

OVERVIEW OF EIGHT MEDICINE DISPOSAL PRODUCTS



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Community Environmental Health Strategies LLC
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Executive Summary

Secure disposal of leftover and expired medications is a key prevention strategy in reducing misuse and diversion of medicines to combat drug abuse and prevent overdoses. Proper disposal of leftover and expired medicines prevents those medicines from contributing to pharmaceutical pollution in waterways and water supplies. Disposing of unwanted medicines in the household trash creates risks of unintended exposures, drug diversion, and environmental pollution. This recognition has increased interest in and implementation of secure medicine take-back programs. It has also sparked a new market sector of products designed for in-home disposal of waste medicines that are described as easy and safe ways to alter pharmaceuticals so that they are safe for trash disposal.

This report examines eight medicine disposal products based on information available from each manufacturer's website, promotional materials, and product labels as of March 2017. Seven products marketed to consumers were reviewed: Deterra, DisposeRx, Drug Buster, Element MDS, Pill Catcher, Pill Terminator, and Rx Destroyer. These products recommend trash disposal of the product-pharmaceutical mixture and are also marketed for use by healthcare facilities and practitioners. Cactus Smart Sink was reviewed as a related product that is intended for use solely by healthcare facilities, with final disposal by incineration according to regulatory requirements.

The medicine disposal products marketed for consumer use are provided in bottles or a pouch. Home users are instructed to add unwanted medicines in pill or liquid form to a stated capacity; some of the products also treat patches. Water needs to be added to most of the products. The mixture is shaken and then disposed of in the household trash. Appropriateness of these products for healthcare facilities and other regulated generators of waste pharmaceuticals depends on the specific waste pharmaceuticals, as well as applicable state and local regulations which may be more stringent than federal regulations.

None of the medicine disposal products are approved by the DEA, the EPA, or any federal agency, which do not evaluate or endorse such products. Four of the products do not provide any testing results to demonstrate their performance. Four other products provide some testing results, although some products provide internal analysis rather than validated independent laboratory testing or peer-reviewed published research. Available test results do not convincingly demonstrate that any product meets the DEA's stringent non-retrievable standard for disposal of controlled substances. The limited data available for several products shows that some of tested drugs are not fully adsorbed and could be potentially extracted from the disposal product under mild conditions. Available test results also do not provide complete waste characterizations of the disposal product-pharmaceutical mixtures, so it is unclear whether any of the products would meet California's regulatory requirements for solid waste disposal.

Federal guidelines from the DEA, EPA, and FDA for disposal of household medicines for residents recommend use of secure medicine take-back programs as the best disposal option, and preferable to disposing of medicines in the household garbage. In situations where residents have no access to a take-back program and trash disposal of pharmaceuticals is allowed by local authorities, these products could be used as potentially more effective deterrents to diversion than mixing medicines with kitty litter or coffee grounds. By adsorbing most of the drugs, even reversibly, or making the drug mixture noxious, the products may make illicit access to the medicines more difficult. However, some of the products may create new exposure risks due to their ingredient chemicals. In addition, the cost of the medicine disposal products may make regular use by consumers unlikely. Examples of product prices and disposal capacities are: \$4.99 for 15 pills; \$4.95 for 120 pills; \$9.95 for 300 pills; and \$15.99 for 300 pills.

Examining the information provided by the manufacturers of these medicine disposal products provides some answers, but leaves many questions about the effectiveness and mode of action of the products. Additional independent laboratory analysis is needed to fully examine and compare the performance of the products and to assess how well they achieve stated goals of preventing drug diversion and environmental contamination.

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I. Overview of Products

Manufacturer's descriptions for seven products marketed to consumers for home disposal of medicines were reviewed: Deterra, DisposeRx, Drug Buster, Element MDS, Pill Catcher, Pill Terminator, and Rx Destroyer. These products are also marketed for use by healthcare facilities, nursing homes, pharmacies, law enforcement, and other entities. Cactus Smart Sink was also reviewed as a related product that is designed and marketed solely for use by healthcare facilities.

This report is a summary and review of information about these eight medicine disposal products that is available to consumers, health care facilities, government agencies, and other decision-makers from each manufacturer's website, promotional materials, and product labels as of March 2017. Additional information about product ingredients and potential mechanisms of action was obtained through searches of research literature and patents. The author welcomes identification of additional information, analysis, and resources about these and other products designed for disposal of waste pharmaceuticals.

Table 1 lists key features of the eight medicine disposal products for comparison. A more detailed overview of each product is provided in Section V, including instructions for use, intended users, and a summary of manufacturer's statements on product performance and testing results. Sections II through IV of the report summarize available information and identify key issues and considerations in evaluating product performance for disposal of waste pharmaceuticals from residential and healthcare generators.

TABLE 1: MEDICINE DISPOSAL PRODUCTS

PRODUCTS MARKETED TO INDIVIDUALS & HEALTHCARE FACILITIES/PROVIDERS

Product Name	Active Ingredient	Mode of Action	Final Disposal Instructions	List Price as of March 2017
Deterra (MedsAway)	activated carbon	adsorption of chemicals to carbon	garbage / solid waste system*	\$4.99 - single pouch / 15 pills \$6.99 - large pouch / 90 pills \$34.99 - 1.8 L bottle / 450 pills
DiposeRx	“cross-linking polymer”	unknown. ingredients not identified	garbage / solid waste system	not stated
Drug Buster	activated carbon	adsorption of chemicals to carbon	garbage / solid waste system per local regulations*	\$9.95 - 4 oz / 50 pills \$15.99 - 16 oz / 300 pills \$34.99 - 64 oz / 1500 pills
Element MDS	“organic plant-based powder”	unknown. ingredients not identified	garbage / solid waste system	\$6.99 - 17 oz / 500 pills not sold individually \$349.50 for 50 kits
Pill Catcher	bentonite clay	adsorption of chemicals to clay	garbage / solid waste system	\$4.95 - pint / 120 pills \$6.96 - quart / 300 pills \$22.60 - gallon / 1500 pills
Pill Terminator	calcium hypochlorite, Fuller’s earth, “absorbent polymer”	oxidation and adsorption	garbage / solid waste system	\$ 9.95 - 300 mL / 300 pills. \$24.95 - gallon size / capacity not stated
Rx Destroyer	activated carbon and proprietary agents	adsorption of chemicals to carbon	garbage / solid waste system. check federal, state, local regulations*	\$4.16 - 4 oz. / 50 pills \$8.75 - 16 oz / 300 pills \$48.75 - 1.0 gallon / 3,000 pills sold in cases

**These products state they are for use with non-hazardous pharmaceuticals only: Deterra (when used by healthcare facilities), Drug Buster, and Rx Destroyer.*

PRODUCT MARKETED SOLELY TO HEALTHCARE FACILITIES

Product Name	Active Ingredient	Mode of Action	Final Disposal Instructions	List Price as of March 2017
Cactus Smart Sink	“proprietary mixture of denaturants and deterrents”	unknown. ingredients not identified. locking unit and cartridge physically captures pills and liquids	dispose per federal and state guidelines depending on medicines; incineration recommended	\$50 per cartridge / 500-1500 pills or roughly 3.0 L liquid locking wall unit roughly \$500, with volume pricing

II. Overview of Issues

A. Compliance with Federal Disposal Guidelines and Regulations

Marketing materials and technical descriptions for the medicine disposal products make broad statements about compliance with federal pharmaceutical disposal guidances and regulations. A consumer would reasonably conclude a product has passed specific tests required by the Drug Enforcement Administration (DEA) or the Environmental Protection Agency (EPA), or has been approved by another federal government agency. Examples include:

“Exceeds Federal Drug Disposal Guidelines”

“Specially formulated to meet and exceed FDA and EPA Guidelines”

“Medications Deemed Non-Retrievable”

“Passes all EPA and DEA laws and regulations”

Federal agencies have not reviewed, evaluated, endorsed, or certified any medicine disposal products. Any statements that imply a product has been approved or meets a specific regulatory requirement should be viewed as the opinion of the product’s manufacturer, not an agency determination.

The DEA has stated in official documents, and informal communications, that it will not evaluate medicine disposal products or technologies and does not endorse products. The DEA’s Final Rule for Disposal of Controlled Substances explains “The DEA will not be routinely engaged in evaluating new technologies intended to render controlled substances “non-retrievable.””¹ The EPA and the Food and

Drug Administration (FDA) also have not reviewed or approved drug disposal products and have policies against approving or endorsing companies or commercial products.^{2,3}

The key federal regulations that apply to disposal of waste pharmaceuticals are the requirements of the DEA for prescription drugs that are controlled substances – such as prescription opioids and stimulants – and the EPA for hazardous waste pharmaceuticals. Regulatory requirements and guidelines depend on the properties and hazards of the pharmaceutical waste, and also on how much waste is generated, and who is generating the waste, i.e. are the waste medicines from a residential source or from a hospital, pharmacy, and other healthcare facility or practitioner.^{4,5} The different disposal requirements depending

The DEA and other federal agencies have not reviewed or approved any medicine disposal products and do not have any performance standards or guidelines specifically for such products.

¹ Department of Justice. Drug Enforcement Administration. Disposal of Controlled Substances; Final Rule. Federal Register 79 (174) September, 2014. https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf. “Non-Retrievable Destruction Standard”, page 53547-8.

² U.S. FDA website. “Is it Really “FDA Approved?” <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm047470.htm>

³ U.S. EPA website “Will the EPA recognize my product as environmentally preferable?” <https://www.epa.gov/greenerproducts/frequent-questions-about-sustainable-marketplace-and-green-products#Eight>

⁴ U.S. DEA website. “Drug Disposal Information” https://www.deadiversion.usdoj.gov/drug_disposal/

⁵ U.S. EPA website. “Learn the Basics of Hazardous Waste” <https://www.epa.gov/hw/learn-basics-hazardous-waste#regulations> and “Categories of Hazardous Waste Generators” <https://www.epa.gov/hwgenerators/categories-hazardous-waste-generators>

on generator status often create confusion as it would seem more logical to regulate disposal of materials consistently based on their inherent hazards and toxicity. Residents are exempt from the federal regulations for pharmaceutical wastes that apply to healthcare facilities, but state and local regulations for pharmaceutical waste management may be different from federal regulations. These distinctions will be further identified in this section.

All of the medicine disposal products reviewed, except for Cactus Smart Sink, are intended to be discarded in the solid waste system after mixing with unwanted medicines. The DEA, EPA, and FDA all recommend secure medicine take-back programs as the best disposal method for unwanted household medicines, and a better choice than trash disposal which is only recommended when no take-back program is available (see details in Section II.A.3. and in Table 2). None of the products marketed to consumers explain in their instructions or promotional materials that the DEA, FDA, and EPA's guidelines encourage the use of medicine take-back programs over trash disposal. Because of that omission, none of the products for consumer use are aligned with federal medicine disposal guidelines.

For the most part the websites and materials for the consumer-marketed products do not mention secure medicine take-back programs. A few of the websites contain inaccurate or negative statements about medicine take-back programs. Some materials state that only law enforcement can take-back controlled substances for disposal and/or that pharmacy take-back and mail-back programs cannot accept controlled substances. These statements are out-of-date since finalization of the DEA's Rule in October 2014. Many communities across the country have pharmacy or hospital based take-back programs that accept prescription drugs that are controlled substances along with other medicines. A smaller number of communities have pharmacies or other local programs that provide or sell mail-back envelopes approved for use with both controlled and non-controlled medicines.

Federal agencies recommend use of secure medicine take-back programs as the best medicine disposal option, preferable to trash disposal. Some local jurisdictions prohibit disposal of waste pharmaceuticals in the household trash and solid waste system.

Federal guidances for trash disposal of medicines, if no take-back program is available, recommend taking medicines out of original containers so that they are not readily identifiable as a drug product. However, someone searching in a garbage can for medicines would be able to identify most of these used medicine disposal products as containing waste medicines from the disposal product label. DisposeRx recommends treating the waste medicines in the original prescription bottle or pill container. The exception is Element MDS which provides an unlabeled white bottle.

In addition, some municipalities have waste acceptance ordinances or policies that prohibit or discourage residents from disposing of waste pharmaceuticals in the trash because of their toxicity and potential for diversion. Cactus Smart Sink, Drug Buster and Rx Destroyer include statements in their instructions or other materials to consult applicable local, state, or federal regulations on proper disposal. Rx Destroyer and Drug Buster state that the product should only be used for disposal of non-hazardous pharmaceuticals, which is a designation that varies depending on state regulatory requirements (see Section II.A.2.). Deterra includes a similar statement if the product is used by healthcare facilities. Drug Buster also states it should not be used for chemotherapy drugs. The Cactus Smart Sink is marketed solely to healthcare facilities and is the only product that recommends disposal of the full cartridges by high temperature incineration and cautions against landfill disposal.

A.1. DEA's non-retrievable standard for controlled substances. A key stated purpose of the medicine disposal products is to prevent drug diversion and misuse. All of the medicine disposal products assert that drugs will be “non-retrievable” after treatment, and most reference compliance with DEA guidelines or meeting the DEA’s standard for controlled substances. Legally prescribed pharmaceuticals that are controlled substances are carefully regulated by the DEA under the federal Controlled Substances Act, as well as regulated by state laws, due to their high potential for misuse and addiction. Schedule II-V controlled substances include legally prescribed drugs like opioid painkillers, stimulants, anti-anxiety medicines, and anti-depressants.

The Drug Enforcement Administration’s Final Rule on Disposal of Controlled Substances⁶ defines a “non-retrievable” standard for destruction of controlled substances by DEA authorized collectors providing take-back of residential medicines and by DEA registrants, such as healthcare facilities:

“Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance’s physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance’s chemical or physical properties. A controlled substance is considered “non-retrievable” when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.”

The DEA states that incineration and chemical digestion are examples of current technologies that achieve the non-retrievable standard, and that trash disposal does not achieve the non-retrievable standard:

“...sewering (disposal by flushing down a toilet or drain) and landfill disposal (mixing controlled substances with undesirable items such as kitty litter or coffee grounds and depositing them in a garbage collection) are examples of current methods of disposal that do not meet the non-retrievable standard.”⁶

Four of the medicine disposal products – Cactus Smart Sink, DisposeRx, Drug Buster, and Element MDS - do not provide any test results to demonstrate that the product irreversibly alters the physical or chemical state of drugs to achieve the non-retrievable standard. However, the Cactus Smart Sink markets its product solely to healthcare facilities, as a means to prevent diversion of unused and partially administered doses of controlled substances, and recommends final disposal of the used product cartridges by incineration, which meets DEA’s non-retrievable standard.

The Pill Catcher, which utilizes bentonite clay, provides results of a mostly independently conducted TCLP (Toxicity Characteristic Leaching Procedure) assay which is an EPA test method to simulate solid waste leaching under landfill conditions. A sample of the Pill Catcher mixed with 13 pharmaceuticals (12 tablets and 1 oz of a liquid) passed the TCLP test. The TCLP, however, does not directly confirm that the controlled substance drugs mixed with the Pill Catcher were irreversibly physically or chemical altered because the assay does not screen for any pharmaceutical compounds. The TCLP also utilizes mild extraction conditions at ambient temperature. Controlled substances might be more readily released from a disposal product under different chemical or physical extraction conditions. The TCLP assay and these results are further described in Section III.C and in the product description in Section V.

⁶ Department of Justice. Drug Enforcement Administration. Disposal of Controlled Substances; Final Rule. Federal Register 79 (174): September, 2014. https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf. “Non-Retrievable Destruction Standard”, page 53547-8. “Non-retrievable” definition, page 53560.

Three other products – Deterra, Pill Terminator, and Rx Destroyer – provide some test results on their websites as evidence that their products render drugs non-retrievable. The results, however, demonstrate that small amounts of the controlled substances tested are readily retrievable. In addition, these test results are unpublished studies or other analysis that is not validated by independent laboratory testing. Deterra provides internal research by its principal scientist that show most of the drugs tested are adsorbed onto the activated carbon product, but small amounts of drugs remain in the liquid phase of the disposal product-pharmaceutical mixture. Additional small amounts of drugs such as fentanyl are released from the disposal product-pharmaceutical mixture by simple washing with water or ethanol. The Pill Terminator provides independent laboratory testing stating that drugs are physically dissolved and made unpalatable by treatment with its chlorine-based reagent. A separate unpublished study shows 45% of a morphine sample can be washed out of the Pill Terminator by water extraction two days after the drug was mixed with the product. Independent analysis provided for the Rx Destroyer consists of the opinion of a scientific consultant who specializes in activated carbon services that the product will render drugs non-retrievable based on other publications showing adsorption of non-pharmaceutical chemicals onto activated carbon. No laboratory testing of Rx Destroyer mixed with drugs is provided and the consultant acknowledges that some amount of drug ingredients will remain unadsorbed in the liquid phase of the disposal product. These test results are further described in the product descriptions in Section V.

The DEA’s non-retrievable standard is stringent in requiring complete and irreversible physical or chemical alteration of the controlled substance, such that no active drug or analogue can be retrieved. The non-retrievable standard is not achieved if even a small percentage of the controlled substance can be recovered from the disposal product. Furthermore, if a small amount of the controlled substance

can be retrieved simply by rinsing the used medicine disposal product briefly with water, it seems likely that some or all of the active pharmaceutical ingredient could be released by other solvents, or through longer extractions under other physical conditions. More rigorous testing using specific analysis for the controlled substances and their analogues is needed to convincingly verify that any of these medicine disposal products is capable of achieving the DEA’s non-retrievable standard.

A.2. EPA and State or local disposal standards for hazardous waste pharmaceuticals. Some pharmaceuticals, including some medicines commonly used in the home, meet the characteristics of hazardous wastes under the federal Resource Conservation and Recovery Act (RCRA)⁷, including warfarin (coumadin), unused nicotine patches, topical solutions of erythromycin or hydrocortisone, epinephrine in EpiPens, and a number of chemotherapy drugs. Some unused pharmaceutical chemicals are hazardous wastes because they are commercial products listed on RCRA’s P list or U list. Other pharmaceutical preparations are hazardous waste because they meet federal RCRA definitions of ignitability, corrosivity, reactivity, or toxicity (“characteristic hazardous waste”). A 2012 review by the EPA’s Office of Inspector General found there may be more than one hundred pharmaceuticals that meet the RCRA criteria for hazardous waste, however EPA has not fully reviewed the characteristics of all pharmaceuticals on the

More rigorous and independent laboratory testing is needed to verify performance claims that drugs are rendered “non-retrievable” by a medicine disposal product.

⁷ U.S. EPA. Management of Pharmaceutical Hazardous Waste.
<https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste>

market.⁸ There are a handful of RCRA hazardous waste pharmaceuticals that are also controlled substances: chloral hydrate, fentanyl sublingual spray, phenobarbital, testosterone gels, and injectable valium.⁹

Healthcare facilities, medical offices, and other businesses that generate pharmaceutical wastes must follow hazardous waste generator regulations for disposing of hazardous waste pharmaceuticals.¹⁰ Specific disposal requirements currently depend on whether the facility is a large quantity generator, a small quantity generator, or a conditionally exempt small quantity generator based on the total amount of hazardous wastes generated each month. Under RCRA, all household wastes generated by residents in their homes are exempt from federal hazardous waste management requirements (see [40 CFR 261.4\(b\)\(1\)](#)). However, when household hazardous wastes (HHW) are collected for disposal, EPA has consistently recommended that HHW should be managed as hazardous waste.

State and local regulations for waste management may be different from federal regulations. Under RCRA, states may adopt regulations that are more stringent than the federal regulations, and RCRA does not preclude states and municipalities from adopting regulations that are broader-in-scope. California, for example, does not recognize the household exemption from RCRA and requires that household hazardous wastes are managed according to California's state rules for hazardous waste.¹¹ In addition, some counties, cities, or other local entities have regulations or solid waste acceptance policies that prohibit or discourage residents from disposing of waste pharmaceuticals in the solid waste system or in the sewer.

Although two of the products reviewed (Rx Destroyer and Drug Buster) include a warning to use only on non-hazardous medicines on their product labels and websites, it would be difficult and very unlikely for a consumer to be able to determine which medicines are non-hazardous from reviewing information available from federal and state agencies.

- Drug Buster's website states "All federal and state guidelines require non-hazardous unused pharmaceuticals be rendered undesirable and unusable. Please refer to your local regulations to ensure specific compliance." The product label states: "Please go to www.drug-buster.com website for federal and state guidelines on how to determine if medications are hazardous waste, how to dispose of them and important product advisory." The website provides a link to EPA's list of state health and environmental agencies.
- Rx Destroyer's product label similarly refers users to their website for "federal, state, and local regulations on how to determine if medications are hazardous". Rx Destroyer's website has a Federal & State Guidelines page with links to DEA and EPA guidances for pharmaceutical waste management, and links to state environmental agencies.

For facilities that generate pharmaceutical wastes, Rx Destroyer has recently added a mail-back option through a partner company and states "Rx Waste Systems uses state compliance regulations for the destruction of the Rx Destroyer." The website notes the Rx Waste System mail-back is prohibited in:

⁸ U.S. EPA, Office of Inspector General. "EPA inaction in identifying hazardous waste pharmaceuticals may result in unsafe disposal" May 25, 2012. <https://www.epa.gov/office-inspector-general/report-epa-inaction-identifying-hazardous-waste-pharmaceuticals-may-result>

⁹ U.S. EPA. Proposed Rule: Management Standards for Hazardous Waste Pharmaceuticals. Federal Register Vol. 80, No. 186. Page 58047, <https://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-23167.pdf>

¹⁰ EPA has been working since 2008 to tailor its hazardous waste disposal regulations for pharmaceutical wastes from hospitals, pharmacies, reverse distributors, and other healthcare facilities to the specific needs of the healthcare sector. EPA is working to finalize a Management Standards for Hazardous Waste Pharmaceuticals Rule proposed in 2015. <https://www.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals>

¹¹ California Department of Toxic Substances Control <http://www.dtsc.ca.gov/HazardousWaste/index.cfm>

Arkansas, California, Connecticut, Illinois, Maine, Massachusetts, Minnesota, New Hampshire, New York, Pennsylvania, Rhode Island, Vermont and Virginia.

A.3. Disposal guidance for waste pharmaceuticals from households. Home-generated medicines are exempt from federal regulation, but the DEA, EPA and FDA, recommend the use of secure medicine take-back programs as the best disposal method, and a better choice than trash disposal. Medicine take-back programs are recommended as providing both secure and environmentally sound disposal of waste medicines. Disposal of medicines in the trash is suggested only in situations when residents cannot access a medicine take-back program. There is no single federal guideline for how individuals should dispose of excess medicines used in the home, but the DEA, FDA, and EPA have guidelines that have become fairly well aligned in recent years (Table 2).

The DEA's Rule for Disposal of Controlled Substances authorized new options for secure take-back programs when it went into effect on October 9, 2014 to implement the federal Secure and Responsible Drug Disposal Act of 2010. Prior to this Rule, leftover prescribed controlled substances could only be legally collected from residents by law enforcement operating take-back events or drop-off programs. The 2014 Rule defined secure protocols for take-back of leftover controlled substances and all other medicines used in the home through secure drop boxes, collection events, and mail-back programs. In addition to law enforcement, secure drop boxes can be operated by DEA authorized retail pharmacies, hospitals or clinics with an on-site pharmacy, narcotic treatment centers, long-term care facilities that partner with an authorized pharmacy, drug manufacturers, distributors, and reverse distributors. Although home consumers are not individually subject to the DEA Rule, collection points for home-generated medicines are subject if controlled substances are received, even inadvertently. In its Rule, the DEA states that patients "may continue to dispose of their own pharmaceutical controlled substances in the manner recommended by other Federal and State agencies, such as the FDA, Office of National Drug Control Policy (ONDCP), and EPA."

The EPA has recommended appropriate disposal facilities for residential medicine take-back programs. In a 2012 guidance – "*Recommendation on the Disposal of Household Pharmaceuticals Collected By Take-back Events, Mail-Back, and Other Collection Programs*"¹² – the EPA recommends disposal of collected pharmaceuticals by high temperature incineration at a permitted hazardous waste combustor. When use of a hazardous waste combustor is not feasible, the EPA recommends a permitted large or small municipal waste combustor. In this memo, EPA also stated that incineration is recommended because it addresses both environmental and diversion concerns for safe disposal of waste household medicines. As previously stated, incineration meets the DEA's "non-retrievable" destruction standard.

Because medicine take-back programs are not yet available in every community, federal agencies do also provide alternative disposal advice for residents. For example, FDA's website states:

"If no medicine take-back programs or DEA-authorized collectors are available in your area, and there are no specific disposal instructions on the label, such as flushing as described below, you can also follow these simple steps to dispose of most medicines in the household trash:"

The steps recommended for trash disposal of medicines by each agency are similar: medicines in pill form should be removed from their original containers, mixed with an undesirable substance, such as kitty litter or coffee grounds, placed into a disposable container with a lid or a sealable bag, then placed in the trash.

¹² U.S. EPA Memorandum to RCRA Division Directors. September 26, 2012. "*Recommendation on the Disposal of Household Pharmaceuticals Collected By Take-back Events, Mail-Back, and Other Collection Programs*" [https://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/\\$file/14833.pdf](https://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/$file/14833.pdf)

Some local jurisdictions have ordinances or waste acceptance policies that prohibit or discourage disposal of waste pharmaceuticals in wastewater or solid waste streams. These laws may be specific for pharmaceuticals, or may prohibit disposal of HHW and other specific wastes in the trash or sewer. In Washington State for example, Kitsap County and Snohomish County prohibit disposal of pharmaceuticals in the trash and recommend using a secure medicine take-back program. Some of the medicine disposal products recommend checking federal and state regulatory requirements, but only a few mention checking local regulations.

Special note: FDA’s flush list. The FDA’s guidance suggests checking the drug product label for disposal instructions because the FDA recommends flushing rather than trash disposal for a specific list of especially dangerous medications. This “flush list” consists of 45 drugs, including products containing oxycodone, buprenorphine, and fentanyl. The FDA specifically recommends flushing for immediate disposal of used fentanyl patches (brand name Duragesic) due to potential risk of exposure to children if used patches are disposed in the household trash.¹³

The FDA’s materials on drug disposal are not entirely self-consistent and clear in prioritizing take-back programs over flushing of medicines on the “flush list”, but that hierarchy is clear in FDA’s online explanation of the “List of Medicines Recommended for Disposal by Flushing”¹⁴, which states:

“Flushing of Certain Medicines. There are a small number of medicines that may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed. To prevent accidental ingestion of these potentially dangerous medicines by children, or pets, it is recommended that these medicines be disposed of quickly through a medicine take-back program or by transferring them to a DEA-authorized collector. If these disposal options are not readily available, it is recommended that these medicines be flushed down the sink or toilet as soon as they are no longer needed.”

It is important to note that the FDA’s medicine “flush list” is not aligned with the disposal guidances of many local jurisdictions across the country that advise that residents should never flush any unwanted medicines. Local wastewater and water agencies, as well as environmental and public health organizations, have asked the FDA to end its “flush list” recommendation and work with other federal agencies to create a consistent medicine disposal guidance that focuses on use of secure medicine take-back programs. In a 2016 letter responding to a statement of concern submitted to the FDA by a large number of organizations, a Deputy Commissioner of the FDA stated¹⁵:

“FDA supports the proper disposal of unused or unwanted prescription drugs through drug take-back programs and continues to include this as the first recommendation in our information to the public.”

“Again, please note that this recommendation (*flushing*) is secondary to the preferred method of disposal of these drugs via a drug take-back program when available.”

¹³ FDA Consumer Update. April 2012, Updated Sept. 2013. “Fentanyl Patch Can Be Deadly to Children”

<https://www.fda.gov/forconsumers/consumerupdates/ucm300803.htm>

¹⁴ FDA website “Disposal of Unused Medicines: What You Should Know”

<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>

¹⁵ National Stewardship Action Council. “End U.S. Food and Drug Administration (FDA) Medicine “Flush List”” webpage at <https://nsaction.us/campaigns/>

Table 2. Household Medicine Disposal Guidelines from Federal Agencies

Drug Enforcement Administration (DEA)

www.dea.gov/diversion.usdoj.gov/drug_disposal/

The DEA encourages residents to use authorized collectors and drug take-back programs for secure drug disposal. Since Fall of 2010, the DEA has been coordinating the National Take-back Initiative and holding twice-a-year National Prescription Drug Take-Back Days in conjunction with local law enforcement.

DEA materials for these take-back events state:

- Unused prescription drugs thrown in the trash can be retrieved and abused or illegally sold. Unused drugs that are flushed contaminate the water supply. Proper disposal of unused drugs saves lives and protects the environment.
- Take-back programs are the best way to dispose of old drugs. But if a program is not available:
 - ▶ Take the meds out of their bottles;
 - ▶ Mix them with something unappealing like used kitty litter or coffee grounds;
 - ▶ Seal them in a bag or disposal container, and throw that away.

The DEA's Drug Disposal Information website links to the medicine disposal guidances of the FDA and the DEA.

Food & Drug Administration (FDA)

www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm

"Many community-based drug "take-back" programs offer the best option." The detailed disposal guidance is:

- Follow any specific disposal instructions on the prescription drug labeling or patient information that accompanies the medicine. Do not flush medicines down the sink or toilet unless this information specifically instructs you to do so.
- Take advantage of programs that allow the public to take unused drugs to a central location for proper disposal. Call your local law enforcement agencies to see if they sponsor medicine take-back programs in your community. Contact your city's or county government's household trash and recycling service to learn about medication disposal options and guidelines for your area.
- Transfer unused medicines to collectors registered with the Drug Enforcement Administration (DEA). Authorized sites may be retail, hospital or clinic pharmacies, and law enforcement locations. Some offer mail-back programs or collection receptacles ("drop-boxes"). Visit the [DEA's website](#) or call 1-800-882-9539 for more information and to find an [authorized collector](#) in your community.

If no disposal instructions are given on the prescription drug labeling and no take-back program is available in your area, throw the drugs in the household trash following these steps:

1. Remove them from their original containers and mix them with an undesirable substance, such as used coffee grounds, dirt or kitty litter (this makes the drug less appealing to children and pets, and unrecognizable to people who may intentionally go through the trash seeking drugs).
2. Place the mixture in a sealable bag, empty can or other container to prevent the drug from leaking or breaking out of a garbage bag.

Environmental Protection Agency (EPA)

www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines

EPA encourages the public to take advantage of pharmaceutical take-back collection programs that accept prescription or over-the-counter drugs, as these programs offer a safe and environmentally-conscious way to dispose of unwanted medicines. This may be at a location such as a local enforcement agency, retail pharmacy, hospital or clinic. To find any available collection programs in your community, contact your city or county government's household trash agency.

As a second choice, the public can utilize EPA's [guidelines for household disposal of medicines \(PDF\)](#).

A.4. Disposal of waste pharmaceuticals by regulated generators. “Regulated generators”, i.e. non-household sources such as hospitals, medical centers, doctor’s and dentists’ offices, long-term care facilities, pharmacies, and other business entities, must manage and dispose of pharmaceutical wastes according to all federal, state, and local regulations. These entities should review all applicable regulations prior to using a medicine disposal product for solid waste disposal of unused pharmaceutical inventory.

Under federal regulations, healthcare facilities cannot dispose of any pharmaceutical inventory that is a controlled substance in the solid waste system. The DEA requires a non-retrievable destruction standard for final disposal of controlled substances by DEA registrants, and has stated that landfill disposal does not meet the non-retrievable standard (see Section II.A.1.)

Regulated generators must also classify their waste pharmaceuticals according to their hazards. Some pharmaceuticals, including a small number of controlled substances, must be managed as hazardous wastes under requirements of the federal Resource Conservation and Recovery Act (RCRA).¹⁶ Under RCRA, states may designate additional pharmaceuticals as hazardous or dangerous and prohibit landfill disposal by regulated generators.¹⁷ Local jurisdictions may also have more stringent disposal requirements.

If any of the drugs added to the disposal product designate as a federal hazardous waste, then all of the disposal product-pharmaceuticals mixture must be managed as hazardous waste, according to EPA’s mixture rule. Similarly, if any of the unused drugs added to the disposal product are controlled substances, the DEA’s non-retrievable destruction standard applies. Waste management regulations vary across the nation, but in many jurisdictions disposal of the product-pharmaceuticals combination in the landfill by hospitals or other regulated generators would not be allowed at all, or would depend on the pharmaceutical types treated and the characteristics of the disposal product-pharmaceutical mixture. In some jurisdictions, use of the medicine disposal products for hazardous waste pharmaceuticals may be considered a form of on-site hazardous waste treatment, and may require a permit.

Healthcare facilities cannot dispose of unused pharmaceuticals that are controlled substances or that are hazardous wastes in the solid waste system.

Several of the products reviewed are marketed for use by regulated generators. Of these, the instructions for Cactus Smart Sink, Drug Buster, and Rx Destroyer include statements that the used product must be managed according to federal, state, and local regulations and guidelines depending on the medicine disposed. Some of the products state they are for non-hazardous pharmaceuticals only, but largely leave it to the user to work out how to identify which medicines are hazardous. This is often challenging for healthcare professionals let alone consumers.

In the healthcare setting, use of the medicine disposal products may be most appropriate as a diversion prevention step in management of pharmaceutical wastage, especially for controlled substances that might otherwise be sewered to prevent diversion. Pharmaceutical wastage is the residual amounts of a pharmaceutical substance that remain in a vial, tube, transdermal patch, or syringe after administration to a patient. In the past, it was common practice in healthcare settings to put pharmaceutical wastage down a sink or drain for disposal, especially to prevent diversion of controlled substances. DEA’s standard

¹⁶ U.S. EPA. Management of Pharmaceutical Hazardous Waste.

<https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste>

¹⁷ U.S. EPA website. “Links to Hazardous Waste Programs and U.S. State Environmental Agencies”

<https://www.epa.gov/hwgenerators/links-hazardous-waste-programs-and-us-state-environmental-agencies>

for non-retrievable destruction applies to unused pharmaceutical inventory, but does not apply to pharmaceutical wastage, and the DEA clarified this in a 2014 memo to practitioners.¹⁸ For unused controlled substances inventory, the DEA no longer recognizes sewerage as non-retrievable destruction and the EPA's proposed rule for managing hazardous waste pharmaceuticals would prohibit sewerage of any hazardous pharmaceuticals.

The Cactus Smart Sink is the only product reviewed that is targeted for healthcare facilities, rather than consumer use. Cactus Smart Sink is specifically marketed to healthcare facilities for management of unused controlled substances, including pharmaceutical wastage, in a manner that prevents diversion prior to transport for final disposal. It is also the only product that recommends final disposal of the used product-pharmaceutical mixture by incineration, and discourages disposal in the solid waste system.

A.5 Disposal requirements for used medicine disposal products. The DEA's non-retrievable standard for controlled substances and the EPA's and state or local requirements for hazardous pharmaceuticals apply to the disposal of specific types of medications. In addition, the used medicine disposal product is subject to EPA and state or local requirements for characterization of the used product as a hazardous or non-hazardous waste. Once the unwanted pharmaceuticals are mixed with the disposal product, and chemical reactions or physical transformations occur, the resulting material may have new and different properties. Characterization of the product-pharmaceutical mixture as disposed is needed to determine the associated waste management requirements for "regulated generators", and also for residential generators in some jurisdictions.

With the exception of the Cactus Smart Sink, all products reviewed state that they can be discarded in the solid waste stream after use, with only a few products referencing caveats about consulting regulatory requirements. The next sections of this report examine information available from the manufacturers' websites and materials to try to understand the modes of action of the medicine disposal products and to look at what testing has been conducted to evaluate the used disposal products.

B. Modes of Action of Medicine Disposal Products

Many of the medicine disposal products reviewed use terms like "deactivate" or "neutralize" or "breakdown" to describe the product's mode of action. These terms suggest a chemical transformation of the pharmaceuticals into inert constituents. However, it is not clear that any of the medicine disposal products are capable of chemically degrading all pharmaceuticals, either partially or completely, and available test results from the manufacturers do not demonstrate chemical destruction. Some of the product manufacturers appear to be using terms like "deactivate" to describe adsorption of a drug onto another material, or to describe physical immobilization of the drug in a gel or solid form. Adsorption or immobilization are not necessarily irreversible or processes that destroy the pharmaceutical's biologic activity.

For products that claim to make potentially harmful pharmaceuticals non-retrievable and safe for trash disposal, the key question is whether the pharmaceutical is rendered completely inaccessible and harmless to people and the environment. Is the pharmaceutical chemically degraded into harmless chemical and elemental constituents by the disposal product? Is the pharmaceutical physically sequestered into an inert form by the disposal product? Is the transformation of the pharmaceutical by the disposal product complete and irreversible such that the active pharmaceutical is non-retrievable? Is the disposal product-pharmaceutical mixture non-toxic and safe to dispose of in a solid waste system?

¹⁸ U.S. DEA. Letter to Registrants clarifying the DEA position regarding a practitioner's disposal of pharmaceutical wastage. October 17, 2014.
https://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf

A general consideration is whether the product is capable of transforming any type of pharmaceutical, or just some. Given the diversity and complexity of pharmaceuticals, it seems a daunting task to design a disposal product capable of chemically degrading every type of pharmaceutical, and also safe for home use. Thousands of prescription and over-the-counter drug products are commonly used in the U.S. The commercial website Drugs.com has a database of more than 24,000 prescription drugs, over-the-counter drugs, and natural products. Each year the FDA approves several dozen novel drugs that are new pharmaceutical ingredients that have not previously been approved.¹⁹ Pharmacy Times provides an annual list of the top 200 prescription drugs based on dispensing and sales, and found the top therapeutic classes of medicines were antihypertensives, mental health medications, pain medications, antibacterials, lipid regulators, diabetes medications, oncology medications, and autoimmune disorders medications.²⁰ The chemistry of these drugs is as diverse as their biological effects. A number of pharmaceuticals, such as some chemotherapeutics, contain metals which cannot be further degraded by a chemical process and are toxic in elemental form, including arsenic and antimony. It would be impractical and cost prohibitive to test the disposal products with every pharmaceutical on the market. At the same time, given the complexity and diversity of pharmaceutical chemicals, it seems a reach to conclude a product is effective and safe for disposal of all pharmaceuticals after testing only a few drugs.

It seems a daunting task to design a disposal product capable of chemically degrading every type of pharmaceutical that is also safe for home use.

Another general consideration is whether the disposal products are capable of transforming pharmaceuticals in any physical form, i.e. pills, tablets, capsules, gels, creams, transdermal patches, lozenges, and liquids. Some of the medicine disposal products specify they can be used with drugs in pill form only; others indicate patches or liquids can also be added. The disposal products for consumers also state the maximum number of pills, liquids, or patches to add, and some products state that effectiveness will be reduced if the capacity is exceeded. None of the manufacturers provide test data to support the stated capacity limits of their products. Ability of the product to adsorb or physically immobilize the pharmaceuticals will be impacted by how carefully consumers follow these instructions. The question of how liquid medicines will impact the efficacy of the medicine disposal products seems ignored or under-addressed in the manufacturer's materials.

A third general consideration is the time needed for the interaction of the disposal product with the pharmaceuticals to render them "non-retrievable" or "safe for landfill disposal" per the manufacturers' descriptions. A number of the products describe the process as quick or fast or instant; however, details in some of the product descriptions explain time is needed for the product's action. Instructions for one product, Drug Buster, state the bottle should be placed in the trash after two hours, or the contents of the bottle can be emptied into the trash after 24 hours. It is important to consider whether an "incubation" period is needed because the products designed for trash disposal are packaged in plastic bottles or plastic pouches which may burst or split during compaction in a waste truck, solid waste transfer

¹⁹ U.S. FDA. Novel Drug Approvals for 2016.

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm483775.htm>

²⁰ Pharmacy Times. "Top Drugs of 2015". July 18, 2016.

<http://www.pharmacytimes.com/publications/issue/2016/july2016/top-drugs-of-2015>

station, or landfill. If this occurs, and the pharmaceuticals are not yet “neutralized” by the product, the treated drugs may be available for diversion or release into the environment.

Three of the eight drug disposal products are described as primarily composed of activated carbon. One utilizes bentonite clay as the adsorbent. One uses calcium hypochlorite, a chlorine source used for pools, as well as “absorbent ingredients”. Three other products do not fully describe their product ingredients, which are described as a “cross-linking polymer”, “an organic plant-based powder”, and “a proprietary mixture of denaturants and deterrents”. The mechanisms of action of these products are not fully analyzed or described in the information available from the manufacturers’ websites, materials, and product labels. For products with identified ingredients, mechanisms of action can be inferred from other sources.

The wide variety of chemicals used in medicines, the availability of medicines in multiple dosage forms, and the time required for medicines and the product to interact are all important considerations in the effectiveness of any medicine disposal product.

B.1. Activated carbon. Activated carbon, also called activated charcoal, is used in granular or powdered form to remove chemical impurities in a range of industrial to home applications, including drinking water filters, air purifiers, groundwater remediation, and wastewater purification to remove odors. The carbon is typically produced from coal, charcoal, or plant matter. It is “activated” by physical or chemical treatment to make the carbon particles more porous, increasing the surface area so that larger amounts of chemicals can adsorb per unit weight of carbon. The specific characteristics of the activated carbon product determine its capacity to adsorb different types and amounts of chemicals.

In a process called adsorption, chemicals attach to the surface of the activated carbon.^{21,22} Adsorption to carbon is a physical interaction between the substance and the carbon surface based on electrostatic (charged) attractions and non-electrostatic interactions, including hydrophobicity. Adsorption may be a chemical interaction for certain substances under appropriate conditions, including at high temperatures. Despite the long use of activated carbon for purification and detoxification, its mechanism of action is not fully understood and is an active area of research and modeling. The exact nature of the interaction may be a combination of physical and chemical adsorption mechanisms and is highly dependent on the substance, the carbon type, and the conditions. A treatment guidance for toxic wastes describes carbon adsorption as a process that “retains and accumulates toxic chemicals present in wastes, yet does not chemically alter them”, and also describes any biodegradation of chemicals as a “secondary effect”.²³

The rate and efficiency of adsorption onto activated carbon can be expected to be different for different pharmaceuticals and for mixtures of pharmaceuticals. Rate and efficiency of adsorption is also dependent on the solution chemistry and conditions, including pH, temperature, electrolyte concentration, and oxygen content. Technical descriptions of activated carbon treatment describe classes of chemical compounds that are readily adsorbable to carbon and those that are poorly adsorbable, which include

²¹ H. Nowicki, and G. Nowicki. Water Technology Online. “The Basics of Activated Carbon Adsorption” Feb. 1, 2016. <http://www.watertechonline.com/the-basics-of-activated-carbon-adsorption/>

²² C. Moreno-Castilla. 2004. Carbon 42. 83–94 “Adsorption of organic molecules from aqueous solutions on carbon materials”. <http://hera.ugr.es/doi/15060081.pdf>

²³ Washington State Department of Ecology. “Carbon Adsorption: Treatment Specific Guidance” Publication # 96-415. <https://fortress.wa.gov/ecy/publications/documents/96415.pdf>

metal containing compounds.^{23,24} A review of potential techniques for removal of pharmaceutical pollutants from water found that studies on some specific pharmaceuticals demonstrate that activated carbons generally have a high capacity to absorb those compounds, but that the capacity depends on pharmaceutical type, carbon type, and solution chemistry.²⁵

The carbon adsorption process is typically not irreversible.^{21,23,24} Spent activated carbon, i.e. carbon that has reached its adsorption capacity for pollutants, can be regenerated by a variety of methods. Chemicals can be removed from activated carbon through thermal reactivation, solvent extraction, ozone treatment, irradiation, and other methods. Some regeneration treatments would also fully degrade the adsorbed chemical molecules, but others may not. For that reason alone, it seems unlikely that treatment by activated carbon could completely achieve the DEA's stringent non-retrievable standard of permanent physical or chemical alteration of a controlled substance. As previously stated, the DEA is not evaluating these medicine disposal products; however, a DEA representative has stated "The liquid carbon products do not render the controlled substances to a non-retrievable state" in response to queries about statements made by some manufacturers.²⁶

Deterra, Drug Buster and Rx Destroyer identify their active ingredient as activated carbon. The manufacturer's website for Drug Buster does not provide any test results or research studies to support the description of the product's mode of action. Deterra and Rx Destroyer provide some analysis of their product's mode of action (also described above in Section II.A.1. and further described in the product descriptions in Section V).

Deterra provides internal research by its principal scientist that show most of nine drugs tested separately are adsorbed onto the activated carbon product, but the analysis also demonstrates the adsorption is not complete because small amounts of the drugs remain in the liquid phase of the disposal product-pharmaceutical mixture. The adsorption also appears to be reversible, at least to some degree, because additional small amounts of drugs such as fentanyl are released by simple washing with water or ethanol. Test results with other solvents or extraction conditions are not provided.

Rx Destroyer provides correspondence from a scientific consultant who specializes in activated carbon services stating that the product will render drugs non-retrievable based on other published research showing adsorption of non-pharmaceutical chemicals onto activated carbon. No direct testing of Rx Destroyer with drugs is provided and the consultant acknowledges that some amount of drug ingredients will remain unadsorbed in the liquid phase of the disposal product. Some of the data referenced by the consultant for Rx Destroyer appears to be the same internal test analysis provided for Deterra.

B.2. Bentonite clay. Bentonite clay is used to absorb water and to adsorb contaminants in filtration, purification, and a variety of other applications. A number of clumping kitty litters are made of sodium bentonite clay²⁷, which expands when wet. The Pill Catcher appears to use a chemically altered sodium bentonite clay from Cetco Corporation called ORGANOCCLAY.²⁸ The Pill Terminator contains Fuller's earth, along with other ingredients according to its Material Safety Data Sheet. Fuller's earth is described by

²⁴ Lenntech. Adsorption/Activated Carbon. <http://www.lenntech.com/library/adsorption/adsorption.htm>

²⁵ Rivera-Ultrilla et al. 2013. "Pharmaceuticals as emerging contaminants and their removal from water. A review" Chemosphere Volume 93, Issue 7, Pages 1268–1287
<http://www.sciencedirect.com/science/article/pii/S0045653513010436>

²⁶ Personal communication from Thomas Prevoznik, Drug Enforcement Administration, October 6, 2016.

²⁷ PetMD "What is the best cat litter? Non-clumping vs. clumping litter".

http://www.petmd.com/cat/centers/litter/evr_ct_clumping-versus-non-clumping-cat-litter

²⁸ CETCO ORGANOCCLAY® <http://www.cetco.com/en-us/Products/Environmental-Products/Organoclays>

TOXNET as a porous colloidal clay containing magnesium aluminum silicate²⁹ and is also described as calcium bentonite by some vendors and sources.³⁰ Fuller's earth is used to adsorb oils and petroleum products.

Bentonite clay interacts with chemicals through an adsorption process, similar to that of activated carbon. The rate and efficiency of adsorption onto bentonite clay depends on the type of chemical, the type of bentonite clay, and the solution chemistry and conditions, including pH, electrolyte concentration, and temperature. Adsorption of pharmaceuticals onto a bentonite clay substrate may be only a physical process and may not chemically alter the pharmaceutical compound, and the adsorption may not be irreversible.

The Pill Catcher's manufacturer provides results of extraction using the Toxicity Characteristic Leaching Procedure (TCLP) of a sample of 13 pharmaceuticals mixed with the disposal product (see product description for list of drugs, and Section III.C. for description of the TCLP extraction method). The analysis found that the organic chemical pollutants in the TCLP analyte panel were at non-detectable levels and metals were below regulatory limits. This analysis of the Pill Catcher-pharmaceutical mixture did not test the extract for the presence of any pharmaceutical compounds or fully characterize the chemical composition of the extract or the disposal product-pharmaceutical mixture.

A separate patent application by Insys Development Company, Inc. describes testing of adsorption of fentanyl by bentonite clay. The Insys patent application for a pharmaceutical disposal product³¹ using bentonite clay fixed to a substrate provides test analysis for adsorption of about 1.6 milligrams of a fentanyl spray. Extraction of the bentonite clay with water and different alcohols resulted in release of some of the fentanyl, with 3.25% of the fentanyl released in ethanol at room temperature and 4.5% released in ethanol at 70°C (158°F). Based on that data, it seems unlikely that bentonite clay treatment could achieve the DEA's non-retrievable standard of permanent physical or chemical alteration of a controlled substance.

B.3. Calcium hypochlorite. Calcium hypochlorite³², Ca(ClO)₂, is listed as an ingredient on a Material Safety Data Sheet (MSDS) for The Pill Terminator, which also lists Fuller's earth and a proprietary "absorbent polymer". Calcium hypochlorite is a white solid that releases chlorine and oxygen when combined with water. Calcium hypochlorite is an oxidizing (bleaching) agent and an anti-microbial agent used in water purification. It is a common component of swimming pool chlorine treatments.

Because calcium hypochlorite is a strong oxidizing agent, the Pill Terminator product must carry a warning label about its toxicity through skin contact, eye exposure or ingestion, and a warning to keep away from children. If combined with other substances, calcium hypochlorite can release chlorine gas and it can react explosively with ammonia and metals. As an oxidizing agent, hypochlorite will react with and chemically alter some pharmaceuticals, depending on their chemical composition. The degree of chemical degradation and resulting chemical by products will depend on the pharmaceuticals being treated.

The Pill Terminator website provides analysis by an independent test laboratory that the product renders aspirin pills unpalatable and foul smelling. Unpublished test results from academic researchers on treatment of morphine show release of 45% of the morphine by simple water extraction after 48 hours

²⁹ U.S. National Library of Medicine. TOXNET. "English fullers earth" RN: 8031-18-3.

<https://chem.nlm.nih.gov/chemidplus/rn/8031-18-3>

³⁰ Encyclopaedia Britannica "Bentonite Clay" <https://www.britannica.com/science/bentonite>

³¹ U.S. Patent US 20160361667 A1. "Disposal System for Unused Pharmaceuticals"

<https://www.google.com/patents/US20160361667>

³² PubChem – Open Chemistry Database. Calcium Hypochlorite.

https://pubchem.ncbi.nlm.nih.gov/compound/calcium_hypochlorite

of incubation with the Pill Terminator. The testing did not fully characterize the chemical composition of the product-pharmaceutical mixtures as they would be disposed. See the product description in Section V for more details.

B.4. Unknown mechanisms of action for proprietary, unidentified ingredients. Three of the eight products do not identify their product ingredients, which are described as:

- “cross-linking polymers” for DisposeRx,
- “an organic plant-based powder” for Element MDS, and
- “a proprietary mixture of denaturants and deterrents” for Cactus Smart Sink.

Because the ingredient information is not disclosed, the mechanism(s) of action of the disposal product cannot be inferred. DiposeRx and Element MDS recommend trash disposal of the disposal product-pharmaceutical mixture, but do not provide any test results on their websites to demonstrate product performance or waste characterization for disposal in the solid waste system.

While it would be useful to know more about the mechanism of action of the “denaturants and deterrents” in the Cactus Smart Sink, this information is not essential to evaluating that use of the product as directed provides non-retrievable and safe disposal. The locking unit design of the Cactus Smart Sink creates a physical barrier to accessing the disposed medicines which makes diversion difficult. The manufacturer recommends final disposal by incineration according to applicable regulations, which achieves the non-retrievable standard for controlled substances and is also appropriate for hazardous waste pharmaceuticals.

C. Environmental Performance Test Results

Testing by the U.S. Geological Service (USGS) has found that pharmaceuticals, and a range of other chemical contaminants, are commonly found in leachate from municipal solid waste landfills.³³ Modern municipal waste landfills are lined to prevent leachate from seeping directly into ground water³⁴; however, landfill leachate is often pumped out to a wastewater treatment plant which cannot effectively remove pharmaceuticals and other organic pollutants. Pollutants in landfill leachate can pass through the wastewater treatment plants in both the water outflow and biosolids. For this reason, pharmaceuticals should not be disposed in the household trash and solid waste system.

Seven of the eight products reviewed recommend putting the final disposal product-pharmaceutical mixture in the household trash after treatment. Cactus Smart Sink is the exception, recommending incineration and stating disposal must be according to federal and state guidelines depending on the types of pharmaceutical waste. For the products designed for solid waste disposal, a key question is whether the disposal product-pharmaceutical mixture irreversibly prevents drugs from leaching out. Most of the products are marketed as protecting water quality and make broad statements about safety and regulatory compliance for disposal as a solid waste in the household trash, such as:

“Passes All EPA Regulations”

“safe for landfills”

“meets and or exceeds disposal regulations for solid waste”

Three of the products – Dispose Rx, Drug Buster, and Element MDS – do not provide any test results to demonstrate the product’s performance in preventing environmental contamination. Deterra and Pill

³³ U.S. Geological Survey “Pharmaceuticals and Other Chemicals Common in Landfill Waste”
https://toxics.usgs.gov/highlights/2014-08-12-leachate_pharm.html

³⁴ U.S. EPA. “Municipal Solid Waste Landfills” <https://www.epa.gov/landfills/municipal-solid-waste-landfills>

Terminator provide unpublished analysis or internal research meant to demonstrate that drugs are non-retrievable after mixing with the disposal product; however, these studies show small amounts of the pharmaceutical are retrievable from the product directly or after brief extraction with water. Rx Destroyer does not provide any test results on their product but cites correspondence from a scientific consultant that is based on other studies. None of the manufacturers provide test data to support the stated capacity limits of their products, i.e. the number of pills and/or liquid medications that can be “neutralized” by the product.

The Pill Catcher provides independent lab results of a TCLP analysis on a sample of their product mixed with 13 pharmaceuticals. The Pill Catcher is the only product to provide results of a TCLP assay. The results show the 8 metals and 32 regulated organic chemical pollutants assayed in the TCLP were non-detectable or below regulatory limits. The TCLP assay does not screen for pharmaceuticals directly.

Is the TCLP test the right analysis to determine whether a medicine disposal product will prevent pharmaceuticals from leaching out of the post-treatment residue? Does it prove the drugs are rendered non-retrievable? The TCLP analysis is useful in understanding the characteristics of the drug disposal product, and is a logical test to perform as part of waste determination. However, it’s important to understand what the TCLP test measures, and what it does not.

The TCLP - Toxicity Characteristic Leaching Procedure - or EPA SW-846 Test Method 1311³⁵ - is one of a series of test methods developed by the EPA to analyze the physical and chemical characteristics of solid wastes, including whether the waste should be characterized as hazardous or non-hazardous under RCRA. The TCLP serves as a general assay surrogate for landfill conditions where rainwater and other liquids percolate over time through the landfill, and chemicals from waste materials seep out into the leachate.

The TCLP method is an extraction of the tested material with a weak acetic acid solution and rotary agitation for 18 hours at 23°C (73°F). The resulting liquid extract is analyzed for the presence of 8 metals and 32 regulated pollutant chemicals using specified laboratory methods such as mass spectroscopy. If any of the 40 regulated chemicals are present in amounts equal to or exceeding regulatory limits³⁶, the tested material is characterized as a hazardous waste. If it is from a regulated generator, the waste cannot be disposed in a solid waste landfill without further treatment. As previously described, the relatively mild extraction conditions of the TCLP would not be sufficient on its own to demonstrate compliance with the DEA’s non-retrievable standard for controlled substances.

The TCLP protocol is not specifically tailored to answering the questions that are most relevant to the performance of medicine disposal products for the following reasons:

- The TCLP analysis does not provide a comprehensive analysis of whether the drug disposal product effectively binds pharmaceuticals to prevent their release into the environment. It does not analyze whether the disposal product chemically alters the pharmaceuticals to a non-toxic form or whether the DEA’s non-retrievable standard is achieved.
- The TCLP test method does not analyze the extract for the presence of any pharmaceutical compounds that have leached out of the waste material, nor does it fully evaluate the chemicals in the leachate. The regulated pollutants in the TCLP chemical panel are not common pharmaceutical

³⁵ U.S. EPA. SW-846 Test Method 1311: Toxicity Characteristic Leaching Procedure. 1992. <https://www.epa.gov/hw-sw846/sw-846-test-method-1311-toxicity-characteristic-leaching-procedure>, and Technical Assistance Document for Complying with the Toxicity Characteristics Rule and Implementing the Toxicity Characteristic Leaching Procedure. May, 1994. <https://www.epa.gov/quality/technical-assistance-document-complying-toxicity-characteristics-rule-and-implementing>

³⁶ 40 C.F.R. 261.24. Toxicity characteristic. (list of TCLP contaminants and regulatory limits) http://www.ecfr.gov/cgi-bin/text-idx?node=se40.26.261_124&rgn=div8

ingredients. TCLP analytes are 8 metals and 32 organic compounds. Only a few of the test analytes are used as ingredients in pharmaceutical preparations, such as: silver is used in burn creams, and m-cresol and mercury may be used as preservatives in pharmaceutical preparations. Possibly some of the TCLP panel chemicals could be chemical breakdown products of certain pharmaceuticals, but it seems a more direct route to test the extract directly for presence of pharmaceuticals and potential breakdown products.

- The TCLP test conditions are designed to simulate landfill leaching conditions, and do not represent the potential extraction methods that could be employed to recover and divert active pharmaceutical compounds from the used disposal product. To meet the DEA's non-retrievable standard, the pharmaceuticals would need to be irreversibly physically or chemically altered by the drug disposal product. The limited TCLP test conditions do not fully examine this question.

Although the TCLP is a key test in characterizing a waste material, it is not the only criteria for hazardous waste determination under federal regulations. Some waste pharmaceuticals are specifically designated under RCRA as hazardous waste (P or U listed wastes). Other pharmaceuticals or disposal product-pharmaceutical mixtures may exhibit one of four specified characteristics of hazardous waste: ignitability, corrosivity, reactivity, or toxicity. Wastes containing any federally listed hazardous wastes must be managed as hazardous wastes by regulated generators under the RCRA mixture rule.

States may also require additional analysis for hazardous waste determination. California, for example, requires evaluation by the TCLP, the WET (Waste Extraction Test), and six other toxicity assays to determine whether a waste material meets the California hazardous waste characteristic of toxicity.³⁷ The WET (Waste Extraction Test) is similar to the TCLP, but is a more stringent leaching analysis that requires a citric acid extraction for 48 hours. California regulations establish standards for 19 inorganic and 18 organic compounds in both total and soluble form. Other assays utilized in California screen waste for oral, dermal, inhalation, and aquatic toxicity. Local jurisdictions may further discourage or prohibit residents from disposing of any type of unused medicine in the solid waste system.

The TCLP assay is not specifically tailored to answering the questions that are most relevant to the performance of medicine disposal products.

D. Ease of Use for Consumers

The medicine disposal products reviewed come in bottles or pouches and consumers are instructed to add pills, patches, and liquids up to the stated capacity of the product. Five of the products require the addition of water and three do not. Product instructions state that the ability of the product to adsorb or sequester the pharmaceuticals will be impacted by how carefully consumers follow these instructions.

Residents who often have large amounts of leftover or expired medications to dispose of after a serious illness, or the death of a family member, would likely find the disposal products to be a time-consuming and relatively expensive disposal method.

It would certainly not be an easy task for a consumer to comply with directions such as "for non-hazardous drugs only". Rx Destroyer and Drug Buster state that the product should only be used for disposal of non-hazardous pharmaceuticals. This guidance is not meaningful for the average consumer who cannot be

³⁷ California Environmental Protection Agency. Department of Toxic Substances Control. "Defining Hazardous Waste" http://www.dtsc.ca.gov/HazardousWaste/upload/HWMP_DefiningHW111.pdf

expected to figure out which drugs are designated as hazardous or non-hazardous.

Care needs to be taken by consumers when using these products to avoid exposure to the mixture of product chemicals and pharmaceuticals. Several of the products carry warning labels about potential skin or eye contact. Most have warnings to keep away from children. Several product directions state that foaming may occur when medicines are added to the product. Some of the products have a vented bottle cap to release produced gas. Based on these warnings and the unidentified ingredients in some products, consumers should use care while mixing and shaking with the pharmaceuticals not to spill the pouch or bottle. None of the products provide instructions for how residents should clean up the disposal product-pharmaceutical mixture in case of a spill or a burst bottle or pouch.

Concerns about exposure to pharmaceuticals through the skin or through inhalation of dust when using these products would be similar to those for the trash disposal instructions from federal agencies that involve mixing leftover medicines with kitty litter or coffee grounds. Exposure risk is increased when consumers are asked to dissolve pills in liquids or crush them to further disguise them. Alternatively, medicine take-back programs allow residents to transport medicines in their original packaging to a secure drop box or collection event.

Residents would likely find these disposal products to be a time-consuming and relatively expensive disposal method for large amounts of leftover or expired medications.

E. Product Costs for Consumers

Affordability is a key consideration in whether consumers will use the medicine disposal products when disposing of leftover medicines in the trash, especially on an ongoing basis. List prices of the products reviewed range from \$4 to \$16 for consumer sized units with capacities of 15 to 300 pills. Some of the products are one time use, others state that pills may be added over time until the product's capacity is reached. Examples of product prices and disposal capacities as of March 2017 are:

- Deterra: \$4.99 for 15 pills or \$6.99 for 90 pills.
- Pill Catcher: \$4.95 for 120 pills or \$6.96 for 300 pills.
- Pill Terminator: \$9.95 for 300 pills.
- Drug Buster: \$9.95 for 50 pills or \$15.99 for 300 pills.

Discounts are available for bulk purchases from some of the manufacturers, but even so these products are a substantial cost. Some government agencies and healthcare entities are distributing free samples of medicine disposal products as part of drug abuse education and prevention campaigns. Residents need ongoing medicine disposal options, however, and the cost of these products is essential a type of disposal fee which is likely to deter proper disposal of hazardous materials by residents.

The costs of the medicine disposal products are high compared to other recommended medicine disposal methods because of the relatively small capacity of the products. For example, a one-time use Deterra pouch with a maximum capacity of 90 pills is \$6.99. If used to dispose of 90 Vicodin pills with an actual weight about 630 mg per pill³⁸, the cost of the Deterra disposal method is about \$56 per pound of

³⁸ Actual weight of Vicodin (500 mg/10mg) pill estimated from: John P. Guidry II "Trafficking in Hydrocodone/Oxycodone" <https://www.jgcrimlaw.com/trafficking-in-hydrocodone-oxycodone.html>; and Watson 540 pill: <http://watsonpills.freehostia.com/watson-540-oval-blue-pill.htm>

medicine disposed.

90 pills x 630 mg/pill = 56.7 grams.

56.7 grams divided by 453.592 grams/pound = 0.125 pounds.

\$6.99 per pouch / 0.125 pounds is \$55.92 per pound of medicine disposed.

In comparison, medicine take-back programs are much less expensive per pound of collected medicines, and are usually provided without a point-of-disposal fee for consumers. Ongoing costs of medicine take-back programs utilizing secure drop boxes at pharmacy or law enforcement locations are often on the order of \$2 to \$5 per pound of collected medicines, depending on design elements of the take-back program, such as transportation method and final disposal facility.³⁹ Costs of medicine mail-back programs are higher than secure drop box programs, but still lower than the medicine disposal products because larger amounts of medicines can be placed in each mailer. Prepaid mailers cost on the order of \$3 to \$7, each accepting about 8 ounces (0.5 pounds) of medicine in containers, or about \$6 to \$14 per pound. Sharps Compliance, Inc. markets prepaid TakeAway Medication Recovery System envelopes⁴⁰ for \$78.00 per 12-unit display kit or \$275.00 for case of 50 mailers, which is \$6.50 and \$5.50 per mailer respectively. Household medicines collected by drop-off and mail-in take-back programs are rendered non-retrievable by high temperature incineration according to the DEA's and EPA's recommendations.

³⁹ Average cost per pound of medicine take-back programs is estimated from author's knowledge of program costs from a variety of community drug take-back programs for collection, transportation, and disposal. Collected medicine weights for drop-off programs include packaging, and programs vary in whether they allow or encourage residents to empty pills out of containers. Packaging was 28% by weight of a sampling of medicines in 2002 by the Environmental Health and Safety Department of the University of Washington and the Local Hazardous Waste Management Program in King County.

⁴⁰ Sharps Compliance, Inc. "TAKEAWAY MEDICATION RECOVERY SYSTEM ENVELOPE (USPS)"
<http://www.sharpsinc.com/store/medication-disposal-envelopes-usps>

III. Research Needs

The product descriptions and test data reviewed in this report for the seven products marketed for use in the home are not sufficient to verify the performance claims that these products render drugs non-retrievable and safe for disposal in the household trash. The limited analysis available from the manufacturers' websites does not thoroughly examine how well pharmaceuticals are sequestered by these products, the extent to which any chemical degradation occurs, whether the active pharmaceutical compounds are rendered irreversibly "non-retrievable", or whether pharmaceuticals will be released from the disposal product under landfill conditions. The types of pharmaceuticals tested with the products are too limited to draw broad conclusions. The test results provided do not address how product capacities are determined or how product performance may be impacted by mixtures of different pharmaceuticals, including drugs in liquid form that may include alcohol solvents.

Additional independent laboratory analysis is needed to fully evaluate and compare the performance of the products. The product manufacturers may be able to provide additional existing test results, or can arrange for new analysis. Manufacturer funding for testing of their product is appropriate, however, the testing must be performed by independent and accredited laboratories to be impartial and credible. Employees of the product manufacturers, as well as companies or researchers with investments in the products, should not be involved in preparing the samples, conducting the tests, or analyzing the results.

Performance testing that simultaneously compares the different medicine disposal products under identical conditions would provide the most useful information. Validation of the same test conditions by several laboratories would also be useful. An appropriate academic center could coordinate a study utilizing several independent laboratory testing facilities.

The experimental conditions and assays to be used need to directly analyze for the tested pharmaceuticals and potential break-down products using appropriate controls and standards. While it is impractical to test all pharmaceutical compounds given the thousands on the market, it would be appropriate to group and test commonly used medications by chemical or therapeutic class. To mimic likely real world scenarios, medicine disposal products should be tested with several mixtures of different types and dosage forms of pharmaceuticals. Testing should also examine impacts of exceeding recommended product capacities.

Experimental design should address the following key questions:

- Is the transformation of the pharmaceutical by the disposal product complete and irreversible such that the active pharmaceutical is no longer biologically active and is non-retrievable?
- Is the product's mode of action a chemical process or a physical process, or a combination?
- If the pharmaceuticals are chemically degraded, are the break down products non-toxic?
- If the pharmaceutical is physically but not chemically sequestered, is the resulting mixture non-hazardous and is the physical transformation irreversible?
- Is the disposal product-pharmaceutical mixture a solid waste appropriate for landfill disposal or a hazardous waste, based on stringent waste determination methods such as California's hazardous waste determination test?

Additional independent laboratory analysis is needed to fully evaluate and compare the performance of the medicine disposal products.

IV. Conclusions

The eight medicine disposal products reviewed claim to provide non-retrievable and environmentally safe disposal of leftover medications. Seven of the eight products are designed for final disposal in the garbage and solid waste system, and are marketed for both household and healthcare facility use. The Cactus Smart Sink alone recommends final disposal by incineration according to federal, state, and local regulations, and is marketed solely to healthcare facilities and other “regulated generators”.

None of the eight products have been reviewed or approved for medicine disposal in the home or in healthcare facilities by any federal agency. In general, federal agencies have long standing policies prohibiting endorsement of specific products or companies.

Examining the information provided by the manufacturers on their websites and marketing materials leaves many questions about the mode of action and effectiveness of the eight medicine disposal products reviewed. Three products use activated carbon as an adsorbent. One product uses bentonite clay as an adsorbent. One product uses calcium hypochlorite as a chemical deterrent and absorbent agents. Three of the eight products do not fully identify their active ingredients, which are described as: “a proprietary mixture of denaturants and deterrents”, “cross-linking polymers”, and “an organic plant-based powder.

Only half of the eight products reviewed provide any performance test results on their websites. Most of the testing was not conducted by independent laboratories or published as peer-reviewed research. Analysis provided for two products show that small amounts of drugs remain unadsorbed or retrievable after treatment with the product. In general, performance of the products has not been evaluated for an adequate variety of pharmaceuticals or treatment conditions. The available testing does not adequately assess whether the treated pharmaceuticals are inactivated through chemical or physical means, or rendered non-retrievable. The test results reviewed also do not appear to adequately characterize the product-pharmaceutical mixture for disposal in the solid waste system.

Adequate independent verification of product performance claims is needed to recommend the use of these medicine disposal products to consumers. The DEA, the EPA, and the FDA all recommend that residents use secure take-back programs for medicine disposal as a first choice, and only suggest disposing of medicines in the trash when no take-back program is available. In many areas, local public health, law enforcement, and solid waste agencies are promoting the use of secure medicine take-back programs. Marketing of these products may complicate that message. Some local jurisdictions prohibit or discourage residents from disposal of waste pharmaceuticals in the household trash and solid waste.

In situations where residents have no access to a secure medicine take-back program and disposal of pharmaceuticals in the solid waste system is allowed, these products may be more effective deterrents to diversion than mixing unwanted medicines with kitty litter or coffee grounds. By adsorbing most of the drugs, even reversibly, or making the drugs noxious, the products may make illicit access to the medicines more difficult.

Some of the products, however, may create new exposure risks due to their ingredient chemicals. More information is needed on the properties and hazards of undisclosed components of these products, as well as on the chemical properties of the used product-pharmaceutical mixture.

The cost of these products, which is on the order of \$5 to \$10 for disposing of 50 to 300 pills, is likely to discourage residents from using a medicine disposal product regularly. Should future independent laboratory testing demonstrate that a medicine disposal product provides secure and environmentally protective disposal, a funding source would be needed to provide an ongoing supply of the product to residents. Jurisdictions with pharmaceutical stewardship ordinances, such as San Francisco, could include approved disposal products as an allowable disposal option and require that drug producers include the

costs of purchase and distribution of the products to residents through their stewardship programs.

For healthcare facilities, medical centers, and other regulated generators of pharmaceutical wastes, the usefulness of these products depends on the specific pharmaceuticals to be disposed and the federal, state, and local regulations applicable to each facility. Federal regulations define how healthcare facilities, pharmacies, medical clinics and other “regulated generators” must dispose of certain types of waste pharmaceuticals, and state and local regulations may define additional waste management requirements. DEA registrants cannot dispose of unused controlled substance inventory in the solid waste system under the DEA’s Rule. Any unused pharmaceutical that designates as RCRA or state-designated hazardous waste must be managed as a hazardous waste. Regulated generators should take special care to review all applicable regulations prior to using one of these medicine disposal products for solid waste disposal of unused pharmaceutical inventory.

This review and analysis of information provided by the manufacturers of the eight medicine disposal products on their websites, promotional materials, and product labels provides some answers, but leaves many questions. Independent laboratory analysis is needed to fully examine and compare the performance of the products and to assess how well they achieve stated goals of providing safe disposal of leftover medicines.

V. Medicine Disposal Product Overviews

Each product description provides a summary and review of information available from the manufacturer’s website, promotional materials, and product labels as of March 24, 2017. These sources may have been updated or changed after this date.

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Cactus LLC

1040 Le Grand Blvd, Charleston, SC 29492
(843) 856-7400

Product Overview

Manufacturer's website states "The Cactus Smart Sink® is a secured, wall-mounted pharmaceutical waste disposal system. It accepts controlled substance waste including solids, liquids and patches. This easy-to-use technology renders unused medications non-retrievable and unrecoverable. The simple, convenient, secure, compliant way to reduce opportunity for diversion while protecting the environment."

"The Cactus Smart Sink is designed to safely and easily dispose of pharmaceutical waste that would otherwise be discarded in red sharps containers, waste bins, or down the drain."

The cartridge capacity for solids is approximately 1.7 L, or 500-1500 tablets/capsules. The capacity for liquids is approximately 3.0 L. Cartridges are designed to last 90 days.

Directions

The self-contained, locking unit mounts onto a wall or countertop. It has two openings for drug disposal: an opening for pills, capsules, and patches with a one-way maze, and a funnel opening for liquid pharmaceuticals from syringes, vials, or IV bags. A battery-operated sensor and alert light system indicates when internal cartridges are full or have expired after 90 days. Access to remove cartridges requires a key, and other attempts to access triggers an alarm.

Cactus LLC recommends disposal of full cartridges through a pharmaceutical waste management company in accordance with guidelines of state and federal agencies, depending on whether disposed pharmaceuticals are hazardous or non-hazardous wastes. Cactus Smart Sink is not intended for: chemotherapy wastes, nuclear medicine wastes, sharps.

Cactus also has a [PharmaLock product](#) for controlled substances in liquid form designed to mount on anesthesia or nursing carts.

Performance Descriptions and Test Results

The manufacturer's website states: "Cartridges inside the unit contain a "proprietary mixture of denaturants and deterrents" that convert the pharmaceuticals "to a semi-solid state within fifteen seconds, rendering waste unrecoverable, non-retrievable and unusable." An FAQ document states "Based on extensive lab recoverability testing, Cactus, LLC maintains a position that unused controlled substances put into the



image © Cactus LLC.

Manufacturer's Description

"A medication waste disposal solution, bringing medical facilities into compliance..."

The Cactus Smart Sink securely captures partially administered or unused controlled substances and renders them "unrecoverable, non-retrievable and unusable". The Smart Sink helps reduce drug diversion and improve patient safety while also reducing the impact on the environment."

Intended Users

Medical facilities, hospitals, hospice, doctor's offices, nursing homes, veterinary clinics, correctional facilities.

Not marketed to consumers.

Manufacturer List Price

Pricing is based on facility size and number of units purchased.

Ballpark cost for the wall-mount unit is \$500. Each cartridge is approximately \$50, with volume discounts.

Product Ingredients

"proprietary mixture of denaturants and deterrents"

Citations, descriptions, and prices are from the manufacturer's website and materials as of March 24, 2017.

Smart Sink® system, will be rendered “unrecoverable, non-retrievable and unusable.” And “The Cactus Smart Sink® meets the DEA requirements for controlled substance waste disposal. (DEA Rule on Disposal of Controlled Substances, 9/9/14),” but does not provide additional documentation.

The FAQ document linked from the website provides additional disposal guidance: “Even though some states may consider the waste or byproduct to be “unusable” or “neutral,” to reduce environmental impact or risk, Cactus recommends final incineration of the used cartridges. (Per standard EPA and state Department of Environmental Protection guidelines). This service can be provided by most contracted waste companies. Should your facility consider trash disposal for the used cartridges, we recommend that you request state Environmental Agency approval prior to doing so.” Other parts of the FAQs state: “If RCRA Hazardous waste is introduced into the Cactus Smart Sink, the appropriate RCRA guidelines for labeling, tracking and disposal must be followed.” Cactus provides a Resources page that offers to recommend a waste service provider in the user’s area, and links to the DEA, EPA, and state environmental agency websites.

The manufacturer’s website does not provide any test results or reference any research studies to support the description of the product’s performance. No technical details are provided on the product’s proprietary ingredients.

The manufacturer’s recommendation to utilize incineration for final disposal of used cartridges per federal, state, and local regulations is compliant with DEA and EPA requirements for disposal of unused controlled substances and other waste pharmaceuticals. The Cactus Sink process is also compliant with the DEA’s October 2014 guidance to practitioners⁴¹ on disposal of pharmaceutical wastage. DEA does not mandate a specific disposal method for controlled substances wastage but recommends “security controls and procedures that ensure pharmaceutical wastage is not diverted.” Healthcare and other facilities using the Smart Sink should ensure use of the unit is compatible with any additional state or local requirements in their area, especially if disposing of pharmaceuticals that designate as hazardous under federal or state regulations.

Available Information on Resulting Waste

Chemical Analysis or Waste Determination of Disposal Product with Pharmaceuticals: No analysis provided.

Manufacturer does not recommend solid waste disposal and the manufacturer’s materials explain that characterization of the used cartridges as “non-hazardous” or “hazardous” depends on the types of pharmaceuticals disposed in the unit.

Cactus recommends incineration of used cartridges even in situations where regulations would allow trash disposal of the disposed pharmaceuticals.

Packaging: The unit’s cartridges are rigid plastic bottles. The manufacturer’s website and FAQ document do not provide any technical information on the type of plastic.

More on Product Ingredients

Manufacturer’s website does not provide a MSDS or further describe the product’s “proprietary mixture”.

Where purchase?

Manufacturer’s website: cactusllc.net

⁴¹ U.S. DEA. Letter to Registrants clarifying the DEA position regarding a practitioner’s disposal of pharmaceutical wastage. October 17, 2014.

https://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf

Verde Technologies

12701 Whitewater Drive, Suite 280, Minnetonka, MN 55343
(612) 568-1128

Product Overview

Manufacturer states “Powered by patented MAT₁₂ Molecular Adsorption Technology, the Deterra system is an environmentally friendly product that works for pills, liquids and patches.” The pouch contains activated carbon, described by the manufacturer as a formulation that is optimized to absorb organic molecules the size of pharmaceuticals and render them “neither water-soluble nor physiologically active when bonded”.

Directions

- Put unused medications in pouch.
- Fill halfway with warm tap water and wait 30 seconds.
- Seal and gently shake pouch and dispose of in normal trash.

Manufacturer’s website states “When used in healthcare facilities, not for use with RCRA listed drugs. State and local regulations may vary, consult authorities with questions.”

Manufacturer describes that deactivation takes time to complete. and during that time the product needs to be “concealed and protected from any persons that may have misuse intentions”. If the user exceeds the recommended amount of pills, liquids, or patches, the deactivation will be inefficient and activated carbon does not bind drugs that are not organic compounds, or that contain metals such as iron or lithium.

Sizes and Pricing

Size	Max. Pills	Max. Liquid	Max Patches	Unit Cost
SP	15	59 mL (2 oz)	2	\$4.99; sold in 3-pack
MP	45	177 mL	6	\$5.99; sold in 3-pack
LP	90	354 mL	12	\$6.99; sold in 3-pack
XL	450	1.8 L	60	\$34.99
3.5	1,800	10 L	320	\$84.25
5.0	2,600	14 L	500	\$106.46

Deterra was originally marketed by Verde as MedsAway and utilizes the same MAT₁₂[®] carbon material.

Performance Descriptions and Test Results

The manufacturers website states: “Patented, proprietary activated carbon bonds to pharmaceutical compounds, rendering drugs ineffective and safe for disposal.” And “renders chemical compounds safe for landfills”.



Manufacturer’s Description

“Neutralizes drugs – effectively, safely, and quickly”
 “The Deterra[®] System is a scientifically proven product, powered by patented MAT₁₂[®] Molecular Adsorption Technology. In a simple 3-step process, a user can deactivate drugs, thereby preventing drug misuse and protecting the environment.”

Intended Users

- Home and Healthcare.
- Pharmacies, law enforcement agencies, healthcare providers, state agencies and non-profits.

Manufacturer List Price

\$4.99-\$6.00 per unit for consumer sized pouches. \$34.99 for XL size.
 \$84.25 or \$106.46 for large disposal units. (see chart)

Products may be purchased by the case at wholesale pricing.

Product Ingredients

Activated carbon: patented MAT₁₂[®] Molecular Adsorption Technology.

Citations, descriptions, and prices are from the manufacturer’s website and materials as of March 24, 2017.

- “99% success in deactivating drugs
 - Narcotics
 - Antibiotics
 - Transdermal patches
- Proprietary activated carbon MAT12 renders drugs non-retrievable
- Works on all organic compounds”

The manufacturer’s website provides some test results to support the description of the product’s performance; however, the testing provided is not from a fully independent laboratory or peer-reviewed published research.

Deterra provides several documents linked from the research section of its website that are internal studies conducted by William Fowler, who is the Principal Scientist at Verde Technologies, and provides unpublished white papers that have not been peer-reviewed. (Five “studies” are provided, but two documents are duplicates; and two of the studies present the same results.) Deterra also provides two additional “University Studies” that are undated poster presentations from an American Association of Pharmaceutical Scientists conference, also unpublished and not peer reviewed. The posters are attributed to researchers at Mercer University with William Fowler and Andrew Korey of Verde Technologies listed as co-authors, and funding provided by Travanti Pharma Inc. or Verde Technologies.

Two documents (dated 2012, and updated in January 2017 to replace the brand name MedsAway with Deterra,) provide the same data from a “wash-out test” to measure how much of nine drugs, including generic Vicodin and generic Percocet, remain bound to the Deterra/MedsAway activated carbon after being sealed in the pouch with water for 7 days. Each drug seems to have been tested separately. The disposal product-pharmaceutical mixture was extracted with water with one hour of agitation. Pharmaceuticals were detected by spectroscopy measurements at signature wavelengths for each drug. They found 98.7% adsorption of the drugs on average, with a range from 94.3% to 100%. Another study similar to an EPA TCLP weak acid extraction was conducted on Deterra used with three drugs (acetaminophen, ibuprofen, and naproxen sodium), and they report greater than 99% absorption, again through spectroscopic analysis. It is difficult to assess the quantitative accuracy of these “wash out” tests because calibration methodology and data for reference standards are not reported. The studies summarized in the conference posters compare Deterra/Medsaway adsorption properties to that of kitty litter or coffee grounds. A sample of Deterra mixed with a fentanyl patch was extracted with water and with 30% ethanol; the extractions recovered 1.6% and 3.9% of the fentanyl sample, respectively.

A literature search identified an analysis of Deterra published in *Pharmaceutics*⁴², an open-access, rapid publication journal. This study is not provided on Deterra’s website, but was co-authored by Fowler and funded by Verde Technologies. The paper describes the time process of adsorption by the activated carbon, which the authors describe as “deactivation”, of three medicines that are controlled substances – diazepam (ten 10 mg tablets), lorazepam (ten 2 mg tablets), and buprenorphine (ten 8 mg sublingual films). After 48 hours, analysis of the water phase in the pouch by HPLC (high pressure liquid chromatography) found most of each drug had been adsorbed by the carbon phase; however, the water phase still contained 28% of the diazepam, 12.5% of the lorazepam, and 1% of the buprenorphine. After 28 days, the water phase contained less than 1% of each pharmaceutical. A comparable 28 day old sample of Deterra plus the three pharmaceuticals was then “washed out” with a five-fold dilution of water, shaken for one hour, then allowed to stand undisturbed for 23 hours at room temperature. The publication states “Addition of excess water facilitated complete release of active pharmaceutical ingredient from the tablets or films with continuous adsorption by the activated carbon”, which suggests researchers noticed that the tablets and films were not fully solubilized by the Deterra mixture during the 28 day incubation. According to their analysis, the water extraction released about 1.0% of the diazepam, about 0.25% of the lorazepam, and about 0.02% of the buprenorphine (estimated from data chart, numbers not

⁴² Song, Y., Mahima, M., Fowler, W., Korey, A., Kumar Banga, A. 2016. “Activated Carbon-Based System for the Disposal of Psychoactive Medications” *Pharmaceutics* 8(4), 31; [doi:10.3390/pharmaceutics8040031](https://doi.org/10.3390/pharmaceutics8040031)

provided). The same sample was extracted a second time with 30% ethanol, shaken for one hour, then allowed to stand undisturbed for 23 hours. The ethanol extraction released an additional 1.6% of the diazepam, 0.25% of the lorazepam, and 0.1% of the buprenorphine. Despite release of small amounts of the drug, the authors conclude that the Deterra activated carbon “did not release adsorbed drug substances when exposed to large volumes of water or 30% ethanol”. The authors did not comment on their selection of extraction conditions, which allowed a 23 hour period without agitation during which the pharmaceuticals could presumably re-adsorb to the activated carbon, reducing the measurement of released drugs.

These Deterra “wash out” tests show that some of the adsorbed pharmaceuticals, including controlled substances, can be recovered through brief physical extraction with plain water and other solvents. Therefore, Deterra does not appear to meet the DEA’s stringent non-retrievable standard.

Deterra’s FAQ document states “In-home drug disposal is generally unregulated by federal, state, and local authorities.” However, there are some local regulations and policies against disposal of pharmaceuticals in the solid waste system.

Available Information on Resulting Waste

Chemical Analysis or Waste Determination of Disposal Product with Pharmaceuticals: No independent analysis or complete waste determination. Some tests conducted by the manufacturer, described above, looked at “wash-out” of pharmaceuticals adsorbed to the activated carbon and detected some release of the drugs upon brief extraction with water.

Package has warnings: “do not consume”, “keep out of reach of children and pets”, and “do not remove contents of pouch.”

Packaging: The packaging of the S, M, L sizes is made from Omnidegradable® material, produced by [Tekpak Solutions](#), which is described as a petroleum based product engineered with organic additives to biodegrade only when exposed to microbes in a landfill. Packaging for larger sizes is a “recycled material”.

More on Product Ingredients

Deterra provides a Material Safety Data Sheet (MSDS) from Norit Americas Inc. for Activated Carbon.⁴³ Under toxicological and ecological information the MSDS states “This material is non-toxic in its original state. Used activated carbon may exhibit characteristics of the absorbed material.”

Where purchase?

Deterra’s website: deterrasystem.com
Amazon.com
Pharmacies
Medical supply retailers

⁴³ Norit. Activated Carbon. Material Safety Data Sheet. <http://deterrasystem.com/wp-content/uploads/2015/09/Deterra-Activated-Carbon-MSDS.pdf>

DisposeRx Inc.

135 West Illinois Ave., Southern Pines, NC 28387
(844) 456-1600

Product Overview

Manufacturer's website states "DisposeRx's patented polymers sequester the added drugs in any form (powders, pills, tablets, capsules, liquids or patches) in a cross-linking bond that chemically interacts with the drugs to deter, slow, or prevent the extraction of the active agent by aqueous, alcoholic means, or vaporization."

"Drugs are dissolved and then sequestered into the solid DisposeRx matrix that solidifies within minutes, and the vial is thrown into the trash. The drugs are progressively dissolved and dispersed into the polymer matrix over time. Once disposed in the trash, the drugs progressively deteriorate into the DisposeRx polymers and are ultimately degraded by bacteria and fungi into a solid waste while releasing methane and other gasses."

Directions

Add DisposeRx powder to prescription drug vial.
Fill 2/3 with warm water.
Close cap tightly. Shake for 30 seconds.
Discard in the trash.

"for all prescription and non-prescription drugs formulated as tablets, capsules, powders, patches, or liquids"

Performance Descriptions and Test Results

Manufacturer's website states: "DisposeRx inactivated drugs cannot be extracted and will not contaminate landfills or water supplies". Manufacturer states that their testing has demonstrated that opioid drugs are both physically and chemically inactivated in the polymer matrix, and cannot be extracted from the polymer using water or alcohol. The product is described as being in compliance with the DEA's "non-retrievable" guideline. The website states that the DisposeRx contaminated drugs will not contaminate landfills or water supplies.

The manufacturer's website does not provide any test results or reference any research studies to support the description of the product's performance. Brief descriptions without supporting documentation are made about the product's mechanism of action and safety as determined by "DisposeRx scientists".

The website also states the mixture of drugs and polymer are "safe if accidentally ingested with or without sequestered drugs" and that the disposal product-pharmaceutical mixture would be excreted in the feces.

Manufacturer's Description

"Solves the problem of leftover drugs with its patented drug disposal technology for site-of-use disposal of expired or leftover drugs."

"Our Goal is to stop the opioid epidemic at the medicine cabinet by dispensing DisposeRx with each Schedule II, III & IV prescription."

Intended Users

Individuals

Manufacturer's website states larger volume containers are available for hospitals, nursing homes, hospices, and correctional facilities.

Manufacturer List Price

Pricing is not provided on manufacturer's website.

Product Ingredients

"cross-linking polymers"
(patent pending)

Citations, descriptions, and prices are from the manufacturer's website and materials as of March 24, 2017.

No test results provided. The manufacturer does not recommend ingestion.

The manufacturer's website confusingly states "There is no US governmental agency with authority to oversee drug disposal" as the header to a section that includes references to the DEA, FDA, and EPA recommendations for medicine disposal. This section of the website does not accurately summarize those recommendations and does not accurately explain that DEA authorized pharmacy and mail-in take-back programs can accept controlled substances.

Available Information on Resulting Waste

Chemical Analysis or Waste Determination of Disposal Product with Pharmaceuticals: No data or test results are provided. The manufacturer asserts that the product creates a "biodegradable matrix", which cannot be evaluated with the available information.

Packaging: Individual packets of DisposeRx are designed to be added directly to a prescription pill bottle. Manufacturer's website states some sizes of the product are provided in "biodegradable bags" without further description.

More on Product Ingredients

Ingredients are not identified beyond description of a non-toxic, cross-linking polymer. No MSDS provided.

Manufacturer's website states "The components of the sequestering polymer are listed by the FDA as generally recognized as safe (GRAS), and in fact, they are often found in various prepared foods."

The co-founder and CEO of DisposeRx, John W. Holaday, has a patent application⁴⁴ that describes a potential disposal device material as: "one or more disposal device agents are selected from a group consisting of carbomers, polyacrylic acid, hydroxypropyl methylcellulose: hydroxypropyl cellulose mixture, polyvinylpyrrolidone, polyethylene oxide, methylcellulose, xanthan gum, guar gum, hydroxypropyl cellulose, polyethylene glycol, methacrylic acid copolymer, colloidal silicon dioxide, cellulose gum, starch, sodium starch glycolate, sodium alginate, and combinations thereof." It cannot be confirmed from available information if these are the potential ingredients in DisposeRx.

Where purchase?

Manufacturer's website states product may be purchased in pharmacies, but does not otherwise provide information on where to purchase. No retail source of DisposeRx was identified through an online search. Website also states goal of having DisposeRx dispensed with every prescription for an opioid or controlled substance drug.

⁴⁴ U.S. Patent Application Number US 12/142/142,736. Publication Number US 20140187842 A1. "Device for Disposal and Neutralization of Pharmaceutical Agents" <https://www.google.com/patents/US20140187842>

Drug Buster

drug-buster.com

Medline Industries, Inc.

One Medline Place, Mundelein, IL 60060
800-633-5463

Product Overview

Manufacturer's website states: "Drug Buster uses activated charcoal to quickly neutralize the active chemicals in pills, liquids, controlled substances and transdermal patches. It takes just 15 minutes to break down non-hazardous pharmaceuticals into a chemically inactive slurry that can be safely put in the regular trash."

4 ounce bottle for approximately 50 pills

16 ounce bottle for approximately 300 pills per bottle

64 ounce bottle for approximately 1500 pills per bottle

Directions

Step 1 – Place unwanted drugs – pills, liquids, narcotics, and transdermal patches – into the bottle.

Step 2 – Invert and swish the bottle twice.

Step 3 – After 2 hours, or when full, discard in regular trash – not hazmat. (Product label also states "Or allow 24 hours before emptying contents into trash, then recycle bottle.")

Direction footnotes state:

Do not overfill. In some cases foaming may occur.

* All federal and state guidelines require non-hazardous unused pharmaceuticals be rendered undesirable and unusable. Please refer to your local regulations to ensure specific compliance.

** Drug Buster cannot accept potassium supplements, antacids, gassing agents, and hazardous medications.

Performance Descriptions and Test Results

The manufacturer's website states "Drug Buster drug disposal system meets FDA, DEA and EPA guidelines for drug disposal." And "The Drug Buster® medication disposal system deactivates and contains the active ingredients in non-hazardous medications, preventing misuse, and deterring them from leaching into soil and water supplies." The product label states "Helps contain the active ingredients of the medication to deter it from leaching into soil & water supplies." Marketing materials state that the disposal product-pharmaceuticals mixture becomes "an environmentally inert slurry that, if consumed, would induce vomiting."

The manufacturer's website does not provide any test results or reference any research studies to support the description of the product's performance.



Manufacturer's Description

"Fast, Effective, Eco-friendly Drug Disposal System"

"Instant. Effective. Safe Drug Disposal"

Intended Users

Physician's Offices, Hospitals, Nursing Homes, Research facilities

Home health/hospice

Product marketing emphasizes use by nurses and "staff" at healthcare facilities who need to dispose of non-hazardous pharmaceuticals.

Manufacturer List Price

4 oz - \$9.95

16 oz - \$15.99

64 oz - \$34.99

per Amazon and ebay list prices. Medline does not list manufacturer price.

Product Ingredients

Activated Charcoal. Water, surfactants, and neutralizing agents.

Citations, descriptions, and prices are from the manufacturer's website and materials as of March 24, 2017.

Available Information on Resulting Waste

Chemical Analysis or Waste Determination of Disposal Product with Pharmaceuticals: None provided. Product directions state product is for non-hazardous unused pharmaceuticals and recommends consulting local regulations on disposal.

Packaging: Not described. Product is sold in an opaque plastic jug bottle which is probably polyethylene or polypropylene.

More on Product Ingredients

Medline provides a Material Safety Data Sheet (MSDS) that lists carbon 25% by weight (CAS 7440-44-0).⁴⁵

The MSDS Hazards Classification states: EYE DAMAGE/IRRITATION - Category 2B; SENSITIZATION - SKIN - Category 1B; SKIN CORROSION/IRRITATION - Category 3

A previous version of a MSDS description, linked from the website during the review period, listed the product as including Diethanolamine and Cocamide DEA which were noted as IARC potential human carcinogen)

Product label states Warnings: Keep out of reach of children; will induce vomiting, may be harmful if swallowed.

Where purchase?

Medline

Amazon.com

Medical supply retailers

⁴⁵ Medline. Drug Buster. Safety Data Sheet.

https://www.medline.com/media/catalog/Docs/MSDS/SDS0138_Drug_Buster.pdf

V23, LLC

300 North Kanawha Street, Suite 201, Beckley, WV 25801
877-441-8906

Product Overview

Manufacturer's FAQs state that "Element MDS works by mixing medications (liquid, solid and even controlled substances) with an organic, plant-based powder and simple tap water in a tamper-resistant container. Shaking this mixture turns it into an undesirable, gel-like substance that is securely contained and ready for disposal in a common trash receptacle."

The 17 ounce bottle handles "approximately 500 tablets".

For drug patches, the manufacturer's FAQs states "This does not make the patch unusable, but it certainly makes it less desirable."

Directions

From box label:

Step 1 – Empty medication from its original packaging into container. Do not fill more than 1 inch below upper molded line on container.

Step 2 – Open MDS Powder Packet and pour all of the powder into the container.

Step 3 – Fill container with water 1 inch above the medicine level but do not exceed the container's upper molded line.

Step 4 – Tighten lid on the container until it locks. Do not try to reopen.

Step 5 – Shake vigorously.

Step 6 – Place container in a standard trash receptacle.

Product packaging states: "Do not use kit for radioactive pharmaceuticals or chemotherapy drugs."

Performance Descriptions and Test Results

Product packaging states "Element MDS can be used for the disposal of controlled substances." The website states the plant-based powder renders pharmaceuticals "undesirable", but does not describe the product as neutralizing or degrading the pharmaceutical compounds.

The manufacturer's website does not provide any test results or reference any research studies to support the description of the product's performance. The manufacturer's website does not provide any detail on the product ingredients or mechanism of action beyond the description listed above under Product Overview.



Manufacturer's Description

"The Ultimate Solution For Proper Medication Disposal"

Intended Users

Originally created for hospice and health care organizations.

Also marketed to community coalitions, and retailers who provide kits to the public, law enforcement agencies, landfill organizations, funeral homes, and others.

Kits can be customized with a group's logo.

Manufacturer List Price

Kits can be purchased in cases of 50 units in two options:

17oz Ready Kit - individually packaged for consumers; \$349.50; \$6.99 per unit

17oz Value Option - bulk for healthcare; \$279.99; \$5.60 per unit

Product Ingredients

"Organic, plant-based powder"

Citations, descriptions, and prices are from the manufacturer's website and materials as of March 24, 2017.

The product packaging and a video linked from the website⁴⁶ states “Element MDS® is in compliance with the EPA’s recommendation of disposing medication in a trash receptacle after rendering the medication undesirable.” This statement does not explain that the EPA recommends and encourages the use of medicine take-back programs, and states that disposing of medicines in the trash is a second choice or “For those without access to a pharmaceutical take-back event...”.⁴⁷

Manufacturer’s website states the product was originally developed for hospice and healthcare facilities, but is useful for home use because:

- Flushing medications in the toilet delivers them to the public water supply.
- Throwing away in the garbage, even when concealed by kitty litter or coffee grounds in a plastic bag, can make them available to unintended users.
- Community drug take-back events are infrequent and may not be accessible by some residents.

Available Information on Resulting Waste

Chemical Analysis or Waste Determination of Disposal Product with Pharmaceuticals: No information provided.

Packaging: Not described, but product is sold in an opaque plastic jug bottle which is probably polyethylene or polypropylene.

More on Product Ingredients

Product manufacturer does not provide a MSDS sheet or list product ingredients.

The manufacturer’s FAQs state the “powder is plant based and harmless to handle.” However, the product packaging has warnings: “Keep out of reach of children”; “Caution: Harmful If Swallowed”; “Swallowing of the medication disposal powder can produce a blockage.” “In case of eye contact, rinse the eye well with water...” “Wash with soap and water after handling”.

Where purchase?

Manufacturers website: ElementMDS.com

⁴⁶ Element MDS-Medication Disposal video on YouTube.

<https://www.youtube.com/watch?v=GW89X6XngiQ&feature=youtu.be>

⁴⁷ U.S. EPA “Collecting and Disposing of Unwanted Medicines” on EPA’s website:

<https://www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines>. And statement made in Federal Register, Vol. 80, No. 186 September 25, 2015, as part of EPA rule-making on pharmaceutical wastes.

The Pill Catcher (F.P.R. Inc.)

P.O. Box 700741 Plymouth, MI 48170
(855) 442-7229

Product Overview

Manufacturer's "How It Works" description states "The Pill Catcher™ is a patented formulation of dry ingredients, including bentonite clay, put into a plastic container. When drugs and water are added to the mixture and the container is shaken for forty seconds, this formula permanently absorbs the dissolving drugs. The clay platelets become open and plastic when wet, then close back together and encapsulate the drug particles, preventing any subsequent discharge into the surrounding environment."

Three product sizes:

- Pint bottles for up to 120 pills, or 450 c.c.'s of liquid medicines
- Quart bottles for up to 300 pills, or 700 c.c.'s of liquid medicines
- Gallon bottles for up to 1,500 pills or 2,500 c.c.'s of liquid medicines

Directions

for pint size bottle

1. Add up to 450 c.c.'s of liquid drugs, or 120 pill of any type or class, into bottle.
2. Add tap water to the water fill line.
3. Cap bottle and shake for 40 seconds.
4. Put capped bottle into any trash receptacle.

Directions state: "Do not re-use bottle after water has been added. If bottle swells during shaking – loosen cap and vent to let excess air out."

Performance Descriptions and Test Results

Manufacturer's website and product label state: "The Pill Catcher™ was tested on all classes of drugs, in pill, gel cap, liquid, and patch form." "Safe for all medications" and "safe for landfills." "Passes all EPA and DEA laws and regulations for safe disposal." "The pharmaceutical waste will remain permanently encapsulated, and cannot be separated from the encapsulating material."

The manufacturer's website provides results of a TCLP (Toxicity Characteristic Leaching Procedure) assay conducted by TestAmerica (Chicago, IL) for Cetco Environmental in 2009.⁴⁸ Cetco is a manufacturer of ORGANOCLAY® products for environmental remediation, which is the

⁴⁸ TestAmerica. Analytical Report. Job Number 500-17908-1 for Cetco Environmental. 2009. <http://www.thepillcatcher.com/files/75371143.pdf>



Manufacturer's Description

"PillCatcher for a cleaner safer world. The ONLY quick, simple way to dispose of unused pills and liquid medicines."

"We certify that The Pill Catcher™ is the only drug disposal product that passes all EPA tests for safe disposal to landfills."

Intended Users

Consumers
Healthcare facilities

Manufacturer List Price

Pint bottle - \$4.95 each.
Quart bottle - \$6.95 each; \$105 for case of 16 (or \$6.56 each).
Gallon bottle - \$22.60 each; \$90 for case of 4 (or \$22.50 each).

Product Ingredients

Bentonite clay and quartz.

Citations, descriptions, and prices are from the manufacturer's website and materials as of March 24, 2017.

bentonite clay used in the Pill Catcher^{49,50,51}. The sample analyzed is not fully described in the online report. Additional materials provided by the manufacturer after a request from the author state that the sample analyzed was 4 ounces of the Pill Catcher mixed for three hours with 13 pharmaceuticals:

- Pain medications: Darvocet (100/650 mg pill), Vicodin (7.5/750 mg pill), Tylenol (1 oz liquid), Aspirin (325 mg pill), Ibuprofen (200 mg gel cap);
- Hormones: Prednisone (20 mg tablet), Premarin (1 mg tablet);
- Antibiotics: Erythromycin (250 mg tablet);
- Psychotropics: Ativan (2 mg tablet), Xanax (2 mg pill), Neurontin (400 mg pill), Prozac (20 mg gel cap);
- Statin: Simvastatin (20 mg tablet).

The test sample was prepared by Fran Parrott Reliv of Michigan, LLC, the patent holder for the Pill Catcher; therefore, the analysis was not entirely conducted by an independent laboratory. The sample was shipped to CETCO and tested for 8 metals and 20 organic compounds under the TCLP protocol. TestAmerica tested the same sample for the same 20 organic compounds, plus two more organics (per 8260B and 8270C methods). Both TCLP analyses found that the organic compounds were non-detectable and the metals were below regulatory limits. Bentonite clay typically contains trace amounts of lead, and lead was detected at 0.10 mg/L, with the regulatory limit for lead at 5.0 mg/L. The manufacturer of The Pill Catcher is accurate in stating that it is the only product that provides any TCLP test results.

The TCLP results show the 40 regulated pollutants were below regulatory levels in the extract from the tested sample. The 13 pharmaceutical compounds used in the test do not appear to include any RCRA designated hazardous waste pharmaceuticals; however, this report's author does not have a complete listing of P and U list pharmaceuticals. The TCLP does not screen for any pharmaceutical compounds in the extract, so the assay is not conclusive in verifying whether the DEA's non-retrievable standard has been achieved.

The manufacturer's FAQs clarify that the Pill Catcher does not have certification from any government agency, but also incorrectly asserts that the EPA has the power to overrule all other government entities. The DEA has authority over regulations pertaining to disposal of pharmaceuticals that are controlled substances. Regulations of both the DEA and the EPA, as well as other federal, state, and local regulations, must be considered by regulated generators of pharmaceutical wastes.

Available Information on Resulting Waste

Chemical Analysis or Waste Determination of Disposal Product with Pharmaceuticals: TCLP analysis, described above. The disposal product-pharmaceutical mixture was not otherwise analyzed.

Packaging: Not described, but the plastic jug bottle is probably polyethylene or polypropylene.

More on Product Ingredients

The manufacturer provides a Material Safety Data Sheet (MSDS) that lists: Bentonite (CAS # 1302-78-9), containing naturally occurring crystalline silica and Quartz (CAS # 14808-80-7).⁵² Bentonite clay is also the main ingredient in clumping kitty litters. Hazard identifications are "Not Classified" or "Not Available", and the product is described as nonhazardous with notations on avoiding inhalation of dust.

Where purchase?

Manufacturer's website: www.thepillcatcher.com

Amazon.com

⁴⁹ CETCO ORGANOCLAY® <http://www.cetco.com/en-us/Products/Environmental-Products/Organoclays>.

⁵⁰ Personal communication with Clyde Parrott, 12/08/16.

⁵¹ U.S. Patent Publication Number US 7918777 B2. "Pill Catcher" <https://www.google.com/patents/US7918777>

⁵² "Full Disclosure Material Safety Data Sheet" <http://www.thepillcatcher.com/files/94362689.pdf>

Pill Terminator

pillterminator.com

Combined Distributors Inc.

2360 LAKEWOOD RD SUITE 3-420 TOMS RIVER, NJ 08755
732-952-8800

Product Overview

Manufacturer states: "Once activated with warm water, the Pill Terminator solution will turn into a gel like substance which has an unpleasant taste and odor (undetectable when the unit is sealed.) This will present a strong deterrent to avoid human or animal consumption."

Sold in 300 cc bottle that can accept 300 pills. Or in Gallon size jug.

Directions

from product label:

Shake container to loosen activating particles.

Fill medications up to green line (on bottle's label).

Fill warm water up to red line (on bottle's label).

Tighten cap onto container. CAP MUST BE CLOSED SECURELY BEFORE SHAKING OR HANDLING.

Immediately after closing cap, shake container firmly for five seconds.

Contents will congeal almost immediately.

Throw closed container into trash.

For single use only. Do not reuse.

Performance Descriptions and Test Results

The manufacturer's website and product label states the product is "Specially formulated to meet and exceed FDA and EPA guidelines for safe disposal of unwanted prescription medications". "The Pill Terminator solution will begin physically destroying the medications and denaturing their chemical composition." Product bottle states "contains inorganic solid solvents that help break down medications." And "Specially formulate to meet and exceed FDA and EPA Guidelines for safe disposal of unwanted prescription medications." Taglines include "Child Safe".

The manufacturer's "Tested and Proven" webpage provides a 2014 analysis by Bureau Veritas Consumer Product Services, Inc (BVCPS) and two unpublished reports from academic researchers. The BVCPS analysis concluded that coated aspirin tablets were "completely destroyed" when mixed with The Pill Terminator and water because the tablets were physically dissolved and combined with particles that emit an undesirable odor. No chemical analysis was performed to assess if the aspirin was chemically degraded.

Two unpublished studies are provided from academic researchers. In 2015, Professor Prierer of Western New England University replicated a



Manufacturer's Description

"Simple Solution ~ Powerful Protection

Safe And Easy Disposal Solution For Expired Prescription Medicines
Child Safe

Household, Clinic And Hospital Applications

An Environmentally Responsible Solution To Pill Disposal"

Intended Users

Households

Medical Centers, Nursing Homes, Drug Rehab Centers, Funeral Homes, Animal Clinics, First Responders.

Manufacturer List Price

\$9.95 per single 300 cc unit, plus \$4.95 shipping & handling.

\$29.85 for 3 single units, free shipping. \$216 for 24 single units, free shipping (\$9 per unit).

\$24.95 for 1 Gallon, plus \$4.95 shipping & handling.

Product Ingredients

Calcium hypochlorite, Fuller's earth, and an "absorbent polymer"

Citations, descriptions, and prices are from the manufacturer's website and materials as of March 24, 2017.

2014 study by Dr. Traynor of University of Hertfordshire that examined treatment of morphine with the Pill Terminator chemicals. Samples of the resulting particles were dissolved in water and HPLC (high pressure liquid chromatography) was performed to detect soluble morphine. Upon initial mixing with The Pill Terminator and 2 hours extraction with water, the author's calculate that 57% of the morphine was released. After 48 hours of incubation with The Pill Terminator and 2 hours extraction with water, 45% of morphine was released. In Traynor's analysis, 30 minutes of rigorous mixing of the morphine with The Pill Terminator, reduced the amount of morphine extracted into the water to 2%. However, 30 minutes is more shaking than a consumer could likely be expected to perform. The quantitative accuracy of these unpublished analyses is difficult to assess, and additional incubation conditions were not tested to assess release of the morphine.

These tests show that some of the controlled substance can be retrieved from the used medicine disposal product. Therefore, the Pill Terminator does not meet the DEA's stringent non-retrievable standard. No analysis is presented to demonstrate the pharmaceuticals are irreversibly altered by the treatment. The manufacturer's description that the product is "child safe" are at odds with the product's warning labels and the irritant and oxidizing potential of calcium hypochlorite.

The website restates and links to the FDA's medicine disposal guidance on disposing of medicine in the trash "If no disposal instructions are given on the prescription drug labeling and no take-back program is available in your area". The manufacturer's website states that pharmacists cannot take back unused prescription drugs, which is not accurate under the DEA's Rule for Disposal of Controlled Substances.

Available Information on Resulting Waste

Chemical Analysis or Waste Determination of Disposal Product with Pharmaceuticals: None provided. Unpublished analysis of treatment of morphine showed residual drug released from the product, see above.

Packaging: Pill Terminator is provided in a solid white plastic bottle, and the website links to a description of Marlex high density polyethylene made by Chevron Phillips Chemical Company.⁵³

More on Product Ingredients

A Material Safety Data Sheet (MSDS)⁵⁴ available on the manufacturer's website lists:

Calcium hypochlorite pellets CAS # 7778-54-3, 1 – 5 % by weight

Fuller's earth (not hazardous) CAS # 8031-18-3, 3 – 7 % by weight

Absorbent polymer (not hazardous) trade secret, no CAS # provided - balance of weight

* Exact percentages are trade secret

The product label has warnings, including "CAUTION! KEEP OUT OF REACH OF CHILDREN". The MSDS states red granules should not be removed from the container to avoid irritation to the skin and eyes. Keep out of reach of children. Do not eat, drink or smoke when using the product. The MSDS states that the product is not a hazardous waste under RCRA.

Where purchase?

From manufacturer: www.pillterminator.com
Amazon.com

⁵³ Marlex HHM 5502BN High Density Polyethylene. <https://cdn.shopify.com/s/files/1/1000/3902/files/MARLEX-5502BN-Material-Specification.pdf?11981800429654242971>

⁵⁴ "MSDS" <https://www.pillterminator.com/pages/msds>

Rx Destroyer

rxdestroyer.com

C2R Global Manufacturing

701 Blackhawk Dr. Suite A, Burlington, WI 53105
888-608-5160

Product Overview

Manufacturer states: “Rx Destroyer™ patented solution begins dissolving medications and permanently bonding medications to solution’s activated charcoal immediately.”

Product is marketed in smaller bottles for consumers and in larger bottles, buckets, or drums for healthcare and law enforcement. Examples of stated capacities for the All Purpose formula are:

- 4 oz – 50 pills
- 16 oz – 300 pills or 8 oz liquids
- 64 oz – 1500 pills or 32 oz liquids
- 1.0 gallon (128 oz) – 3000 pills or 64 oz liquids

Directions

- Load medications into bottle.
- Tightly replace cap.
- Gently shake to mix solution over medications.
- Store and use again.
- Bottle full when contents 2” from cap. DO NOT OVERFILL.
- Discard into common garbage, however:
- Check with your institutional policies.
- Check with your state & local disposal regulations for compliance.

- 16 oz. Product Label instructions states Not intended for:
- Effervescent property medications
 - Hazardous medications (u and p-list)
 - Needle or syringe waste

Label states: “The outer shell of capsule and patch material will not dissolve.”

Manufacturer states: “Rx Destroyer™ can be used till full. Store in a controlled area when not in use.”

C2R Global Manufacturing also markets an activated carbon product called Narc Gone (narcgone.com) for drug disposal by law enforcement that appears similar or identical to Rx Destroyer.

Performance Descriptions and Test Results

The product label states: “Independent Lab Tested: Medications Deemed Non-Retrieveable. Exceeds Federal Drug Disposal Guidelines.” The website also states: “Rx Destroyer™ meets “non-retrieveable” DEA standards for controlled substances.” “Rx Destroyer™ brands support EPA and FDA



Manufacturer’s Description

“DEA & EPA COMPLIANT. Patented fast acting formula begins neutralizing medications on contact. Rx Destroyer™ minimizes drug diversion and abuse as well as protects our environment’s water supply and food chain. Rx Destroyer™ formula is 100% natural and meets DEA definition of Non-Retrieveable.”

Intended Users

- Healthcare facilities
- Consumers
- Law Enforcement

Manufacturer List Price

- 4 oz. All Purpose, case of 24 – \$99.95 (\$4.16 ea)
- 16 oz All-Purpose, case of 12 - \$105 (\$8.75 ea). (\$13.84 on Amazon)
- 1.0 gallon (128 oz) Pro-Series Liquids, case of 4 – \$195 (\$48.75 ea)

Product line includes a funnel and a wall mount, purchased separately, for larger size bottles.

Product Ingredients

Activated carbon and other agents.

Citations, descriptions, and prices are from the manufacturer’s website and materials as of March 24, 2017.

efforts to help prevent leaching of pharmaceutical into drinking water, soil, and waterways. In most states, Rx Destroyer™ meets AND OR EXCEEDS disposal regulations for solid waste, which allows the Rx Destroyer™ bottle and its contents to be discarded with common trash. For additional topic related information, please refer to your facilities, local, state and or federal regulations.” And “Once medications are attached to activated charcoal a temperature of 1,700°F is required to release drugs.”

More recently added to the Rx Destroyer website is a section on Bottle Disposal Options, <http://www.rxdestroyer.com/masswastedisposal/>, which lists garbage disposal, medical waste hauler, or mail-back disposal. This page references the generator’s responsibility for ensuring only non-hazardous pharmaceuticals are disposed in Rx Destroyer for garbage or medical waste hauler disposal. At additional cost, an affiliated company called Rx Waste Systems provides a mail-back option for multiple used bottles for “state compliant” destruction. The website states this mail-back service is prohibited in: Arkansas, California, Connecticut, Illinois, Maine, Massachusetts, Minnesota, New Hampshire, New York, Pennsylvania, Rhode Island, Vermont and Virginia.

The manufacturer’s website provides some test results to support the description of the product’s performance; however, the testing was not performed by an independent laboratory or the subject of peer-reviewed published research.

Under Test Data, the manufacturer’s website provides five communications (two memos with three attachments) from Dr. Nowicki, the president of PACS Activated Carbon Services (pacslab.com), providing his professional opinion on RxDestroyer. The documents do not provide results of direct testing of the product with pharmaceuticals. Dr. Nowicki describes the properties of activated carbon in general, the adsorption capacity of Rx Destroyer’s activated carbon, and references work of other researchers on activated carbon adsorption of other organic compounds, such as pesticides. One document⁵⁵, in sections labeled Appendix C and D, provides unattributed results tables for “deactivation” of pharmaceutical compounds with activated carbon; however, the test methodology is not explained and data is not provided. The source of the results table in Appendix C is not identified, but the table appears to be identical to a results table in the internal unpublished research conducted by Verde Technologies on their Deterra product, except that the name “Deterra” has been replaced with “Rx Destroyer”. Appendix C includes Dr. Nowicki’s recommendation that “the test results can be applied to the activated carbon used in Rx Destroyer and there is no need to recreate the study.”

Statements in the provided documents indicate that some amount of controlled substances is retrievable from activated carbon, which would negate compliance with the DEA’s non-retrievable standard. One of Dr. Nowicki’s memos says “Typically there will be a small trace amount of drug ingredients remaining in the liquid phase at completion.” The unattributed data tables also show less than 100% adsorption of controlled substances and other drugs on the carbon. No extraction analysis is provided; however, extraction tests of other activated carbon disposal products show some retrieval of pharmaceuticals as well (see Section II.B.).

The Narc Gone website - narcgone.com – for what appears to be a similar or identical activated carbon product also produced by C2R Global Manufacturing recommends the product for public take-back programs operated by the law enforcement agency, and also for illicit drug disposal. This disposal recommendation conflicts with the DEA’s Rule governing medicine take-back programs operated by law enforcement and DEA authorized collectors, which requires use of a secure collection receptacle meeting specific requirements and requires non-retrievable destruction of collected medicines. DEA has stated that carbon products do not render drugs non-retrievable and that it is not reviewing or approving such products.

⁵⁵ RxDestroyer. Test Data. Appendix A. http://www.rxdestroyer.com/wp-content/uploads/5-Dr.-Cooney-Activated-Carbon_Pharmaceuticals.pdf

Available Information on Resulting Waste

Chemical Analysis or Waste Determination of Disposal Product with Pharmaceuticals: Third party lab analysis of properties of carbon product. Not tested with pharmaceuticals.

Packaging: Manufacturer states bottle is manufacturer with “recyclable plastics”; however, the bottle is designed to be disposed in the solid waste system, not recycled. The Rx Destroyer LE website states “The bottle is biodegradable and any unused carbon solution will actually clean the landfill around it.”

More on Product Ingredients

The manufacturer provides a Safety Data Sheet (SDS) for Rx Destroyer and a separate sheet for the hardening agent.⁵⁶ Both of the SDS list 2-propenoic acid, homopolymer sodium salt (sodium acrylate) as a dangerous component that is a skin and eye irritant and a potential respiratory irritant. Sodium acrylate is an absorbent that polymerizes, used in products like baby diapers.

Product label has warnings: “Keep Away From Children”; “Do not ingest will produce vomiting.”; “May be harmful if swallowed”. “First Aid Eyes...”.

Where purchase?

RxDestroyer.com – sold in cases only

Walgreens –4 oz size available

Amazon.com

Distributed by McKesson, Cardinal Health, and other drug distributors, medical supply retailers, and pharmacies. See <http://www.rxdestroyer.com/where-to-buy/>.

⁵⁶ RxDestroyer. Safety Data Sheets. <http://www.rxdestroyer.com/wp-content/uploads/rx-destroyer-product-sds-2.pdf> and <http://www.rxdestroyer.com/wp-content/uploads/rx-destroyer-hardener-sds.pdf>

VI. End Notes

This report was researched and written by Community Environmental Health Strategies LLC with funding from the San Francisco Department of the Environment.

Information referenced and analyzed in this report was obtained from the online sources cited, including manufacturers' websites, product materials, and product labels, as of March 24, 2017. Direct quotations of excerpts of manufacturer's materials are provided to accurately communicate the manufacturer's description of their product.

Samples of the following products were purchased from Amazon.com in February 2017: Deterra (SP pouch); Drug Buster (16 oz.); Pill Catcher (pint); Pill Terminator (300 cc); Rx Destroyer (16 oz). A free sample of an Element MDS 17 oz. Ready Kit was obtained from Medline Industries, Inc. Product samples of DisposeRx and Cactus Smart Sink were not obtained.

The image of the Cactus Smart Sink was used with permission of Cactus LLC. All other product images were photographed by Community Environmental Health Strategies LLC.

The author welcomes identification of additional pertinent information, analysis, and resources on products designed for disposal of waste pharmaceuticals.

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