statement to consumers that they should not flush drugs.

Eliminating the flushing recommendation on drug labels will allow federal government agencies and a growing number of state and local agencies active on this issue to state clearly and consistently that leftover drugs should not be flushed. While we understand that concerns about diversion may lead pharmaceutical companies and the FDA to recommend the disposal of a drug by flushing, the current list of 13 substances applies only to nine controlled substances out of hundreds on the market, as well as three antiviral medications commonly used for the treatment of HIV, and one oral antibiotic.

If you have any questions about this document, or are interested in getting involved with the Product Stewardship Institute's ongoing National Dialogue on Waste Pharmaceuticals, please contact:

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Endorsements of Input on Federal Legislation to Amend Statutes Related to Safe Drug Disposal

The following agencies, organizations, and companies have indicated their support for these comments by endorsing this document.

Alliance for the Great Lakes	Minnesota Technical Assistance Program
American Nurses Association	National Association of Clean Water Agencies (NACWA)
Bay Area Pollution Prevention Group, CA	New York Department of Environmental Conservation
California Association of Sanitation Agencies (CASA)	North America Hazardous Materials Management Association (NAHMMA)
California Product Stewardship Council (CPSC)	Oregon Association of Clean Water Agencies (OR ACWA)
Central Contra Costa Sanitary District, CA	Product Policy Institute (PPI)
City and County of San Francisco, CA	Prescription Pill and Drug Disposal Program Network (P2D2) Program Network
City of Frisco Environmental Services Division, TX	PSC Environmental Services
City of Palo Alto, CA	Public Employees for Environmental Responsibility
Elder Abuse Task Force of Midcoast Maine	Sharps Compliance, Inc.
EXP Pharmaceutical Services Corp.	Snohomish County Solid Waste Division, WA
Franklin County Solid Waste Management District, MA	Stericycle
Health Care Without Harm (HCWH)	Teleosis Institute
Health Care Without Harm - Nurses Work Group	Thurston County Public Health and Social Services Department, WA
Heritage Environmental Services	Tri-County Hazardous Waste and Recycling Program, OR
Illinois-Indiana Sea Grant College Program	Washington State Department of Ecology
Iowa Department of Natural Resources	Washington State Hospice and Palliative Care Organization
Iowa Pharmacy Association	Washington State Nurses Association
Karen Bowman & Associates, Inc.	Waste Management
Local Hazardous Waste Management Program of King County, WA	
Maine Department of Environmental Protection	
Massachusetts Water Resources Authority	
Metro, Portland, OR	