



MEDICINE DISPOSAL PRODUCTS

an overview of products &
performance questions

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Executive Summary

Secure disposal of leftover and expired medicines is a key prevention strategy in reducing misuse and diversion of medicines to combat drug abuse and prevent overdoses. Safe disposal of medicines also helps prevent accidental ingestion by children, seniors, and pets. Proper disposal of the significant amounts of leftover and expired pharmaceutical waste generated in our homes and healthcare system also 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 throughout the United States. It has also sparked a new market sector of products for in-home disposal of waste medicines intended to alter pharmaceuticals so that they are not available for abuse and are safe for trash disposal. Medicine disposal products are also marketed to hospitals, pharmacies, physician's offices, law enforcement, and other facilities as a treatment method to make pharmaceuticals safe for solid waste disposal or as a pre-treatment to prevent diversion prior to disposal at a permitted facility.

This report, which updates a version produced in April 2017, profiles ten medicine disposal products based on promotional materials, product labels, and product testing results available from the manufacturers. Eight products marketed to both consumers and the healthcare sector were reviewed: Deterra, DisposeRx, Drug Buster, Element MDS, NarcX, Pill Catcher, Pill Terminator, and Rx Destroyer (also sold as Narc Gone HD). Cactus Smart Sink and CsRx System were also reviewed as related products that are marketed for use solely by healthcare facilities, prior to final disposal by incineration at permitted facilities.

None of the medicine disposal products are approved by any federal agency; no federal agency endorses such products, and none appear to be actively evaluating these products at this time. For disposal of home-generated medicines, federal guidelines from the DEA, EPA, and FDA recommend secure medicine take-back programs as the best disposal option, and preferable to disposing of medicines in the household garbage. Marketing of the medicine disposal products focuses on trash disposal of medicines and does not fully explain these federal disposal guidelines. For healthcare facilities and other regulated generators of waste pharmaceuticals, appropriate use of medicine disposal products depends on the type of pharmaceutical waste treated, as well as applicable federal, tribal, state, and local disposal regulations. In many jurisdictions, regulated generators of pharmaceutical wastes are prohibited from disposing waste medicines in the solid waste system even with this pre-treatment by a medicine disposal product.

Verifying performance claims of these medicine disposal products is challenging because four manufacturers do not disclose any product testing and available testing for the other six products does not thoroughly examine key performance questions. Active ingredients are disclosed for only six of the ten products. Available test results do not convincingly demonstrate that any product meets the DEA's stringent non-retrievable standard for disposal of medicines that are controlled substances. The limited data available for several products shows that some of the tested drugs are not fully "treated" and can be extracted from the disposal product by simple washes with water at room temperature. Complete waste determinations have not been conducted to assess whether the product-drug mixtures are non-hazardous and thus appropriate for solid waste disposal. Overall, the product testing examined treatment of only a small number of pharmaceuticals. In almost all

cases the product was tested for treatment of a single drug at a time, rather than in a real-world scenario where a combination of different pharmaceuticals would be mixed with the product.

In hospitals and facilities that are regulated for management of controlled substances and pharmaceutical wastes, these products may be appropriate for deterring diversion of pharmaceutical wastage of controlled substances before final disposal at an appropriate permitted facility. For residents with no access to a medicine take-back program, in an area where trash disposal of pharmaceuticals is allowed by local authorities, these products could be used as alternatives to mixing medicines with dirt, kitty litter, or coffee grounds. By physically immobilizing most of the drugs, even reversibly, or making the drug mixture noxious, the products may make the medicines less appealing and make illicit access more difficult. However, most of the products are in liquid form after use, creating counterbalancing concerns about potential human exposure to dissolved pharmaceuticals as well as environmental releases if a bottle or pouch is spilled during use or when the container is crushed in a garbage compactor truck. 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 product testing information made available by manufacturers, including new information obtained for this updated version of our April 2017 report, provides some answers but still leaves many questions about the effectiveness, mode of action, and safety of the medicine disposal products. As concluded in our earlier report, additional independent laboratory analysis is needed to fully examine product performance and assess how well these treatments achieve stated goals of making pharmaceuticals non-retrievable, or inaccessible, and preventing environmental contamination. Product manufacturers should improve consumer safety warnings about avoiding dermal exposure, provide instructions for safe clean-up of spills, and align their use recommendations with federal agency guidelines that recommend trash disposal of medicines only when a medicine take-back program is not available. A new development is the increasing distribution of medicine disposal products for consumer use through major retail pharmacies. Formal review and regulation of these products at the federal level is needed now more than ever, while at the same time maintaining local authority for more stringent solid waste management regulations and policies.

Glossary of Abbreviations

API	Active pharmaceutical ingredient
DEA	United States Drug Enforcement Administration
EPA	United States Environmental Protection Agency
FDA	United States Food & Drug Administration
g	gram
GC-MS	Gas Chromatography Mass Spectrometry
HHW	Household hazardous waste
HPLC	High Performance Liquid Chromatography
L	liter
LC-MS	Liquid Chromatography Mass Spectrometry
mg	milligram
mL	milliliter
ng	nanogram
MSDS	Material safety data sheet (or safety data sheet)
OTC	Over-the-counter
RCRA	Resource Conservation and Recovery Act
TCLP	Toxicity Characteristic Leaching Procedure, EPA test method 1311
UV/Vis	Ultraviolet-visible spectroscopy
VOC	Volatile organic compound

I. Overview of Products and Questions Examined

This report reviews available information about ten medicine disposal products to help inform government agencies, healthcare facilities, consumers and others. The product manufacturers assert and believe that their products are appropriate and beneficial for use in medicine disposal. It is our intention to assist readers in making their own determinations about appropriate use of the products by presenting available information, examining key performance questions, and describing relevant regulatory and policy considerations. Further research needs and recommended actions for both manufacturers and governmental entities are suggested.

Eight of the products are marketed to consumers for home disposal of medicines: Deterra, DisposeRx, Drug Buster, Element MDS, NarcX, Pill Catcher, Pill Terminator, and Rx Destroyer (Table 1). Users are instructed to add unwanted medicines in pill or liquid form to a stated capacity in the product's bottle or pouch. Some of the products also state they can be used with other drug dosage forms, such as transdermal patches. Water needs to be added to some of the products, but several are provided in liquid form. The mixture is shaken and then disposed of in the household trash. Some of the products form a gel or solidify.

These eight products are also marketed for use by healthcare facilities, nursing homes, pharmacies, law enforcement, and other facilities for disposal of unused pharmaceutical inventory and wastage. Two other related products, the Cactus Smart Sink and CsRx System, were also reviewed although they are designed and marketed solely for use by healthcare facilities (Table 2). These two products have similar use directions and include other physical barriers to deter attempts at diversion of waste medicines. Unlike the other eight products, pharmaceuticals treated by the Cactus Smart Sink and the CsRx System are intended to be managed by a pharmaceutical waste service provider with final disposal by high temperature incineration.

A version of this report was first completed in April 2017 and it may have been the first effort to catalog and examine the products in what appears to be a growing market sector. In this 2019 update, two new products, NarcX and CsRx System, were also reviewed and product testing summaries were expanded for a number of the products. Information from each manufacturer's website, promotional materials, and product labels was reviewed, as of February 2019. Additional information about product ingredients and potential mechanisms of action was obtained through searches of research literature and patents. For this updated version, the author also contacted each of the ten manufacturers to request additional information, including any additional testing to demonstrate product performance. Six manufacturers responded, and, in several cases, the additional information provided helped clarify testing methodology, including whether the product was tested after treatment of medicines and what pharmaceuticals were tested.

Tables 1 and 2 in this section lists key features of the ten medicine disposal products for comparison. Figure 1 provides a big picture outline of the product performance questions examined in this report.

TABLE 1: MEDICINE DISPOSAL PRODUCTS MARKETED TO CONSUMERS, HEALTHCARE FACILITIES, AND OTHERS

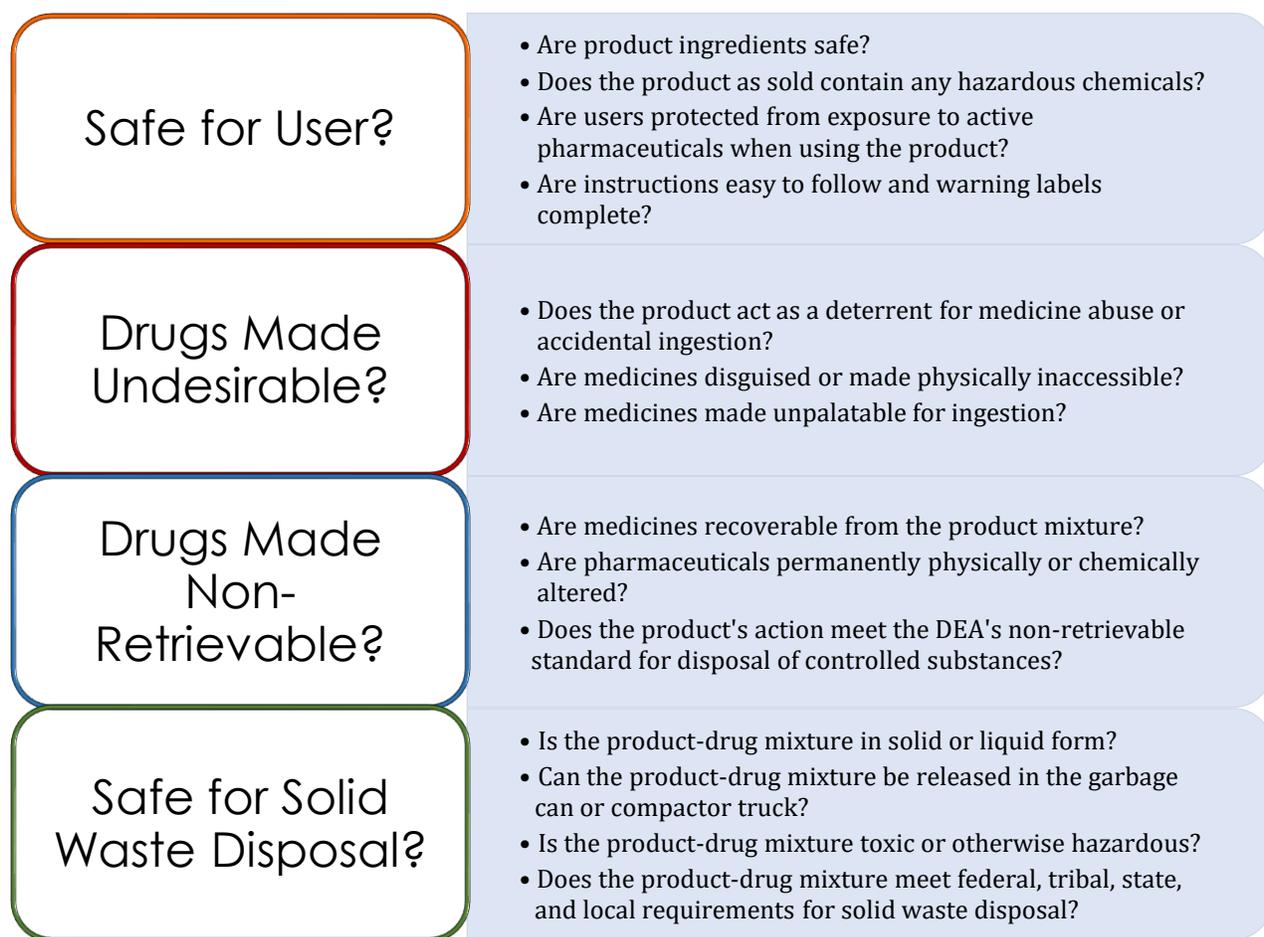
Product	Active Ingredient & Mode of Action	Final Disposal Method & Product Form	List Price as of February 2019
Deterra*	Activated carbon Physical adsorption of drugs to carbon	Garbage / Solid waste Liquid slurry in pouch with ziplock closure	\$4.99 SP / 15 pills \$6.99 LP / 90 pills Also in larger sizes
DisposeRx	“Cross-linking polymer” Sequesters drugs in viscous gel.	Garbage / Solid waste Gel or solid in prescription medicine vial	\$9.85 - 6 packets / ~25 pills per packet \$127.04 - 100 packets Also in other sizes
Drug Buster*	Activated carbon Adsorption of drugs to carbon	Garbage / Solid waste per local regulations Liquid slurry in plastic bottle with childproof cap	\$9.95 4 oz / 50 pills \$15.99 16 oz / 300 pills \$34.99 64 oz / 1500 pills
Element MDS	“Organic plant-based powder” Makes drugs undesirable	Garbage / Solid waste system Liquid or gel in plastic bottle with screw cap	\$8.99 17 oz / 500 pills \$349.50 for 50 17 oz kits
NarcX	Activated carbon and undisclosed ingredients Adsorption of drugs to carbon; unknown	Garbage / Solid waste Liquid slurry in plastic bottle with childproof cap	\$9.99 16 oz / 100 pills \$18.99 32 oz / 250 pills Also in larger sizes
Pill Catcher	Bentonite clay Adsorption and/or absorption of drugs to clay	Garbage / Solid waste Liquid slurry in plastic bottle with screw cap	\$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, adsorption and/or absorption of drugs	Garbage / Solid waste Gel or solid in plastic bottle with child resistant cap	\$ 9.95 300 mL / 300 pills. \$24.95 gallon size
Rx Destroyer* (also sold as Narc Gone HD)	Activated carbon, undisclosed ingredients Adsorption of drugs to carbon	Garbage / Solid waste, or incineration per federal, state, local regulations Liquid slurry, or solid gel if hardener used, in plastic bottle with childproof cap	\$6.29 - 4 oz. / 50 pills \$108.95 case of 12 16 oz / 300 pills Also in larger sizes & 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.

TABLE 2: MEDICINE DISPOSAL PRODUCTS MARKETED SOLELY TO HEALTHCARE FACILITIES

Product	Active Ingredient & Mode of Action	Final Disposal Method	Pricing
Cactus Smart Sink	<p>“Proprietary mixture of denaturants and deterrents” in cartridge in locking unit</p> <p>Unknown; ingredients not identified</p>	<p>Dispose per federal and state guidelines depending on medicines</p> <p>Medical waste hauler recommended</p>	Contact Stryker for price quote
CsRx System	<p>Unidentified denaturing agent-deterrent and solidifying agent in bottle in locking unit</p> <p>Unknown; ingredients not identified</p>	<p>Incineration</p> <p>System includes prepaid shipping to a permitted Stericycle facility</p>	Flat monthly fee service; Contact Stericycle for price quote

Figure 1: Key Performance Questions for Medicine Disposal Products



II. Medicine Disposal Background

A. Medicine Disposal Guidelines and Regulations

Marketing materials and technical descriptions for the ten medicine disposal products reviewed make broad statements about compliance with federal pharmaceutical disposal guidelines and regulations. A consumer could 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 a federal government agency.

Examples of product claims include:

“Exceeds Federal Drug Disposal Guidelines”

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

“Complies with non-retrievable DEA standards”

“Passes all EPA tests”

“DEA and EPA compliant”

Federal agencies have not reviewed, evaluated, endorsed, or certified any medicine disposal products for home use or for healthcare facility use. 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.

In fact, the EPA and the Food & Drug Administration (FDA) have policies against approving or endorsing companies or commercial products.^{1,2} The DEA has also stated in official documents, as well as 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.’ ”³

What regulations, guidelines, or standards apply to medicine disposal products? It is a tale of two regulatory contexts for disposal of pharmaceutical waste: home generated wastes and healthcare generated wastes. The regulatory requirements and guidelines for disposal of waste medicines depend on who is generating the waste as much as the particular properties and hazards of the pharmaceutical waste. Waste medicines from a residential source are regulated differently

The DEA, FDA, and EPA have not reviewed or approved any medicine disposal products and do not have any performance standards specifically for such products.

¹ U.S. FDA website. “Is it Really “FDA Approved?”

<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm047470.htm>

² 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>

³ Department of Justice. Drug Enforcement Administration. Disposal of Controlled Substances; Final Rule. Federal Register 79 (174) September 2014. “Non-Retrievable Destruction Standard”, page 53547-8.

https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf

from the same medicines from a healthcare or business source, such as a hospital, pharmacy, long-term care facility, reverse distributor, or a practitioner.^{4,5}

Key federal regulations that apply to disposal of waste pharmaceuticals are the requirements of the DEA and the EPA. The DEA regulates management of prescription drugs that are controlled substances, such as prescription opioids and certain addictive stimulants.⁶ The EPA regulates management of hazardous waste pharmaceuticals under the Resource Conservation and Recovery Act (RCRA).⁷ The regulations of the DEA and the EPA apply to management of waste medicines from healthcare and other facilities, but residents and household wastes are exempt from the federal regulations. However, the DEA, FDA, and EPA do recommend disposal options for household medicines.

State governments also regulate pharmaceutical waste management and may have additional requirements for how pharmaceuticals are disposed by the healthcare sector and by residents. Local governments, responsible for solid waste collection systems and landfills, may also have ordinances or policies about what materials can or cannot go into the solid waste system.

Because of the two different regulatory contexts, the regulations that apply to medicine disposal products depend on who is using the product. When used for medicine disposal by a regulated healthcare entity, federal regulations of the DEA, EPA and other agencies apply. State and local regulations also apply and may be more stringent than federal requirements. Allowable disposal methods for regulated entities will also depend on whether the medicine disposal product is used to treat pharmaceuticals that are hazardous or non-hazardous. 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 resulting product-drug mixture as hazardous or non-hazardous is needed, and may be required, to determine the associated waste management requirements for regulated generators.

When used at home by residents, these medicine disposal products appear to fall into a federal regulatory gap. Federal regulatory requirements of the EPA and the DEA do not apply due to exemptions for household wastes and for disposal of controlled substances by patients. The products are marketed for medicine disposal, but are not considered drugs or devices, so the FDA has not reviewed or regulated them. The Consumer Product Safety Commission and the Federal Trade Commission have authority to regulate product safety, labeling, child-safe packaging, and marketing claims, but to our knowledge to date have not reviewed any medicine disposal products.

Most states recognize the federal exemption for household-generated wastes, although some states do not. However, state-level agencies do not appear to be actively regulating consumer use or disposal of medicine disposal products at this time. Some local jurisdictions have waste acceptance regulations or policies that apply to the disposal of household-generated medicines, such as policies

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>

⁶ Title 21 – Food and Drugs. Code of Federal Regulations, Chapter 11, Part 1300-END. <https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>

⁷ U.S. EPA. “Summary of the Resource Conservation and Recovery Act” <https://www.epa.gov/laws-regulations/summary-resource-conservation-and-recovery-act>

excluding pharmaceutical wastes specifically from the solid waste system or excluding liquid wastes or HHW generally. However, it is also not clear that local governments have the authority to apply these regulations or policies to restrict sales or use of the medicine disposal products within their jurisdictions.

Several of the medicine disposal product manufacturers caution in product instructions about complying with regulatory requirements but leave it up to the user to sort it out. Key relevant regulations and guidelines are overviewed in this background section. First the DEA's non-retrievable standard for disposal of controlled substances is summarized because that standard is central to many of the claims of the product manufacturers. Next disposal of medicines by households is described, with an emphasis on the recommended guidelines of the DEA, FDA, and EPA. Finally, disposal of waste pharmaceuticals by the healthcare sector and other regulated generators is overviewed, although those regulatory requirements are too complex to cover in detail. State and local regulations are also relevant, and some examples are provided to demonstrate the importance of considering differences in waste disposal regulations across the country.

B. DEA's non-retrievable standard for controlled substances

A key stated purpose of all the medicine disposal products is to prevent drug diversion and misuse. Marketing materials for most of the medicine disposal products assert that medicines will be “non-retrievable” after treatment, and some reference compliance with DEA guidelines or the ability to meet the DEA's non-retrievable standard.

Legally prescribed pharmaceuticals that are controlled substances are carefully regulated by the DEA under the federal Controlled Substances Act, as well as by state laws, due to their high potential for misuse and addiction. The DEA's list of Schedule II through V controlled substances are legally prescribed drugs like opioid painkillers, stimulants, anti-anxiety medicines, and anti-depressants. Illicit drugs like heroin, cocaine, and methamphetamine, as well as marijuana at the federal level, are Schedule I drugs. DEA requires that any of its registrants that are authorized to handle controlled substances, including pharmacies or hospitals, follow security procedures to prevent drug diversion, including disposal by a method that makes the controlled substance non-retrievable.

The DEA's Final Rule on Disposal of Controlled Substances⁸ defines a “non-retrievable” standard for destruction of controlled substances by DEA registrants, including authorized collectors providing take-back of residential medicines:

“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

⁸ DEA Final Rule on Disposal of Controlled Substances. Full citation in footnote 3. See “Non-Retrievable Destruction Standard”, page 53547-8; and “Non-retrievable” definition, page 53560.

render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.”

In addition, the DEA Rule states that all methods of controlled substance destruction must comply with applicable federal, state, tribal, and local regulations.

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 pharmaceutical ingredient (API) or analogue can be retrieved. Some aspects of the standard are not detailed, however, such as what “for all practical purposes” means. The DEA clearly states that incineration and chemical digestion are examples of current technologies that achieve the non-retrievable standard, and that sewer or trash disposal do 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

Patients disposing of medicines at home are not subject to the DEA Rule’s disposal requirements. 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.” Those agency guidelines recommend using a secure medicine take-back program as the best medicine disposal option and are further described in Section II.C.

Federal agencies recommend secure medicine take-back programs as the best medicine disposal option, preferable to trash disposal.

The DEA and other federal agencies are aware that companies are marketing disposal products, and that some are making claims related to non-retrievability. At this time the DEA has not reviewed any of these disposal products, and its Rule documentation states that DEA does not plan to “evaluate, review, or approve the processes or methods utilized to render a controlled substance non-retrievable, as long as the desired result is achieved.”⁹ Section III. E. provides a summary of whether available analytical testing demonstrates that any of the medicine disposal products meet the DEA’s non-retrievable standard.

C. Disposal of waste pharmaceuticals from households

Home-generated medicine wastes and other household hazardous wastes (HHW) are exempt from the EPA’s RCRA regulations. The DEA’s non-retrievable disposal standard also does not apply to patients and family members when they dispose of medicines prescribed to them that are controlled substances. However, the DEA, FDA, and EPA, do have medicine disposal guidelines with recommended disposal options for consumers. States and local governments may also have regulations or guidelines for disposal of household medicines.

Federal agency guidelines. The DEA, FDA, and EPA each define a disposal option hierarchy that encourages residents to use a secure medicine take-back program as the best or first option for disposal of unwanted household medicines. Because medicine take-back programs are not yet

⁹ DEA Final Rule on Disposal of Controlled Substances. Full citation in footnote 3. See page 53547, column 3, Issue 1.

available in every community, federal agencies provide alternative disposal options for residents. Disposal of medicines in the trash is suggested only in situations when residents cannot reasonably access a take-back program. For a small list of very dangerous medicines, the FDA recommends flushing, but only if a medicine take-back program is not readily available. Although there is no single federal guidance for household medicine disposal, the wording of the DEA, FDA, and EPA guidelines have become quite well aligned in recent years (Table 3).

A recently released “Drug Disposal Options” infographic¹⁰ from the FDA illustrates the disposal hierarchy recommended by all three federal agencies, asking first if a drug take-back option is available.

Drug Disposal Options
Do you have medicine you want to get rid of?

I need to get rid of this medication.

Do you have a drug take-back option readily available?
Check the **DEA website**, as well as your local drugstore and police station for possible options.

NO

YES

Is it on the FDA flush list?

NO
Follow the FDA instructions for disposing of medicine in the household trash.

YES
Immediately flush your medicine in the toilet.
Scratch out all personal info on the bottle and recycle/throw it away.

Take your medicine to a drug take-back location.
Do this promptly for **FDA flush list** drugs!

www.fda.gov

¹⁰ FDA Drug Disposal Options Infographic available from “Disposal of Unused Medicines: What You Should Know” webpage:
<https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm>

TABLE 3. HOUSEHOLD MEDICINE DISPOSAL GUIDELINES FROM FEDERAL AGENCIES

Drug Enforcement Administration (DEA)

https://www.deadiversion.usdoj.gov/drug_disposal/ and takebackday.dea.gov

The DEA promotes twice-a-year National Prescription Drug Take-Back events and using authorized collectors, e.g. pharmacies and hospitals, with ongoing medicine take-back programs.

[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 webpage links to the medicine disposal guidelines of the FDA and the EPA.

Food & Drug Administration (FDA)

<https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicines/safedisposalofmedicines/ucm186187.htm>

The FDA's "Disposal of Unused Medicines: What You Should Know" guideline states:

"Medicine take-back options are the preferred way to safely dispose of most types of unneeded medicines. There are generally two kinds of take-back options: periodic events and permanent collection sites."

The guideline also describes disposal options.

Your best choices for disposal of unused or expired medicines are:

Medicine take-back options,

Disposal in the household trash and

Flushing certain potentially dangerous medicines in the toilet

The section on disposal in the household trash begins with "If no take-back programs or DEA-registered collectors are available in your area, and there are no specific disposal instructions in the product package insert, such as flushing described below, you can also follow these simple steps to dispose of most medicines in the household trash..."

The section on flushing certain potentially dangerous medicines begins with "A small number of medicines have specific instructions to immediately flush down the toilet when no longer needed and a take-back option is not readily available."

Environmental Protection Agency (EPA)

<https://www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines>

EPA's webpage on "What to do with Unwanted or Expired Medicines" states:

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.

As a second choice, the public can utilize EPA's guidelines for household disposal of medicines ([PDF](#)). This 2011 handout lists "1st Choice: Drug Take-Back Events", but also provides instructions for trash disposal after disguising medicines with kitty litter or coffee grounds and putting the mixture into a container or a sealable bag.

FDA's flush list. The FDA recommends flushing rather than trash disposal for a specific list of especially dangerous medicines only if no take-back program is readily available. The FDA "flush list" consists of 13 API, sold under 48 brand names, including products containing oxycodone, buprenorphine, and fentanyl.¹¹ The FDA specifically recommends flushing for immediate disposal of used fentanyl patches (brand name Duragesic) due to the potential exposure risk for children if used patches are disposed in the household trash.¹²

The FDA's website and materials on medicine disposal are not entirely consistent between older¹³ and newer materials in prioritizing take-back programs over flushing of medicines on the "flush list". The FDA's recent update to its main webpage, "Disposal of Unused Medicines: What You Should Know", and its new infographic make this hierarchy more understandable.

It is important to note that the FDA's medicine "flush list" is not aligned with the disposal regulations or recommendations 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 stated¹⁴:

"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."

Trash disposal. The steps recommended for trash disposal of medicines by each federal agency are similar and attempt to address concerns that trash cans are not secure at the curb for disposal of frequently abused medicines like opioids. The agencies recommend disguising the medicines: drugs in pill form should be removed from their original containers, mixed with an undesirable substance, such as dirt, kitty litter or coffee grounds, placed into a disposable container with a lid or a sealable bag, then placed in the trash. The guidelines do not recommend adding liquid, so the resulting mixture is in solid form and not in a recognizable pill bottle.

The DEA's 2018 handout "How To Properly Dispose of Your Unused Medicines" does not describe how to locate and use medicine take-back programs in detail, which is potentially confusing. The handout states "If no disposal instructions are given on the prescription drug labeling and no prescription drug take-back program is available in your area, then follow these simple steps to throw the drugs in the household trash...", then describes mixing medicines with coffee grounds or

¹¹ U.S. FDA "List of medicine recommended for disposal by flushing" Updated April 2018. <https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM588196.pdf>

¹² FDA Consumer Update. April 2012, Updated Sept. 2013. "Fentanyl Patch Can Be Deadly to Children" <https://www.fda.gov/forconsumers/consumerupdates/ucm300803.htm>

¹³ An October 2017 "Where and how to dispose of medicines" Consumer Update on FDA's website is an out-of-date example: <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm>

¹⁴ National Stewardship Action Council. See section on "End U.S. Food and Drug Administration (FDA) Medicine "Flush List"" at <https://www.nsaction.us/>

kitty litter and disposing in a sealable bag or container in the household garbage.

Regulation of Medicine Take-Back Programs. Secure medicine take-back programs have become more accessible in most states since the release of the DEA's 2014 Rule for Disposal of Controlled Substances. The DEA Rule authorized new options for secure take-back programs to implement the federal Secure and Responsible Drug Disposal Act of 2010. Prior to this Rule, leftover prescription drugs that are controlled substances could only be legally collected from residents by law enforcement, primarily through collection events or drop-off programs. The 2014 Rule defined secure protocols for collecting 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, drug distributors, and reverse distributors.

Disposal of medicines collected through medicine take-back programs is specifically regulated by the DEA and the EPA, as well as other applicable federal, state, and local regulations. The DEA Rule requires "non-retrievable" destruction of all collected medicines in accordance with federal, tribal, state, and local laws and regulations¹⁵ (see also Section II.B. on the non-retrievable standard). The EPA's 2019 hazardous waste pharmaceuticals rule also defines medicine disposal methods for all pharmaceuticals collected through take-back programs operated by DEA-authorized collectors.

The EPA initially recommended appropriate disposal facilities for residential medicine take-back programs in a 2012 guidance¹⁶, and has now formalized requirements for disposal of medicines by DEA-authorized collectors in its final rule for management of hazardous waste pharmaceuticals.¹⁷ Under the EPA's new 2019 rule, home-generated medicines collected by a DEA-authorized collector's take-back program are conditionally exempt from EPA regulation as a RCRA hazardous waste if they are properly disposed by: (1) combustion at specific types of permitted high temperature incineration facilities or (2) another method that is formally approved by the DEA as meeting the non-retrievable standard. Medicine take-back programs operated by law enforcement are not regulated under the EPA rule; however, a 2018 EPA guidance also recommends that law enforcement use the same types of permitted incinerators, as well as smaller municipal waste combustors.¹⁸ Certain aspects of the EPA rule take effect federally in August 2019, but in 48 states (Iowa and Alaska are the exceptions) most elements of the rule will not go into effect until those RCRA authorized states adopt the rule.

¹⁵ DEA Final Rule on Disposal of Controlled Substances. Full citation in footnote 3. See part § 1317.90(a).

¹⁶ 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://rcrapublic.epa.gov/rcraonline/>, search for RCRA Online Number 14833.

¹⁷ U.S. EPA. December 2018. "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine". <https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>

¹⁸ U.S. EPA Memorandum from Barnes Johnson, Director of the Office of Resource Conservation and Recovery to RCRA Division Directors. September 11, 2018. "Management of Household Pharmaceuticals Collected by Law Enforcement During Take-Back Events and Programs." <https://www.epa.gov/hwgenerators/management-household-pharmaceuticals-collected-law-enforcement-during-take-back-events>

Product marketing largely overlooks medicine take-back programs. 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 as the best or preferred medicine disposal option. Marketing materials skip over that portion of the federal agency guidelines and only describe how to dispose of medicines in the household trash, as if that is the only recommendation. Because of that omission, none of the products for home use are well aligned with federal agency guidelines for medicine disposal.

For the most part, the websites and other promotional materials for the consumer-marketed products do not mention secure medicine take-back programs. A few of the websites contain negative statements about medicine take-back programs, leaving the impression that take-back programs are unavailable or inaccessible. Such statements are out-of-date since the DEA's 2014 Rule removed barriers to collecting controlled substances. Many communities across the country now have pharmacy, clinic, or hospital-based take-back programs that accept prescription drugs that are controlled substances along with other medicines.¹⁹ These programs are becoming more commonly available through voluntary programs, such as those operated by major drug store chains²⁰, and through legislative mandates that are creating statewide medicine take-back systems. 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. Many law enforcement agencies continue to operate secure medicine drop boxes, and partner with the DEA on the National Take-back Initiative²¹, holding twice-a-year National Prescription Drug Take-Back Days in the spring and fall.

State and local regulations and policies for household medicine disposal. Although all household wastes generated by residents in their homes are exempt from federal hazardous waste management requirements²², RCRA allows states and municipalities to adopt regulations that are more stringent or broader-in-scope.²³ 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. These laws may be specific for pharmaceuticals or may generally prohibit disposal of HHW and other dangerous or special wastes in the trash or sewer.

A few examples of state and local regulations and codes that are more stringent than federal regulations are:

- California does not recognize the household exemption from RCRA and requires that household hazardous wastes are managed according to California's state rules for

¹⁹ DEA online locator tool for authorized collectors, such as pharmacies, that have amended their DEA registration to operate a medicine drop box, takebackday.dea.gov/#collection-locator

²⁰ Nationwide pharmacy chains that provide medicine drop-off bins in some or all of their stores include CVS www.cvs.com/content/safer-communities-locate, Walgreens www.walgreens.com/topic/pharmacy/safe-medication-disposal.jsp, and Rite Aid www.businesswire.com/news/home/20180601005382/en/Rite-Aid-Announces-New-In-Store-Safe-Medication

²¹ DEA National Prescription Drug Take-Back Day website: takebackday.dea.gov

²² See 40 CFR 261.4(b)(1) and U.S. EPA's website "Household Hazardous Waste" <https://www.epa.gov/hw/household-hazardous-waste-hhw>

²³ U.S. EPA website "State Authorization under the Resource Conservation and Recovery Act (RCRA)" <https://www.epa.gov/rcra/state-authorization-under-resource-conservation-and-recovery-act-rcra>

hazardous waste. In California, all HHW has been banned from the household trash.²⁴

- Kitsap County and Skagit County in Washington State prohibit disposal of moderate risk wastes, the state's term for HHW, in the solid waste system or sewer system.²⁵
- Snohomish County, WA prohibits disposal of pharmaceutical wastes in the solid waste system.²⁶
- Municipal solid waste programs also commonly do not accept liquid wastes, which is the final form after use for several of the medicine disposal products reviewed.

Rather than a specific law or regulation, other state and municipalities may have policies to encourage management of HHW, also called "special wastes" or "diverted wastes", separately from household trash because of toxicity or other characteristics. Municipalities may provide HHW drop-off facilities and promote take-back programs that can provide environmentally preferable disposal. Household pharmaceutical wastes have been particularly challenging because of diversion concerns and because municipal HHW programs cannot obtain DEA approval to collect controlled substances. In many communities, local agencies responsible for health, solid waste, and wastewater have partnered with law enforcement to provide secure medicine take-back events and ongoing drop boxes, and also encourage pharmacies and hospitals to host drop boxes. Federal, state, and local government promotion of medicine take-back programs as the preferred disposal method for residents is contradicted by the marketing efforts of the companies promoting their medicine disposal products.

D. Disposal of waste pharmaceuticals by the healthcare sector and other regulated generators

Regulated generators, i.e. non-household sources such as hospitals, medical centers, doctor's and dentists' offices, nursing homes, pharmacies, and other business entities, must manage and dispose of pharmaceutical wastes according to all federal, state, and local regulations. The DEA's regulations for controlled substances and the EPA's regulations for hazardous waste pharmaceuticals are key federal regulations for proper management of pharmaceutical wastes, although many other regulations also apply. Pharmaceutical disposal methods may also be restricted in additional ways by state and local regulations.

Controlled substances. Under federal regulations, healthcare facilities and other regulated generators cannot dispose of any unused pharmaceutical inventory that is a controlled substance in the solid waste system or down the sewer. The DEA requires compliance with a non-retrievable destruction standard for final disposal of controlled substances by DEA registrants, and has stated

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

²⁴ CalRecycle <https://www.calrecycle.ca.gov/HomeHazWaste> and California Department of Toxic Substances Control <https://www.dtsc.ca.gov/HazardousWaste/UniversalWaste/HHW.cfm>

²⁵ Kitsap County Board of Health, Solid Waste Regulations, Section 305(6)(d)(i): <https://www.kitsappublichealth.org/environment/files/regulations/swregs.pdf>; and Skagit County Code 12.16.210: <https://www.codepublishing.com/WA/SkagitCounty/#!/SkagitCounty12/SkagitCounty1216.html>

²⁶ Snohomish County Code 7.41.050 Types of wastes that are unacceptable. <https://snohomish.county.codes/SCC/7.41.050>

that landfill disposal and sewerage does not meet the non-retrievable standard (see Section II.B.). Waste pharmaceuticals that are controlled substances are currently destroyed through high temperature incineration at permitted facilities. Healthcare facilities typically contract with reverse distributors or pharmaceutical waste services that are DEA-authorized to provide final destruction of controlled drugs.

DEA's standard for non-retrievable destruction applies to unused pharmaceutical inventory but does not apply to pharmaceutical wastage.²⁷ 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. Preventing diversion of these residual amounts of controlled substance drugs is a key goal in the healthcare setting. In the past, it was common practice to put pharmaceutical wastage down a sink or drain for disposal, but alternative disposal methods are now being sought to protect water quality. Although the DEA allows sewerage of pharmaceutical wastage, the EPA's final rule for managing hazardous waste pharmaceuticals prohibits sewerage of any controlled substances that are also hazardous pharmaceuticals.

Hazardous waste pharmaceuticals. Healthcare facilities must follow EPA regulations for managing and disposing of hazardous waste pharmaceuticals.²⁸ The EPA issued a new rule for management of hazardous waste pharmaceuticals in December 2018 after many years of work to streamline requirements and facilitate compliance in the healthcare sector. Because it is challenging for healthcare staff to distinguish which pharmaceuticals are hazardous and which are not²⁹, the rule encourages and facilitates the management of all pharmaceutical wastes as hazardous waste to better protect human health and the environment. The new rule, formally published in February 2019, has many impacts on how reverse distributors and healthcare facilities, including pharmacies, dispose of pharmaceuticals. This subsection touches on issues pertinent to evaluating use of medicine disposal products.

Under EPA's 2019 rule, all healthcare facilities and reverse distributors will be prohibited from disposing of any hazardous waste pharmaceutical, including pharmaceutical wastage, in the sewer beginning in August 2019. Prescription hazardous waste pharmaceuticals must be sent to a reverse distributor for return credit or disposed at a hazardous waste facility. Over-the-counter (OTC) hazardous waste pharmaceuticals can be returned to a reverse logistics center if they are a potentially reusable product, and otherwise must be disposed at a hazardous waste disposal facility. Hazardous waste pharmaceuticals must be properly treated at the hazardous waste disposal facility, and typically are incinerated. Hazardous waste pharmaceuticals cannot be put into a solid waste landfill by healthcare facilities, with an exception for very small quantity generators (VSQGs) such as long-term care facilities with twenty or fewer beds.³⁰ The new rule's management standards are the same across the regulated healthcare sector and, with the exception of VSQGs, do not depend on the total amount of hazardous waste generated by a facility each month.

²⁷ U.S. DEA letter to practitioners regarding disposal of pharmaceutical wastage. October 17, 2014. <https://www.dea.gov/division-5/office-of-legal-counsel/press-releases/2014/10/17/2014-10-17-dea-letter-to-practitioners-regarding-disposal-of-pharmaceutical-wastage>

²⁸ EPA Final Rule on Hazardous Waste Pharmaceuticals. Full citation in footnote 17.

²⁹ Healthcare Environmental Resource Center. Pharmaceuticals – Hazardous Waste page, <https://www.hercenter.org/hazmat/pharma.php>

³⁰ EPA Final Rule on Hazardous Waste Pharmaceuticals. Full citation in footnote 17. See page 5876 on “Land Disposal Restrictions for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals”.

Most pharmaceuticals are not regulated as RCRA hazardous wastes, even though some are known to possess hazardous waste-like qualities. For many years, the EPA has encouraged disposal of non-RCRA pharmaceuticals according to the best management practices in its 2008 Blueprint guidance document for healthcare facilities.³¹ That EPA guidance recommends that non-RCRA pharmaceuticals with known hazardous properties are destroyed at hazardous waste incinerators and other pharmaceuticals are combusted at municipal solid waste or medical waste incinerators. The EPA discourages landfill disposal of all pharmaceuticals from regulated generators.³²

A 2012 review by the EPA's Office of Inspector General³³ found that the EPA has not fully reviewed the characteristics of all pharmaceuticals on the market since 1980, therefore its list of hazardous waste pharmaceuticals is incomplete. The Inspector General's review found there may be more than one hundred pharmaceuticals that meet the RCRA criteria for acute hazardous waste but are not currently regulated as such. Pharmaceuticals can be considered hazardous wastes if they meet the federal RCRA definitions of ignitability, corrosivity, reactivity, or toxicity (called "characteristic hazardous wastes").³⁴ Examples include warfarin (coumadin), topical solutions of erythromycin or hydrocortisone, epinephrine in EpiPens, and many chemotherapy drugs. Other unused pharmaceuticals are hazardous wastes because they contain specific hazardous chemicals listed on RCRA's P list or U list. All pharmaceuticals have biological activity, but most have not been fully assessed for ecotoxicity. The environmental impacts of pharmaceutical mixtures are even less well understood.³⁵

There are a small handful of RCRA hazardous waste pharmaceuticals that are also controlled substances regulated by the DEA. These drugs are: chloral hydrate, fentanyl sublingual spray (Subsys), phenobarbital, testosterone gels, and injectable/gel valium (Diazepam). The EPA's new rule provides a conditional exemption from RCRA regulation for these hazardous pharmaceuticals so long as the DEA's regulations are followed and appropriate disposal methods are used.³⁶ DEA requires non-retrievable destruction for unused controlled substances, therefore these pharmaceuticals cannot be disposed of in the trash or the sewer. The EPA's conditional exemption applies if these hazardous controlled drugs are destroyed by:

- (1) a method DEA has defined in writing as meeting the non-retrievable standard, or
- (2) incinerated at any of five types of permitted high temperature incineration facilities.

The 2019 EPA hazardous waste pharmaceuticals rule takes effect federally in August 2019, but in the 48 states authorized by EPA to implement RCRA (Iowa and Alaska are the exceptions), the rule will not go into effect until those states complete an adoption process. States must adopt all part of the new rule (codified as Subpart P in Title 40 CFR Part 266) that are more stringent than existing

³¹ U.S. EPA August 2008. "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States" <https://www.hercenter.org/hazmat/tenstepblueprint.pdf>

³² EPA Final Rule on Hazardous Waste Pharmaceuticals. Full citation in footnote 17. See page 5840.

³³ 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>

³⁴ U.S. EPA. Defining Hazardous Wastes: Listed, Characteristic, and Mixed Radiological Wastes. <https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes>

³⁵ BIO Intelligence Service (2013), "Study on the environmental risks of medicinal products", Final Report prepared for Executive Agency for Health and Consumers (European Union). https://ec.europa.eu/health/sites/health/files/files/environment/study_environment.pdf

³⁶ EPA Final Rule on Hazardous Waste Pharmaceuticals. Full citation in footnote 17. See Section 266.506.

state regulations by July 1, 2022. RCRA Authorized states can also retain or create regulations that are even more stringent than the new EPA rule. The sewer ban portion of the rule takes effect nationwide in August 2019 and state adoption is not required.

Currently, state regulations for pharmaceutical waste management by regulated generators may already be different from federal regulations. Under RCRA, states may adopt regulations that are more stringent than the federal regulations, or broader in scope. States may designate additional pharmaceuticals as hazardous wastes, or prohibit landfill disposal of any types of pharmaceuticals by regulated generators.³⁷ For example, the California Medical Waste Management Act requires that regulated generators use incineration as the disposal method for non-RCRA pharmaceuticals that are not regulated under the EPA rule.³⁸ Local jurisdictions may also have more stringent disposal requirements for what materials are accepted or excluded from their solid waste and sewer systems.

Waste determination test methods. The EPA, state agencies, and perhaps even some local agencies, have defined specific waste determination or waste designation assays used to define the properties of a waste material and determine appropriate waste management. The EPA has approved hundreds of analytical methods for sampling and analyzing wastes to make a hazardous waste determination. The standard analytical method for determining whether a solid waste is a hazardous waste and therefore inappropriate for landfill disposal is called the Toxicity Characteristic Leaching Procedure, or TCLP. States may define additional tests to determine whether the toxicity of a waste material is within regulatory limits, such as California's Fathead Minnow Bioassay which is key to aquatic toxicity determinations. Several of these assays are further described in Section III.F. on Environmental Performance in the context of product testing conducted by some of the product manufacturers.

Considerations for use of medicine disposal products by healthcare and other regulated generators. Manufacturers are marketing the medicine disposal products to hospitals, doctor's offices, long-term care facilities, veterinary clinics, other healthcare facilities, and law enforcement for disposal of pharmaceutical wastes. These entities should review all applicable regulations prior to using a medicine disposal product and disposing of it in the solid waste system. Several of the products do include statements that the used product must be managed according to federal, state, and local regulations and guidelines depending on the types of medicine disposed.

Cactus Smart Sink and CsRx System are products targeted solely for healthcare sector use, rather than consumer use. Both are designed for management of unused controlled substances in healthcare facilities, including pharmaceutical wastage, in a manner that prevents diversion prior to transport for final disposal. Cactus Smart Sink recommends final disposal of the product-drug mixture through a pharmaceutical waste management company and discourages disposal in the solid waste system. CsRx System is marketed by Stericycle with a prepaid mail-back service to transport filled containers to permitted incinerators.

Several of the medicine disposal products include warnings on their product labels and websites to use only on non-hazardous medicines but leave it to the user to work out which medicines are

³⁷ 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>

³⁸ California Department of Public Health. Medical Waste Management webpage:
<https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/MedicalWaste.aspx>

hazardous and what disposal requirements apply. (See more about the medicine “exclusions” for specific medicine disposal products in Section III.D.) If any individual medicine added to the disposal product designates as a federal hazardous waste, then all of the resulting product-drug mixture must be managed as hazardous waste, according to EPA’s mixture rule. Similarly, if any of the unused medicines added to the disposal product are controlled substances, the DEA’s regulatory requirements and non-retrievable destruction standard applies. As described in Section II.B., the DEA has not reviewed or approved any of the medicine disposal products as achieving its non-retrievable standard and has specifically stated that landfill disposal does not achieve the non-retrievable standard.

Waste management regulations vary across the nation, but many jurisdictions do not allow hospitals or other regulated generators to dispose of pharmaceuticals in the landfill, even after treatment by a medicine disposal product. In some jurisdictions, use of the medicine disposal products for hazardous waste pharmaceuticals may be considered a form of on-site hazardous waste treatment, which may require a permit or may not be allowed.

In California, medicine disposal products may have value as a pre-treatment in healthcare facilities to reduce drug diversion, however, the resulting product-drug mixture must be disposed by incineration or other approved alternative technologies according to state regulations. California’s Department of Public Health is responsible for the approval of alternative technologies and, as of February 2019, specifically does not allow disposal of pharmaceuticals with charcoal-based products in the solid waste system. DPH’s website³⁹ states:

Charcoal-Based Pharmaceutical Waste Disposal Products

Pharmaceutical waste generated in California must be treated by incineration, or by an alternative treatment technology that has received approval from the Department. The technologies on the Department’s alternative medical waste treatment technologies list are the only alternative treatments approved for use in California. None of the charcoal-based products currently in use have gained this approval, so they must be disposed of in a pharmaceutical waste container. Do not place pharmaceuticals mixed with these products into the solid waste.

In Colorado, healthcare facilities cannot dispose of any pharmaceuticals in the solid waste system or down the drain, regardless of whether they are hazardous or non-hazardous under state solid waste statutes.⁴⁰ The Colorado Department of Public Health and Environment (CDPHE) has also determined that medicine disposal products are not approved for use by healthcare facilities in Colorado and cannot be used for trash disposal. In a 2013 letter⁴¹, CDPHE described its review of Verde Technologies’ Medsaway product, now marketed as Deterra, for disposal of non-hazardous pharmaceuticals and determined “while activated carbon appears suitable to render waste pharmaceuticals unrecoverable for diversion purposes, it does not, by itself, meet the regulatory requirement for long term disposal in a solid waste facility in Colorado.” In addition, CDPHE

³⁹ California Department of Public Health. Medical Waste Management Program.

<https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/MedicalWaste.aspx>

⁴⁰ Colorado Department of Public Health and Environment memo to health care facilities in Colorado. March 7, 2017. <https://environmentalrecords.colorado.gov/HPRMWebDrawerHM/RecordView/415841>

⁴¹ Colorado Department of Public Health and the Environment letter to Verde Environmental Technologies, Inc. RE Activated carbon for disposal of non-hazardous waste pharmaceuticals. November 5, 2013. <https://environmentalrecords.colorado.gov/HPRMWebDrawerHM/RecordView/415750>

referenced independent analytical data showing that activated carbon will release adsorbed chemical compounds under acidic conditions in a landfill and stated concerns that the used Medsaway product is in a liquid form that cannot be accepted by most Colorado landfills.

III. Medicine Disposal Products: Performance Questions & Available Product Testing

A. Performance Questions

The medicine disposal products reviewed in this report claim to make potentially harmful pharmaceuticals unusable or non-retrievable, as well as safe for trash disposal.⁴² Key performance questions are:

- ▶ What are the product's active ingredients? Is the mechanism of action chemical or physical, or both? What is the time course of the product action?
- ▶ Does the product deter misuse or abuse of the medicine by making it unusable or unpalatable?
- ▶ Is the transformation of pharmaceuticals by the disposal product complete and irreversible such that any controlled substance is non-retrievable per the DEA's standard?
- ▶ Is the product capable of transforming any type of pharmaceutical, or just certain medicines?
- ▶ Does the product work with all common drug dosage forms, which include: pills, coated tablets, capsules, gels, creams, transdermal patches, sublingual films, lozenges, and liquids?
- ▶ Is the final product-drug mixture non-hazardous and safe for disposal in a solid waste system?
- ▶ Can APIs or any hazardous compounds be released from the disposal product under landfill conditions?
- ▶ Does the product meet applicable federal, tribal, state, and local disposal requirements for pharmaceuticals?
- ▶ Are product instructions clear and easy to follow?
- ▶ For consumer use, is the product safe for use in the home? Do product ingredients pose any exposure risks? How are risks of exposure to solubilized pharmaceuticals addressed?
- ▶ Is the product affordable for regular use to dispose of leftover medicines?
- ▶ What do we know about consumer attitudes about using different methods for medicine disposal?

This section examines information available from the product manufacturers to try to evaluate these key questions about medicine disposal products. More detailed information about each product is provided in Section V.

B. Summary of Available Analytical Testing

Each of the manufacturers asserts their medicine disposal product is safe and effective for the disposal of medicines as directed. A key goal of this report is to summarize the available product testing so that readers can form their own conclusions about whether the experimental design and results support the manufacturer's performance claims.

Tables 4 and 5 in this section identify products with and without publicly available test results. For products with available test information, Table 5 lists the assay type and the pharmaceuticals or

⁴² Eight of the ten medicine disposal products are intended for solid waste disposal, see list in Table 1.

drug tested. Summaries of each test and the results are provided in the product profiles in Section V along with links to analytical reports or research publications where available.

Some type of product testing information is available for six of the ten products: Deterra, DisposeRx, NarcX, Pill Catcher, Pill Terminator, and Rx Destroyer. In some cases, manufacturers provide a full analytical report or peer-reviewed publication. In other cases, only a statement of the result is provided. Some testing was conducted by accredited analytical labs, other testing was conducted by or with company scientists. For the other four products, Cactus Smart Sink, CsRx System, Drug Buster, and Element MDS, the manufacturers state their product has been tested but they consider the test results proprietary and confidential (Table 4).

Table 5 provides a summary of the pharmaceuticals or illicit drug tested with each of the six products with available analytical testing. Only the manufacturer of The Pill Catcher tested a combination of different medicines together, 13 API in total, in a single test that was not designed to test for pharmaceuticals. All other product testing was conducted on a single drug at a time. For some assays, the test was conducted on the product material without additional of any pharmaceuticals.

TABLE 4: PRODUCTS WITH NO PUBLICLY AVAILABLE TESTING	
Cactus Smart Sink	Drug Buster
CsRx System	Element MDS
Manufacturers of these four medicine disposal products do not provide test results on their websites as of February 2019 and did not provide testing data or descriptions in response to the author's query letter. Some manufacturers describe their test results as proprietary. See profile of each product in Section V for a summary of available information.	

TABLE 5: PRODUCTS WITH PUBLICLY AVAILABLE TESTING

Product	Type of Test / Laboratory	Drugs Tested?
Deterra	Adsorption & Wash-out / company scientists	Yes – overall 23 controlled drugs and 12 non-controlled drugs, each tested individually; in pill, coated tablet, capsule, film, transdermal patch.
	Adsorption & Wash-out / academic lab with company scientists	<i>Controlled drugs:</i> alpraxalone, buprenorphine, dextroamphetamine, diazepam, Endocet, fentanyl (Duragesic patch), fluoxetine, hydromorphone, ketamine, lorazepam, loxapine, meperidine, methadone, methylphenidate, morphine, OxyContin, generic Percocet, quetiapine, Suboxone, temazepam, tramadol, generic Vicodin, zolpidem <i>Non-controlled drugs:</i> acetaminophen, amoxicillin, aspirin, dexamethasone, diphenhydramine, duloxetine, ibuprofen, ketoprofen, metformin, naproxen, omeprazole, venlafaxine
DisposeRx	EPA TCLP / accredited analytical lab	No - product material only.
	Static Acute Fish Toxicity / unidentified lab	No - product material only.
	Fathead Minnow Bioassay / unidentified lab	No - product material only.
	Extraction test / accredited analytical lab	Yes – 2 or more controlled drugs, each tested individually: alprazolam, oxycodone, and other unidentified frequently abused drugs; in tablet and unknown dosage forms.
NarcX	Adsorption / accredited analytical lab	Yes – oxycodone tablet
	Adsorption & Extraction / accredited crime lab	Yes – 5 illicit drugs, each tested individually: cannabidiol (CBD), cocaine, heroin, methamphetamine, tetrahydrocannabinol (THC)
	EPA TCLP / accredited analytical lab	No - product material only.
Pill Catcher	EPA TCLP / accredited analytical lab; sample prepared by manufacturer	Yes - 13 drugs, tested together; in tablet, capsule, liquid forms. <i>2 Controlled drugs:</i> Darvocet, Vicodin, and <i>11 Non-controlled drugs:</i> aspirin, Ativan, erythromycin, ibuprofen, Neurontin, prednisone, Premarin, Prozac, Simvastatin, Tylenol, Xanax
Pill Terminator	Aspirin treatment / accredited analytical lab	Yes – aspirin, enteric coated tablet
	Morphine treatment / academic labs	Yes – morphine (pure API)
Rx Destroyer (Narc Gone HD)	Adsorption / unidentified lab	Yes - 1 illicit drug: methamphetamine (liquid)

Manufacturers of these six medicine disposal products provide some type of testing information on their websites as of February 2019. In some cases, manufacturers provided additional test results or descriptions in response to the author’s query letter. Full analytical test reports were not made available for all studies. See the profile of each product in Section V for summaries of available testing data.

C. Active Ingredients and Mechanisms of Action

What are the active ingredients and mechanism of action of these medicine disposal products? The active ingredients are identified in only six of the ten products:

- Four of the medicine disposal products use activated carbon: Deterra, Drug Buster, NarcX, and Rx Destroyer.
- One product utilizes bentonite clay: Pill Catcher.
- One product is a mixture of calcium hypochlorite, Fuller's Earth (a form of clay), and "absorbent ingredients": Pill Terminator

The four other products do not fully describe their product ingredients, which are described as:

- a "cross-linking polymer": DisposeRx
- "an organic plant-based powder": Element MDS
- "a proprietary mixture of denaturants and deterrents": Cactus Smart Sink
- a "denaturing agent-deterrent": CsRx System.

C.1. Activated carbon. Deterra, Drug Buster, Narc X, and Rx Destroyer identify activated carbon as a key active ingredient. Activated carbon may also be one of the ingredients in the CsRx system. These products also contain other unidentified ingredients that may contribute to their mechanism of action.

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, such as 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 an activated carbon product determine its capacity to adsorb different types and amounts of chemicals.

The process of chemicals attaching to the surface of the activated carbon is called adsorption.^{43,44} Adsorption and absorption are related, but different, processes for interactions between two types of molecules or materials.⁴⁵ Adsorption is a surface process where molecules of an adsorbate (e.g. an API) concentrate on the surface of the adsorbent (e.g. carbon). Absorption, in contrast, is a process in which molecules of the absorbate dissolve or diffuse into a liquid or a solid to become part of the same solution or structure. Whether the adsorption or absorption process is complete or

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 for the effectiveness of any medicine disposal product.

⁴³ H. Nowicki, and G. Nowicki. Water Technology Online. "The Basics of Activated Carbon Adsorption" Feb. 1, 2016. <https://www.watertechonline.com/the-basics-of-activated-carbon-adsorption/>

⁴⁴ C. Moreno-Castilla. 2004. Carbon 42. 83-94 "Adsorption of organic molecules from aqueous solutions on carbon materials". <https://hera.ugr.es/doi/15060081.pdf>

⁴⁵ Chromatography Today "Adsorption, Absorption, Desorption – What's the difference" <https://www.chromatographytoday.com/news/hplc-uhplc/31/breaking-news/adsorption-absorption-and-desorption-mdash-whatrsquos-the-difference/31397>

irreversible depends on the nature of the chemicals and materials involved as well as the environmental conditions.

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”.⁴⁶

Activated carbons generally have a high capacity to adsorb pharmaceuticals, but that the capacity depends on pharmaceutical type, carbon type, and solution chemistry, according to a review of potential techniques for removing pharmaceutical pollutants from water.⁴⁷ 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 metal containing compounds.^{46,48}

The carbon-based disposal products are either sold in liquid form (Drug Buster, NarcX, and Rx Destroyer) or require addition of water (Deterra). Efficient adsorption of APIs to the carbon material requires that the medicine is soluble enough to dissolve in the liquid/water phase to enter the pores of the carbon. Efficient adsorption also requires that the API molecules have more affinity for the carbon surface than for the water/liquid phase. Solubility in water will depend on each pharmaceutical’s molecular properties and may also be impacted by excipient (inert) materials in the pill, tablet, or other dosage form.

The physical process of adsorption occurs over time. Some of the product test results, such as those provided by Verde Technologies for Deterra, show most adsorption of APIs occurs in the first eight hours, but complete adsorption takes days, depending on the medicine. After testing the carbon-based product NarcX on several illicit drugs (not in a pharmaceutical dosage form), the Wyoming Crime Lab recommended a minimum 72-hour reaction time. For in-home use, the directions for these disposal products recommend putting the liquid mixture in the trash immediately after mixing with medicines (Deterra) or after 2 hours (Drug Buster) or when full after multiple uses (NarcX and Rx Destroyer).

⁴⁶ Washington State Department of Ecology. “Carbon Adsorption: Treatment Specific Guidance” Publication # 96-415. <https://fortress.wa.gov/ecy/publications/documents/96415.pdf>

⁴⁷ Rivera-Ultrilla *et al.* 2013. “Pharmaceuticals as emerging contaminants and their removal from water. A review” *Chemosphere* Volume 93, Issue 7, Pages 1268–1287
<https://www.sciencedirect.com/science/article/pii/S0045653513010436>

⁴⁸ Lenntech. Adsorption/Activated Carbon. <https://www.lenntech.com/library/adsorption/adsorption.htm>

Is adsorption to carbon irreversible? The carbon adsorption process is typically not irreversible.⁴⁹ 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 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 discussed, 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.⁵⁰

In a 2013 review of Verde Technologies' Medsaway product, now marketed as Deterra, for disposal of non-hazardous pharmaceuticals, the Colorado Department of Public Health and Environment (CDPHE) determined "while activated carbon appears suitable to render waste pharmaceuticals unrecoverable for diversion purposes, it does not, by itself, meet the regulatory requirement for long term disposal in a solid waste facility in Colorado."⁵¹ In addition, CDPHE referenced independent analytical data showing that activated carbon will release adsorbed chemical compounds under acidic conditions in a landfill.

Testing of disposal products using activated carbon. Three of the four manufacturers of carbon-based disposal products provide some type of test information.

Drug Buster does not provide any test results or research studies to support the description of the product's mode of action. In addition to activated carbon, Drug Buster also contains unidentified "surfactants and neutralizing agents". Perhaps because of the action of these ingredients, it is also the only carbon-based product that cautions that foaming may occur when medicines are added, and states it is not for use with antacids, potassium supplements, and other gassing agents.

Deterra provides a number of adsorption and desorption tests with controlled substance and non-controlled drugs using an experimental design that detects "free" or unadsorbed API in the liquid phase of the Deterra pouch. All of Verde Technologies' testing of Deterra was conducted on individual medicines, not on "real world" combinations of medicines or dosage forms. In these studies, many APIs are no longer detectable, i.e. fully adsorbed, after treatment with Deterra, with time courses varying from 8 hours to 1 day to several days. But for other medicines, these studies show the adsorption is not complete and small amounts of the API remain in the liquid phase of the product-drug mixture. The Deterra "wash out" tests show that some of the adsorbed APIs, including controlled substances, can be recovered through brief physical extraction with tap water at room temperature. Additional API is often released by a subsequent wash with 30% ethanol.

Some of Verde's results demonstrate what seem to be inherent differences in the solubility and adsorption of different pharmaceuticals:

⁴⁹ See resources on carbon adsorption cited in footnotes 43, 46, and 48.

⁵⁰ Personal communication from Thomas Prevoznik, Drug Enforcement Administration, October 6, 2016.

⁵¹ Colorado Department of Public Health and the Environment letter to Verde Environmental Technologies, Inc. Full citation in footnote 41.

- One of Verde’s early published studies on Deterra found that two dosage form medicines – dexamethasone tablets and amoxicillin capsules – did not fully dissolve in water added to a Deterra pouch (Herwadkar *et al.* 2015, see test description in Section V). This was apparent from comparison to a “blank” pouch with no adsorbent material in which dexamethasone tablets and amoxicillin capsules were largely insoluble after 7 days in 250 mL water. Without examination of data from appropriate controls, the insolubility of the API or the dosage form could be misinterpreted as adsorption or sequestration of the API by the disposal product’s material.
- Metformin, a commonly used diabetes medicine, was not well adsorbed by Deterra’s activated carbon in one of Verde’s published reports (Herwadkar *et al.* 2015, see test description in Section V). Metformin was 84% unadsorbed after 1 day and 60% unadsorbed after 7 days in a Deterra pouch. The researchers conclude that metformin’s molecular properties cause it to prefer the water phase to adsorbing on the carbon, described as a “worst case” drug for adsorption.

NarcX, a liquid solution of carbon and other ingredients, was tested with oxycodone and with five illicit drugs (CBD, cocaine, heroin, methamphetamine, THC), each drug tested separately. NarcX provided a brief summary of these tests results but did not disclose quantitative data or an analytical report. The amount of adsorption and whether any drug was released in a solvent extraction was dependent on the ratio of drug to NarcX liquid and reaction time. Based on their testing of each of the illicit drugs, the Wyoming Crime Lab recommended a minimum 72-hour reaction time and a minimum ratio of 1 mg drug to 30 mL NarcX liquid solution. A complete analytical report was provided for a separate TCLP assay on the product material alone, without any pharmaceuticals, which determined that unused NarcX solution as sold is not a hazardous waste.

Rx Destroyer provides test results for treatment of one illicit drug, methamphetamine. Their results show a time course where complete adsorption of the drug takes 7 days, with about 86% of the drug adsorbed after 24 hours with the product. Rx Destroyer also provides correspondence from a scientific consultant who specializes in activated carbon stating that the product will render medicines non-retrievable based on other published research showing adsorption of non-pharmaceutical chemicals onto activated carbon. However, the consultant also notes that some amount of pharmaceutical ingredients will remain unadsorbed in the liquid phase of the disposal product.

C.2. Bentonite clay. The Pill Catcher uses a chemically altered sodium bentonite clay from Cetco Corporation called ORGANOCCLAY.⁵²

Bentonite clay is described as both an absorbent and an adsorbent material⁵³, used to absorb liquids and to adsorb contaminants.⁵⁴ Bentonite clay is used in filtration, purification, and a variety

⁵² CETCO ORGANOCCLAY® <https://www.cetco.com/en-us/Products/Environmental-Products/Organoclays>

⁵³ Chromatography Today “Adsorption, Absorption, Desorption – What’s the difference” <https://www.chromatographytoday.com/news/hplc-uhplc/31/breaking-news/adsorption-absorption-and-desorption-mdash-whatsquos-the-difference/31397>

⁵⁴ General references on clays and bentonite clay (a type of smectite clay containing montmorillonite): U.S. Geological Survey “Environmental Characteristics of Clays and Clay Mineral” Deposits <https://pubs.usgs.gov/info/clays>; and Encyclopaedia Britannica “Clay mineral – Chemical and Physical Properties” <https://www.britannica.com/science/clay-mineral/Chemical-and-physical-properties>

of other applications. Several clumping kitty litters are made of sodium bentonite clay⁵⁵, which expands when wet.

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. For these reasons, 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 manufacturer of The Pill Catcher, F.P.R. Inc., describes the mechanism of action of bentonite clay as absorption not adsorption. A letter from F.P.R. Inc in response to the author's query letter, describes a process where dissolving pharmaceuticals become encapsulated between platelets of the bentonite clay that have separated in the presence of water. F.P.R. Inc. describes this encapsulation as permanent once the clay dries.

Testing of bentonite clay product. The Pill Catcher's manufacturer provides results of extraction using the TCLP method on a sample of 13 pharmaceuticals (1 pill or dosage unit of each) mixed together with the disposal product (see product profile in Section V for list of medicines, and Section III.F. 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 breakdown products, so it does not provide information about whether APIs could leach out of the product-drug mixture.

Treatment of fentanyl by bentonite clay was tested in a separate patent application by Insys Development Company, Inc. for a product that does not appear to have reached the market. The Insys patent application⁵⁶ for a pharmaceutical disposal product using bentonite clay fixed to a substrate describes a test using 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 without other agents could achieve the DEA's non-retrievable standard of permanent physical or chemical alteration of a controlled substance.

C.3. Calcium hypochlorite, Fuller's earth, and an "absorbent polymer". The Pill Terminator lists calcium hypochlorite⁵⁷, Ca(ClO)₂, as an ingredient on its Material Safety Data Sheet (MSDS), 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.

⁵⁵ PetMD "What is the best cat litter? Non-clumping vs. clumping litter".

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

⁵⁶ U.S. Patent US 20160361667 A1. "Disposal System for Unused Pharmaceuticals"

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

⁵⁷ PubChem-Open Chemistry Database. Calcium Hypochlorite.

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

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 can also 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 also contains Fuller's earth, along with other ingredients, according to its Material Safety Data Sheet. Fuller's earth is described by TOXNET as a porous colloidal clay containing magnesium aluminum silicate⁵⁸ and is also described as calcium bentonite by some vendors and sources.⁵⁹ Fuller's earth is used to adsorb oils and petroleum products.

Testing available. 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 of treatment by the Pill Terminator. The testing did not fully characterize the chemical composition of the product-drug mixture as it would be disposed. See the Pill Terminator's profile in Section V for more details.

C.4. Unknown mechanisms of action for proprietary, unidentified ingredients. Four of the ten products reviewed in this report do not fully identify their ingredients, which are described as:

- "cross-linking polymers" for DisposeRx,
- "an organic plant-based powder" for Element MDS,
- "a proprietary mixture of denaturants and deterrents" for Cactus Smart Sink, and
- a "deactivating agent-deterrent" for CsRx System.

Because the ingredient information is not disclosed, the mechanism(s) of action of the disposal product cannot be fully understood.

DisposeRx's mechanism of action is described as "chemically and physically sequester(ing) medications in a viscous gel" that becomes solid over time. The product ingredients are described as safe and approved for use in oral medications and food.

V23, LLC, the manufacturer of Element MDS, describes the mechanism of action on medicines as "holds the medication in suspension and forms a solid gel making the medication undesirable". Descriptions on the Element MDS website do not claim that it makes drugs non-retrievable, but say the medicines become "undesirable". Descriptions of the product's ingredients as an "organic, plant-based powder" seem out of sync with the product label's warnings about avoiding skin and eye contact and "Caution: harmful if swallowed". Element MDS recommends trash disposal of the product-drug mixture but does not provide any waste determination data.

Regarding Cactus Smart Sink and CsRx System, it would be useful to know more about the mechanism of action of the ingredients in these two products. However, this information is not essential to evaluating that use of the products as directed provides non-retrievable and safe disposal of pharmaceutical wastage in healthcare settings. The locking unit design of the Cactus

⁵⁸ U.S. National Library of Medicine. TOXNET. "English fullers earth" RN: 8031-18-3. <https://chem.nlm.nih.gov/chemidplus/rn/8031-18-3>

⁵⁹ Encyclopaedia Britannica "Bentonite Clay" <https://www.britannica.com/science/bentonite>

Smart Sink creates a physical barrier to accessing the disposed medicines which makes diversion difficult. Similarly, a CsRx System bottle can be locked into a wall mount. The manufacturers recommend 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.

D. Types of Pharmaceuticals and Dosage Forms

Does the product work with all pharmaceuticals? Given the diversity and complexity of pharmaceuticals, it seems a daunting task to design a disposal product capable of degrading every type of pharmaceutical, that is also safe for home use. Thousands of prescription and OTC drug products are commonly used in the U.S. The commercial website Drugs.com has a database of more than 24,000 prescription drugs, OTC drugs, and natural products. Each year the FDA approves several dozen novel drugs that are new pharmaceutical ingredients.⁶⁰ An article in Pharmacy Times provides a review 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.⁶¹ The chemistry of these medicines is as diverse as their biological effects. Some 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 seems a daunting task to design a disposal product capable of degrading every type of pharmaceutical, that is also safe for home use.

Does the product work with all dosage forms? Another consideration is whether the disposal products are capable of transforming medicines in any physical form, i.e. pills, tablets, capsules, gels, creams, transdermal patches, autoinjectors, lozenges, and liquids. Some of the medicine disposal products specify they can be used with medicines in pill form only; others indicate patches or liquids can also be added. Pills will have to be removed from blister packs. Medicines in autoinjectors could only be treated with these products if the drug could be dispensed into the product container which may be difficult with some types of injector pens.

The eight disposal products for consumers also define a maximum number of pills, liquids, or patches to add, and some products state that effectiveness will be reduced if the capacity is exceeded. For most products, the capacity appears to have been determined based on the volume of the container rather than on the “treatment” capacity of the product material. None of the manufacturers provide test data to support the stated capacity limits of their products, so it is not clear whether different dosage forms were tested together. The question of how liquid medicines will impact the efficacy of the medicine disposal products seems ignored or under-addressed. The ability of a disposal product to adsorb or physically immobilize the pharmaceuticals will be impacted by how carefully consumers follow instructions on dosage forms and limits.

⁶⁰ U.S. FDA. Development & Approval Process (Drugs)
<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/>

⁶¹ Pharmacy Times. “Top Drugs of 2015”. July 18, 2016.
<https://www.pharmacytimes.com/publications/issue/2016/july2016/top-drugs-of-2015>

What medicines have been tested with the disposal products? The medicine disposal products are described as capable of providing safe disposal for almost any type of medicine, or for any non-hazardous pharmaceutical for several of the products. The number of APIs and dosage forms tested with the products is small, as summarized in Table 5. Verde Technologies has tested the largest number of different pharmaceuticals with its Deterra product, but each medicine was tested individually which is not a “real world” test. Only The Pill Catcher’s manufacturer has tested a combination of different medicines (13 in total), however the experimental design of the single test, a TCLP analysis, did not include any analysis for APIs or pharmaceutical breakdown products.

It may 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.

Medicine “exclusions” for some products. Specific medicine disposal products state they should not be used with certain types of medicines or dosage forms:

Not for use with hazardous (RCRA) pharmaceuticals: Drug Buster, Rx Destroyer and Deterra (when used in healthcare setting).

Not for use with chemotherapy drugs (which would also usually be hazardous RCRA drugs): Drug Buster and Elements MDS.

Not for use with antacids or gassing agents: Drug Buster, NarcX, and Rx Destroyer.

Rx Destroyer’s website also states not for use with “drugs known to react with one another such as sodium bicarbonate and aspirin.”

Drug Buster also states not for potassium supplements.

Not for narcotic transdermal patches: NarcX.

Not for creams: None of the medicine disposal products were tested on creams or specifically state that they can be used for medicines in cream form. Two manufacturers specifically state their products are not for medicines in cream form: DisposeRx, NarcX.

Are medicine exclusion directions reasonable for consumers? These medicine exclusions are often listed in the small print on the product label, or only listed on the product website. Would a consumer see that medicine exclusion? Would they comply with it?

For example, it would certainly not be an easy or quick task for a consumer to comply with label directions such as “for non-hazardous drugs only”. The average individual cannot know which pharmaceuticals are hazardous or even know where to go to find that information. In a healthcare facility setting, clear labelling and segregation of waste containers, along with training, is needed to help staff know the proper disposal method for different types of pharmaceuticals.

Rx Destroyer’s product label refers users to their website for “federal, state, and local regulations on how to determine if medications are hazardous”. The website has a Federal & State Guidelines page with links to DEA and EPA guidelines for pharmaceutical waste management, and links to state environmental agencies. But these links do not take a consumer to an understandable list of non-hazardous medicines.

E. Deterrence and Non-Retrievability

Mixing unneeded medicines with a substance to make them undesirable or unpalatable prior to disposal is a deterrence strategy to prevent diversion or misuse of medicines. Altering the medicine so that it is no longer physiologically active and becomes permanently unusable may meet the more rigorous condition of rendering the medicine non-retrievable. Someone addicted to drugs may be willing to go to surprising lengths to obtain medicines that are being discarded, so the distinction between deterrence and non-retrievability is substantive. A key question about each medicine disposal product is whether it acts as a deterrent, or whether its action goes farther to make drugs non-retrievable.

Are the medicine disposal products deterrents? The eight products marketed for home and healthcare use, listed in Table 1, do appear likely to act as deterrents by dissolving pills into a less palatable mixture. Exactly how unpalatable varies with the look and smell of the products. DisposeRx is made of edible ingredients approved for use in food or medicine, so the product seems to rely on the solid nature of the polymer to deter ingestion. The two products marketed solely for healthcare use, listed in Table 2, also create a physical barrier that make access to the pharmaceuticals more challenging.

The FDA's recommendation for disguising medicines in the trash, in situations where no take-back program is available, include taking the medicines out of a labeled container. In contrast, seven of the eight disposal products marketed for home use could be identified by their labels as containing some type of medicine by someone searching in a garbage can. DisposeRx is designed to be added directly to a prescription vial containing unneeded pills, so the name of the medicine encapsulated in the DisposeRx gel will be identifiable from the prescription label. Directions for DisposeRx do not suggest removing the prescription label or marking out information prior to disposal in the household trash. The exception among the consumer-marketed products is Element MDS which provides a plain, unlabeled white bottle, not identifiable as containing medicines.

Do the medicine disposal products make medicines "non-retrievable"? Deterra, Drug Buster, NarcX, Rx Destroyer, Cactus Smart Sink, and CsRx System each describe their disposal treatment of medicines as non-retrievable in their marketing materials. DisposeRx says it makes medicines "unavailable and unusable" and describes the DEA standard in detail in the Education section of its website. In some cases, promotional materials also describe these products as deterrents, making medicines "unusable" or "undesirable".

Element MDS, The Pill Catcher, and the Pill Terminator do not make non-retrievable claims. Element MDS says medicines are made "undesirable" and Pill Terminator says it acts as a "strong deterrent". The Pill Catcher's marketing focuses on environmental protection and EPA standards, rather than the DEA's non-retrievable standard.

Many of the medicine disposal products reviewed use terms like "deactivate" or "neutralize" or "destroy" or "degrade" to describe the product's mode of action. These terms suggest a chemical transformation of the pharmaceuticals into inert constituents. It is not clear that any of the disclosed active ingredients are capable of chemically degrading all pharmaceuticals, either partially or completely. Other statements about how the products work clarify that the mechanism of action is physical rather than chemical. Some product manufacturers seem to use terms like "deactivate" or "neutralize" to describe adsorption of a pharmaceutical onto another material (such as carbon), or to describe physical immobilization of the medicine in a gel or solid form. Adsorption or

physical immobilization are not necessarily irreversible processes, and not necessarily processes that will destroy the pharmaceutical's biologic activity, as discussed further in Section III.C.

"Non-retrievable" is the DEA's stringent regulatory standard for complete destruction of controlled substances to prevent diversion. The term is defined in federal regulations:

"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."^{62,63}

The non-retrievable standard is results-oriented and allows for changing technologies, so it does not list specific disposal methods that achieve the standard. The DEA explained in its rule on disposal of controlled substances⁶⁰ that:

- incineration and chemical digestion are current technologies that can achieve the non-retrievable standard, and
- sewerage and "landfill disposal (mixing controlled substances with undesirable items such as kitty litter or coffee grounds and depositing in a garbage collection" do not meet the non-retrievable standard.

Stryker (Cactus Smart Sink) and Stericycle (CsRx System) market their products solely to healthcare facilities and recommend or provide final disposal by incineration, which meets DEA's non-retrievable standard. The Cactus Sink and CsRx System processes also appear to be compliant with the DEA's October 2014 guidance to practitioners on disposal of pharmaceutical wastage.⁶⁴ 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 Cactus Smart Sink or CsRx System should ensure use of the unit is compatible with any additional state or local requirements in their area, especially when disposing of hazardous pharmaceuticals. It is important for healthcare facilities to be aware of any applicable state or local regulations or restrictions about on-site treatment of pharmaceutical wastes.

Manufacturers of three medicine disposal products – Drug Buster, Element MDS, and The Pill Catcher - do not provide any test results that would demonstrate that the product makes medicines non-retrievable. No performance testing of any kind is available for Drug Buster and Element MDS. F.P.R. Inc. provides an analytical report showing that a sample of The Pill Catcher mixed with 13

⁶² DEA Final Rule on Disposal of Controlled Substances. Full citation in footnote 3. See "Non-Retrievable Destruction Standard", page 53547-8. "Non-retrievable" definition, page 53560.

⁶³ The destruction method must also comply with all applicable Federal, State, tribal and local laws and regulations. The DEA's non-retrievable standard applies to DEA registrants and to medicines collected by take-back programs, not to "ultimate users", i.e. individuals, as explained in more detail in Section II B.

⁶⁴ DEA letter to practitioners. Full citation in footnote 27.

pharmaceuticals passed an EPA TCLP assay.⁶⁵ However, the TCLP method does not screen for pharmaceutical compounds, and therefore does not provide any information about the state of the medicines treated by The Pill Catcher.

Manufacturers of the remaining five medicine disposal products for consumer use – Deterra, DisposeRx, NarcX, Pill Terminator, and Rx Destroyer – provide some test results as evidence that their products render medicines non-retrievable. Several of these tests, however, demonstrate that small amounts of the controlled substance drugs are retrievable after treatment with the product. Or, in other cases, the test did not thoroughly examine retrievability. For a number of the tests, the manufacturer has not released the complete analytical test report, making it difficult to assess the experimental design, controls, and results. Available test results are summarized in more detail in the product profiles in Section V.

Testing of Deterra, DisposeRx, and the Pill Terminator, showed that trace or small amounts of the API of a controlled substance drug were not fully adsorbed and/or could be recovered under simple “wash-out” conditions. For NarcX, drugs could be recovered from the product under certain test conditions, and complete quantitative test results were not provided to assess the extent of recovery. For Rx Destroyer, the experimental protocol did not attempt to recover APIs after adsorption by the carbon product.

Overall the “wash-out” or extraction protocols used in the assays were limited. A wider range of solvents along with heat or pressure treatments should be examined to adequately test whether APIs can be recovered. If a small amount of the controlled substance can be retrieved simply by rinsing a used medicine disposal product briefly with water, it seems likely that some or all of the API could be released by other solvents, or through longer extractions under other physical conditions.

Based on this 2019 review of available test results, none of the products thoroughly demonstrate irreversible physical or chemical destruction of the medicines.

The test results available for some of the products also suggest the reaction time course needs to be considered. How much time is needed for the interaction of the disposal product with the pharmaceuticals to render them “non-retrievable” or “safe for landfill disposal” per the manufacturer’s description? If medicine disposal products are put into the trash before the reaction process is complete, the treated pharmaceuticals may create exposure risks or be available for diversion or release into the environment. Plastic bottles or ziplock pouches containing the product-drug mixture are likely to burst or split during storage in a trash can, and especially in a garbage compactor truck, solid waste transfer station, or landfill. Several products describe the “reaction” as quick or fast or instant; however, details in some of the product descriptions or testing results 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. After testing the carbon-based product NarcX on several illicit drugs, the Wyoming State Crime Lab recommended a minimum 72-hour (3-day) reaction

⁶⁵ The TCLP assay and The Pill Catcher test results are further described in Section III.F. and in the product profile in Section V.

time. A test of Rx Destroyer treatment of methamphetamine found 65% adsorbed in 2 hours, 86% adsorbed in 24 hours, and 7 days for full adsorption.

Based on this 2019 review of available test results, none of the products thoroughly demonstrate permanent, irreversible physical or chemical destruction of the medicines. The DEA's non-retrievable standard is not achieved if even a small percentage of the controlled substance can be recovered. In most cases the experiments were not designed to differentiate chemical degradation over physical sequestration, or to look for breakdown analogues. More rigorous testing using specific analysis to detect the controlled substances and their analogues is needed to convincingly demonstrate that these medicine disposal products can achieve the DEA's non-retrievable standard.

Perhaps in stating their products make medicines non-retrievable, the manufacturers are focusing on the "unavailable and unusable for all practical purposes" portion of the DEA non-retrievable definition. Perhaps they are concluding that their product fits the description even if trace amounts of API are not destroyed or can be recovered through solvent extractions or some other means. However, the complete "non-retrievable" definition suggests an absolute interpretation that no amount of recoverable API is allowed, such as in the sentence "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.". Ultimately the DEA's determination is needed to evaluate any proposed disposal technology for use in situations where the DEA's "non-retrievable standard must be achieved.

F. Environmental Performance

Pharmaceuticals, and a range of other chemical contaminants, are commonly found in leachate from municipal solid waste landfills.⁶⁶ Modern municipal waste landfills are lined and maintained to prevent leachate from seeping directly into ground water⁶⁷; however, landfill leachate is often pumped out to a wastewater treatment plant which cannot effectively remove pharmaceuticals or other organic pollutants. Pollutants in landfill leachate, including pharmaceuticals, have been shown to pass through wastewater treatment plants and escape into the environment through both the water outflow and biosolids. For this reason, pharmaceuticals and other toxic or hazardous chemicals should not be disposed in the household trash and solid waste system.

Eight of the ten products reviewed recommend that residents put the final product-drug mixture in the household trash after treatment. Some products also state solid waste disposal is appropriate for healthcare facilities and other regulated generators that are disposing of nonhazardous pharmaceuticals. Cactus Smart Sink and CsRx System are the exception, recommending that healthcare facilities dispose of full containers through pharmaceutical waste service providers and by incineration at permitted facilities.

For the products designed for solid waste disposal, key questions are whether the product-drug mixture is non-toxic and appropriate for solid waste disposal, including whether active API or toxic byproducts can leach out. Most of the products are marketed as protecting the environment or water quality. Some products make broad statements about safety and regulatory compliance for disposal as a solid waste in the household trash, such as:

⁶⁶ U.S. Geological Survey "Pharmaceuticals and Other Chemicals Common in Landfill Waste" https://toxics.usgs.gov/highlights/2014-08-12-leachate_pharm.html

⁶⁷ U.S. EPA. "Municipal Solid Waste Landfills" <https://www.epa.gov/landfills/municipal-solid-waste-landfills>

“passes All EPA tests”
“safe for landfills”
“environmentally-friendly”

Available product testing. None of the eight products designed for solid waste disposal, listed in Table 1, provide complete waste determination analysis to support claims that pharmaceuticals mixed with the product are made safe for solid waste disposal. Two of the products –Drug Buster and Element MDS – do not provide any test results to demonstrate the product’s performance. The limited testing available for Rx Destroyer and the Pill Terminator does not examine whether APIs would leach out, from the product. Manufacturers of the other four products intended for solid waste disposal - Deterra, DisposeRx, NarcX, and The Pill Catcher – provide results of assays used for waste determination that are summarized in this section, but the testing does not provide a complete waste determination or thoroughly address whether the product-drug mixture is non-hazardous and non-toxic for landfill disposal.

The manufacturers of Dispose Rx, NarcX, and The Pill Catcher provide results of an EPA test method called the TCLP (Toxicity Characteristic Leaching Procedure) that simulates solid waste leaching under landfill conditions, and assays for the presence of metals and key pollutants such as volatile organic compounds (VOCs). However, only the TCLP test for The Pill Catcher was performed on the product mixed with pharmaceuticals to provide some meaningful waste determination information about the product as it is intended to be used. Dispose Rx and NarcX provide results of TCLP assays conducted on the product material only, without the addition of any pharmaceuticals. While those tests show the food safe materials in DisposeRx and the activated carbon mixture in NarcX pass a TCLP test, they do not provide any information about whether a mixture of these products with medicines would pass the TCLP or release toxic leachate under landfill conditions.

F.P.R. Inc. provides results of a mostly independently conducted TCLP assay on a sample of The Pill Catcher mixed with a combination of medicines. A sample of The Pill Catcher mixed with 13 pharmaceuticals (12 tablets and 1 oz of a liquid) passed the TCLP test. The 8 metals and 32 regulated organic chemical pollutants assayed in the TCLP were non-detectable or below regulatory limits. However, the TCLP assay does not screen for any pharmaceutical compounds. Therefore, this analysis provides useful information, but is not a complete waste determination that assesses potential toxicity of the product-drug mixture. F.P.R. Inc. asserts that the EPA is the only governmental agency with regulatory authority over solid waste disposal, and the TCLP is the only required test method. This viewpoint neglects state regulatory authorities which often require additional waste determination assays and also neglects local regulatory authorities and solid waste acceptance policies.⁶⁸

Verde Technologies, the manufacturer of Deterra, provides test results meant to demonstrate that medicines mixed with the disposal product do not wash out; however, these studies show small amounts of pharmaceuticals are retrievable from the product directly or after brief extraction with water. Verde Technologies also provides an unpublished internal study that mimics the TCLP’s weakly acidic extraction conditions on a sample of Deterra mixed with three OTC pain relievers, but the test does not follow the EPA test method in entirety. In their NIDA grant report and publications, Verde’s researchers describe other extractions using tap water and 30% ethanol as representative of landfill conditions, but these tests neglect consideration of pH of the solvent.

⁶⁸ See Section II for a brief background on federal, state, and local solid and hazardous waste regulations.

Rainwater leaching through a landfill would be more acidic than tap water (pH 7.2 to 7.5 in the Atlanta area where Verde's tests were conducted). Unpolluted rain water is roughly pH 5.6 and acid rain is roughly pH 4.3. The EPA's TCLP method requires use of weak acid extraction at pH 4.9 to approximate landfill leaching conditions, followed by testing for specific metals and other pollutants.

DisposeRx also provides a brief non-technical statement that it has conducted two fish toxicity assays used for hazardous waste determinations in California and Washington State; however, DisposeRx tested only their product as sold, without the addition of any pharmaceuticals. It is unsurprising that the food-approved ingredients of DisposeRx passed these tests. The results do not provide any information about whether a DisposeRx-drug mixture would meet the toxicity criteria of a hazardous waste under these bioassays.

Colorado determination on an activated carbon disposal product. State agencies have largely not formally reviewed the use of medicine disposal products; however, after producing the first version of this report in 2017, the author learned of a 2013 evaluation by a Colorado agency. Verde Technologies' Medsaway product, now marketed as Deterra, was reviewed by the Colorado Department of Public Health and Environment (CDPHE) for disposal of non-hazardous pharmaceuticals.⁶⁹ CDPHE determined "while activated carbon appears suitable to render waste pharmaceuticals unrecoverable for diversion purposes, it does not, by itself, meet the regulatory requirement for long term disposal in a solid waste facility in Colorado." Colorado's solid waste regulations require either incineration, encapsulation, or stabilization for disposal of non-hazardous pharmaceuticals. CDPHE determined that adsorption of pharmaceuticals by activated carbon does not meet the requirements of any of these methods. CDPHE's analysis also referenced independent analytical data showing that activated carbon will release adsorbed chemical compounds under acidic conditions in a TCLP. Because the used Medsaway product is in liquid form, CDPHE also pointed out that it cannot be accepted by most Colorado landfills without further treatment to solidify the mixture. In a 2017 memo to health care facilities, the Colorado Department of Public Health and Environment states that medicine disposal products are not approved for use by healthcare facilities in Colorado and cannot be used for trash disposal.⁷⁰

About the TCLP and other waste characterization tests. 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 medicines are made non-toxic or non-retrievable? The TCLP analysis is useful in understanding the characteristics of the medicine disposal product and is an essential test to perform as part of waste determination. However, it is important to understand what the TCLP test measures, and what it does not. Also, some states require other types of waste determination assays in addition to the TCLP.

The TCLP - Toxicity Characteristic Leaching Procedure - or EPA SW-846 Test Method 1311⁷¹ - is one of a series of test methods developed by the EPA to analyze the physical and chemical

⁶⁹ Colorado Department of Public Health and the Environment letter to Verde Environmental Technologies, Inc. Full citation in footnote 41.

⁷⁰ Colorado Department of Public Health and Environment memo to health care facilities in Colorado. Full citation in Footnote 40.

⁷¹ 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

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 other regulated pollutant chemicals using specified laboratory methods such as mass spectrometry. If any of the 40 regulated chemicals are present in amounts equal to or exceeding regulatory limits⁷², 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 assay is not specifically tailored to answering the questions that are most relevant to the performance of medicine disposal products.

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:

- *Does not screen for pharmaceuticals or breakdown products:* The TCLP test method does not analyze the extract for any pharmaceutical compounds that have leached out of the waste material, nor does it fully evaluate the chemical composition of the leachate. The regulated pollutants in the TCLP chemical panel are not common pharmaceutical ingredients. Only a few of the test analytes are used as ingredients in pharmaceutical preparations, such as: silver used in burn creams, and m-cresol and mercury which may be used as preservatives in pharmaceutical preparations. Some of the TCLP panel chemicals potentially could be chemical breakdown products of certain pharmaceuticals, but it would be more appropriate to test the extract directly for pharmaceuticals and known breakdown products.
- *Does not fully examine API retrievability:* The TCLP test conditions are designed to simulate landfill leaching conditions, and do not represent the range of 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 medicine disposal product. The limited TCLP test conditions do not fully examine this question.
- *Does not examine other toxic characteristics:* The TCLP screens for specified metals, VOCs, and pesticides to identify key pollutants that should be excluded from solid waste landfills. The test method is not designed to fully characterize whether a waste material is non-toxic and non-hazardous based on other criteria.

Toxicity Characteristic Leaching Procedure. May 1994. <https://www.epa.gov/quality/technical-assistance-document-complying-toxicity-characteristics-rule-and-implementing>

⁷² 40 C.F.R. 261.24. Toxicity characteristic. https://www.ecfr.gov/cgi-bin/text-idx?node=se40.26.261_124&rgn=div8

Overall, the TCLP analysis alone is not sufficient to determine whether a medicine disposal product effectively binds pharmaceuticals to prevent their release into the environment or makes pharmaceuticals safe for landfill disposal.

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 pharmaceutical chemicals are specifically designated under RCRA as hazardous waste (P or U listed wastes). Other pharmaceuticals, or the product-drug mixture, may exhibit one of the other specified characteristics of hazardous waste (ignitability, corrosivity, reactivity) that are not assessed by the TCLP. Wastes containing any federally listed hazardous wastes must be managed as hazardous wastes by regulated generators, such as hospitals, under the RCRA mixture rule.

States may also require additional analysis for hazardous waste determination by regulated generators. 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.⁷³ 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 additional regulatory limits 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.

Bioassays test the toxicity of a substance by measuring its effects on living cells, tissues, or model organisms. Aquatic toxicity is commonly determined by measuring how many fish of a representative species die during exposure to the substance in a test chamber. For hazardous waste classification, California regulations define a Fathead Minnow Bioassay.⁷⁴ Washington State's Dangerous Waste regulations define a Static Acute Fish Toxicity Test using coho salmon, rainbow trout, or brook trout and an Acute Oral Rat Toxicity Test.⁷⁵ The bioassay determines a LC₅₀ for the substance, which is the concentration required to kill 50% of the test fish or animal within a given time period. Waste materials that fail a fish bioassay, i.e. are more toxic than the allowable LC₅₀ limit, are designated as hazardous or dangerous wastes. DisposeRx provides a brief summary of results from the California and Washington fish toxicity assays on their cross-linking polymer alone, without any addition of pharmaceuticals, and therefore the test was not conducted on the material as it would be disposed after use.

Local jurisdictions may further discourage or prohibit residents from disposing of specific products, such as pharmaceuticals or products that are HHW, in the solid waste system. Such special wastes must be managed separately. Many local health, solid waste, and water agencies are actively promoting the use of secure medicine take-back programs for proper disposal of unneeded household medicines. Municipal solid waste programs generally do not accept liquid wastes because containers will spill or burst during collection or transportation, releasing the liquid

⁷³ California Environmental Protection Agency. Department of Toxic Substances Control. "Defining Hazardous Waste" <https://www.dtsc.ca.gov/HazardousWaste/upload/DefiningHazardousWaste.pdf>

⁷⁴ CA Dept. Fish and Game. Water Pollution Control Laboratory. Static Acute Bioassay Procedures for Hazardous Waste Samples. Polsini & Miller, 1988. https://www.dtsc.ca.gov/HazardousWaste/upload/HWMP_bioassay_report.pdf

⁷⁵ WA State Department of Ecology. Biological Testing Methods 80-12 For the Designation of Dangerous Waste. Part A. Static Acute Fish Toxicity Test. <https://fortress.wa.gov/ecy/publications/documents/8012.pdf>

material and resulting in human exposure and/or environmental release. Five of the eight medicine disposal products designed for solid waste disposal will be in liquid form when disposed, and the three others will be in a liquid or semi-liquid form (summarized in Table 1).

Product Packaging. Solid waste professionals, zero waste advocates, and others may also be interested in the fate of the packaging for these medicine disposal products. Is the packaging material non-toxic and/or biodegradable in landfill conditions? Each product profile, in Section V, provides a brief summary of what is known about packaging materials from the manufacturer's website and materials. Some manufacturers do not characterize the plastic containers used; others are touting the green benefits of their packaging. Review of the packaging was beyond the scope of this report, which focuses on the primary issue of whether these products are appropriate for disposal of pharmaceuticals. None of the products recommending solid waste disposal are aligned with zero waste goals of diverting materials from landfills and some increase the amount of plastics being landfilled.

G. Safety, Ease of Use, Product Costs, and Consumer Preferences

Several questions about these medicine disposal products are most relevant to home use of the products by consumers: safety, ease of use, and product costs. These factors also influence the likelihood that consumers will routinely use these products for disposal of medicines in the household trash.

Safety. A person using any of the eight medicine disposal products marketed for home use will be mixing their medicines with a chemical solution, so exposure and safety is a consideration. Seven of these eight disposal products come in bottles or a pouch, and one is a powder designed to be added to a prescription vial. Five of the products require the addition of water and three are already in liquid form. Users are instructed to add pills and other indicated drug dosage forms, and to not exceed the stated capacity of the product. Some of the products are designed for use followed by immediate disposal in the trash. Others state that users can continue to add medicines to the liquid container until it is full, which means the pharmaceutical mixture needs to be kept in a safe place in the home while in use. Product instructions often state that the ability of the product to adsorb or sequester the pharmaceuticals will be impacted by how carefully consumers follow these instructions.

Consumers should be cautioned to exercise care to avoid exposure to the mixture of pharmaceuticals and product material when using any medicine disposal product. Several of the products carry warning labels about potential eye contact. Most products have warnings to keep away from children. Warnings do not specifically caution against dermal exposures, including avoiding dermal exposure after addition of pharmaceuticals, and this is an omission. Several product directions state that foaming may occur when medicines are dissolved in the product. Some 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 the product with the pharmaceuticals, as well as take care not to overfill or spill the pouch or bottle.

Some concerns about product instructions were identified in a 2016 survey of consumers who were given a free Deterra pouch. Verde Technologies' survey of 233 respondents found that most users considered the instructions clear and easy to understand, but 3% found the instructions confusing and 5% had some challenges in adding the water or opening and sealing the pouch. As a recommendation from these survey results, Verde's report states, "Online FAQ should include

troubleshooting tips for when consumers add too much water, spill the carbon, etc..."⁷⁶ No other consumer survey data about ease of use of other medicine disposal products was identified in this review.

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 to mix leftover medicines with kitty litter or coffee grounds. However, exposure risk is increased because consumers are asked to dissolve pills in liquids creating opportunities for spills and exposures. In comparison, medicine take-back programs allow residents to transport medicines in their original packaging to a secure drop box or collection events.

Spill clean-up. None of the medicine disposal products provide instructions to users on how to clean up a spill from a tipped over or a burst container. In a healthcare setting, staff are trained on proper clean-up of pharmaceutical spills, and EPA regulations require proper disposal of clean-up materials if the spilled pharmaceutical is hazardous.⁷⁷ In the home setting, residents need instructions on how to safely clean-up a liquid mixture of medicines to avoid exposure to potentially harmful pharmaceuticals through skin contact. Gloves should be worn, and the counter top or floor surface should be thoroughly cleaned with soap and water to avoid exposure to residues. Disposal of clean-up materials in the household trash is not optimal but seems a better option than washing residues down the drain.

Transdermal patches. Avoiding skin contact is especially important for safe disposal of used opioid transdermal patches because much of the pharmaceutical remains in the patch. The amount of fentanyl remaining in a used patch can be deadly to children and harmful to adults. The FDA currently recommends flushing used fentanyl patches, after folding the patch in half with sticky sides together.⁷⁸ FDA recommends returning any unused, unopened fentanyl patches through a medicine take-back program, or to dispose by flushing.⁷⁹

Most of the medicine disposal products state they can be used for disposal of patches, including Deterra, Dispose Rx, Drug Buster, Element MDS, Pill Catcher, Rx Destroyer, as well as Cactus Smart Sink and CsRx System. NarcX states it should not be used for narcotic patches. Usage with patches is not noted for the Pill Terminator.

Special handling instructions for how to safely add a used patch to a medicine disposal product are not provided for most of the products. Medline states that their Drug Buster product can be used for disposal of non-hazardous patches and provides directions in online FAQs to "avoid touching the medicine pad, then fold the patch in half, sticky sides together and place into the Drug Buster container." Disposal of patches was described as a "special case" in Verde Technologies' studies on "deactivation" of fentanyl patches with Deterra carbon, because the sticky patch could adhere to the sides of the pouch or to itself, affecting the "deactivation process". To prevent this, the researchers

⁷⁶ Verde Technologies Grant Report to NIDA "In-Home Deactivation System for Psychoactive Drugs" September 2016. <https://deterrasystem.com/wp-content/uploads/2018/03/NIDA-Final-Report.pdf>

⁷⁷ EPA Final Rule on Hazardous Waste Pharmaceuticals. Full citation in footnote 17.

⁷⁸ FDA Consumer Update. April 2012, Updated Sept. 2013. "Fentanyl Patch Can Be Deadly to Children" <https://www.fda.gov/forconsumers/consumerupdates/ucm300803.htm>

⁷⁹ FDA Drug Safety Communication. September 2013. "FDA requiring color changes to Duragesic (fentanyl) pain patches to aid safety—emphasizing that accidental exposure to used patches can cause death" <https://www.fda.gov/Drugs/DrugSafety/ucm368902.htm>

covered the patch's sticky side with a Kimwipe tissue.⁸⁰ Such additional handling of the patch may create an exposure risk and Deterra does not instruct a user to do this, however, the study conditions then do not mimic real-world use.

Ease of Use. Residents often have large amounts of leftover or expired medicines to dispose of after a serious illness, or the death of a family member. They would likely find the disposal products to be a time-consuming and relatively expensive disposal method. The eight medicine disposal products marketed to consumer use in the home are designed for relatively small amounts of medicines.

If residents read the label directions carefully, they will often find instructions that are difficult to follow. It would not be an easy task for a resident to comply with product directions such as “for non-hazardous drugs only”, or do not use with medicines known to react with each other, as discussed in Section III.D. There is no simple resource guide to identify which medicines are in these categories.

Some of the product labels have “fine print” that instructs users to consult state and/or local disposal regulations, putting the burden on the user to sort out solid waste acceptance policies. Such complicated instructions are not meaningful for the average consumer, so it is not reasonable to expect good compliance. Further, local solid waste authorities likely do not have access to sufficient information about the ingredients, mechanism of action, and performance of these products to recommend their use. Some local agencies recommend use of local medicine take-back programs and caution against the use of in-home medicine disposal products because they have not been proven safe or effective.

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 eight products marketed for home use range from about \$1.60 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 February 2019 are:

- Deterra: \$4.99 for 15 pills or \$6.99 for 90 pills.
- Pill Catcher: \$4.95 for 120 pills or \$6.95 for 300 pills.
- Pill Terminator: \$9.95 for 300 pills.
- Drug Buster: \$9.95 for 50 pills or \$15.99 for 300 pills.
- DisposeRx: \$9.85 for 6 packets to treat 6 prescription vials (each approximately one-third full of unwanted pills).

Some manufacturers offer discounts for bulk purchases, but even so these products are a substantial cost for regular use. Some government agencies and healthcare entities are distributing free samples of medicine disposal products as part of drug abuse education and prevention campaigns. Many residents need ongoing medicine disposal options, however, and the cost of these products is essentially 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

⁸⁰ Verde Technologies Grant Report to NIDA. Full citation in footnote 76.

pills with an actual weight of about 630 mg per pill⁸¹, the cost of the Detera disposal method is about \$56 per pound of medicine disposed.^{82,83}

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.⁸⁴ 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 envelopes⁸⁵ at \$150 for a case of 25 mailers, which is \$6.00 per mailer. In addition, medicine drop-off and mail-back programs are regulated by the DEA, FDA, and other agencies, ensuring that the collected household medicines are rendered non-retrievable by high temperature incineration at permitted facilities.

The cost of these products 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, non-retrievable, and environmentally protective disposal, a funding source and distribution mechanism would be needed to provide an ongoing supply of the product to residents.

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

Consumer preferences. Some companies marketing medicine disposal products for in-home use promote their products as more convenient than secure medicine take-back programs. What do we know about consumer attitudes and preferences for proper medicine disposal? Surveys commonly find that consumers know that leftover medicines need to be disposed of properly, but often are not

⁸¹ Actual weight of a Watson 540 generic Vicodin pill (500 mg acetaminophen/10mg hydrocodone) estimated from John P. Guidry II “Trafficking in Hydrocodone/Oxycodone” <https://www.jgcrimlaw.com/trafficking-in-hydrocodone-oxycodone.html>

⁸² Calculation of cost per pound for Detera disposal: 90 Vicodin pills x 630 mg/pill = 56.7 grams = 0.125 pounds. \$6.99 per Detera pouch / 0.125 pounds Vicodin pills = \$55.92 per pound.

⁸³ Similar cost calculations for medicine disposal products and comparisons to medicine take-back program costs have been circulated on the pharmwaste listserv in recent years, including analysis by Jennifer Volkman, Minnesota Pollution Control Agency and Ed Gottlieb, Ithaca Area Wastewater Treatment Facility, see <https://lists.dep.state.fl.us/pipermail/pharmwaste/2018-October/006058.html>

⁸⁴ Average cost per pound of medicine take-back programs is estimated from author’s knowledge of program costs from a variety of community medicine 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 in 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.

⁸⁵ Sharps Compliance, Inc. “TAKEAWAY MEDICATION RECOVERY SYSTEM ENVELOPE (USPS)” <https://www.sharpsinc.com/store/medication-disposal-envelopes-usps>

aware of the best disposal method.^{86,87} Publicity around the DEA's National Prescription Drug Take-back Days, as well as promotion of ongoing medicine drop box programs, appears to be increasing awareness of medicine take-back programs as a safe disposal method. More efforts to increase consumer awareness and provide consistent medicine disposal guidance are needed.

Not much information is available about consumer attitudes towards use of medicine disposal products. This review identified only one direct consumer survey about a medicine disposal product that is publicly available. Verde Technologies' grant report to NIDA⁸⁸ includes a survey of users of a free Detera pouch. In 2016, Verde distributed free Detera pouches and surveys to 1665 consumers ("users") through pharmacies and law enforcement, and distributed provider surveys to pharmacists and law enforcement. Results of 233 consumer responses and 18 provider responses, included:

- 96% of consumers used the free Detera pouch within 4 weeks; 49% used it within 24 hours.
- Respondents stated multiple reasons for using the Detera pouch, with the most common reason being protecting the environment (88%), lower risk of abuse or diversion (40%), and lower risk of poisoning (37%).

Other surveys on medicine disposal in general have found consumer concerns about disposing of medicines in the household trash. Surveys that asked about take-back programs found substantial interest in using medicine drop boxes at pharmacies, as in the three examples below.

The Consumer Healthcare Products Association, representing OTC drug manufacturers, commissioned a Harris Poll in 2015.⁸⁹ The survey of 2,002 residents found that many are resorting to disposing of medicines in the trash, but they do not like that disposal practice:

- Half (50%) state they typically dispose of their unwanted or expired OTC medicines by throwing them in the trash, but only 8% mix them with an undesirable substance before doing so.
- Only 1 in 5 adults (18%) believe disposing of OTC medicines in the household trash or mixing them with an undesirable substance before doing so is the best way to discard unwanted or expired OTCs.

The Los Angeles County Pharmaceutical Working Group conducted a survey⁸⁷ in early 2016 of 1,062 residents about their concerns, practices, and preferences for disposal of leftover pharmaceuticals and sharps. Some of the relevant findings were:

- A majority of residents (54%) believe that putting medicines in the trash is harmful to the environment.
- Few residents seem to be willing or able to follow the cumbersome advice of disguising medicines to prevent diversion from unsecured trash cans. Only 12% of respondents said

⁸⁶ Kinrys, G., Gold, A.K., Worthington, J.J., Nierenberg, A.A. "Medication disposal practices: increasing patient and clinician education on safe methods" J. Intl. Medical Research. 2018. 46(3) 927-939.

<https://journals.sagepub.com/doi/pdf/10.1177/0300060517738681>

⁸⁷ Los Angeles County Department of Public Health. "Los Angeles County Medicines & Sharps Disposal Consumer Survey Results". April 8, 2016. Online at:

<http://publichealth.lacounty.gov/docs/SharpsDisposalSurvey.pdf>

⁸⁸ Verde Technologies Grant Report to NIDA. Full citation in footnote 76.

⁸⁹ CHPA Educational Foundation "Consumer Attitudes on Over-the-Counter Medicine Use, Storage, and Disposal. September 2015. Online at: <https://www.chpa.org/MedicineUseStorageDisposal.aspx>

that they mixed medicines with coffee grounds or kitty litter to disguise them prior to throwing them in the trash, while 35% of participants overall said that they dispose of medicines in the trash as is.

- 87% of respondents thought medicine drop-off programs in pharmacies are a “good approach”. When asked to select a preferred option for medicine disposal, free of charge, two-thirds of residents (69%) would prefer a medicine drop-off program in a pharmacy and 15% of residents would prefer a mail-back envelope.

In November 2016, Contra Costa Health Services in California conducted a survey of 1,600 residents that was modeled on the LA County survey and they found consistent results.⁹⁰ Survey results included:

- 94% of respondents believe it is inappropriate to flush leftover medicines and 84% believe it is inappropriate to put leftover medicines in the trash.
- 83% of residents said they would be likely or very likely to dispose of unwanted medicines at a pharmacy. 55% would be likely or very likely to use a prepaid return envelope.

Consumers need clear and consistent guidance on how to safely dispose of their leftover prescription and OTC medicines. The key federal agencies – FDA, DEA, and EPA – have significantly improved the consistency of their medicine disposal guidelines in recent years, with the encouragement of local agencies and advocates. Federal agencies are now aligned in recommending the use of secure medicine take-back programs as the best method for disposal of household medicines, as shown in Table 3. The marketing messages put out by medicine disposal product manufacturers focus on use of their products for trash disposal and do not explain disposal options in the same way as those federal guidelines, see Section II.C, which is likely to cause consumer confusion.

⁹⁰ Memo from Contra Costa Human Services to the Family and Human Services Committee of the Contra Costa Board of Supervisors. Nov. 14, 2016. Online at: <https://cchealth.org/hazmat/hmc/pdf/2016-1114-Safe-Drug-Disposal.pdf>

IV. Research Needs & Other Recommendations

Manufacturers of medicine disposal products are convinced their products provide safe and appropriate disposal of pharmaceuticals for users in home, healthcare, and other settings. Review of additional materials provided by some manufacturers for this updated 2019 report addressed a few questions about how products were tested. However, some manufacturers are not disclosing any test data, or will only provide summaries of results without a complete analytical test report. For other products, the test results available do not fully support the product claims or the testing methodology did not address all relevant performance questions. Overall, the limited product testing available does not thoroughly examine product performance and verify product claims. This review also examined regulatory considerations and identified other questions about recommended use of the products.

Research needs

The test data reviewed in this report for the eight products marketed for household use are not sufficient to verify the performance claims that these products are capable of rendering medicines fully non-retrievable and safe for disposal in the household trash. Based on currently available information, the active ingredients and mechanisms of action of these products seem unlikely to fully achieve all of the performance claims. Additional carefully designed testing is needed to more thoroughly address questions about product effectiveness and performance.

Independent laboratory analysis and disclosure of analytical reports. 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, analyzing the results, or writing reports or publications. Manufacturers have a right to protect proprietary information but must also understand they need to disclose analytical testing reports, at a minimum to regulatory agencies and preferably to the public, to support their performance claims.

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

Additional independent laboratory analysis that examines how medicine disposal products will be used with mixtures of medicines is needed to fully evaluate product performance.

Accredited analytical labs will include appropriate controls and perform quality assurance and quality control (QA/QC) measures. For medicine disposal product testing, the analysis needs to consider appropriate controls or blanks to verify that excipient ingredients in drug dosage forms do not interfere with the detection method or interfere with solubilization of the dosage form. Excipients are natural or synthetic chemicals used to add mass, color, flavor, or other properties to

the dosage form of a drug.⁹¹ A medicine in pill form is mostly excipient material by weight, with a small amount of API. Most of the available test data that described controls used pure API without excipients as standards and did not appear to examine impacts of excipients. Solubility of different APIs in water or the product must also be considered. As noted in one study⁹², the amount of “free” API in a product’s liquid phase cannot be accurately determined if the drug dosage form or the API does not fully dissolve in tap water.

Manufacturers used independent analytical labs for some of the testing, but sometimes declined to identify the lab or declined to release a complete analytical report. Some analysis used a standardized test method, like the EPA TCLP method, but others used their own methodology which was not fully described. This makes review of the results difficult. The questions that need to be addressed will likely require a combination of standardized test methods for waste determination, as well as tailored studies for detection of pharmaceutical compounds or breakdown products.

“Real world” use testing. To mimic likely “real world” use, medicine disposal products should be tested with several different types and dosage forms of pharmaceuticals in combination. The product’s ability to chemically or physically alter a single medicine could be different than its action on a mixture of medicines with different chemical and physical properties, and in the context of a mixture of excipients. Analyzing pharmaceuticals in a mixture will require adjustments to chromatographic separation and detection methods, such as HPLC or GC-MS, to distinguish individual APIs. Techniques for simultaneous identification and quantification of multiple pharmaceuticals have been developed for environmental samples and may be applicable.

Analysis for five of the six products with available testing was conducted on a single medicine at a time (Table 5). Some of these studies used pure API or illicit Schedule I controlled substances rather than a pharmaceutical in dosage form. Several of the products were tested with only a small number of different medicines. While those analyses are useful, they do not represent how these products are marketed to be used to dispose of many different types of medicines at the same time. Only The Pill Catcher was tested on a mixture of 13 medicines (1 pill or dose each) in a TCLP assay.

Real-world testing should also examine impacts of combining dosage forms. Cough syrups or other liquid medicines need to be assessed to understand the impacts of dilution or addition of solvents like alcohol. The effects of exceeding recommended product capacities, i.e. number of pills added, on product performance should also be examined. For many of the products, the capacity seems to have been determined by the volume of the container, rather than on testing. Given the relatively small capacity of some of the products and the price per unit, it is likely that consumers will add the maximum quantity of medicines in a mixture of dosage forms.

It may be impractical to test all pharmaceutical compounds given the thousands on the market, and the pace of new drug development. Testing a wide array of APIs is not necessary with a disposal technology that inherently breaks down all chemical compounds, such as high temperature incineration. But for a product that relies on physical attractions or the action of a single chemical agent, a test protocol should at least examine performance on a representative range of

⁹¹ American Pharmaceutical Review. Pharmaceutical Excipients webpage. <https://www.americanpharmaceuticalreview.com/25335-Pharmaceutical-Raw-Materials-and-APIs/25283-Pharmaceutical-Excipients/>

⁹² Herwadkar *et al.* 2015, see test description under profile of Deterra in Section V.

pharmaceuticals. Methodologies for designing a thorough examination of different pharmaceutical classes⁹³ could include:

- Testing commonly used medicines in different pharmacologic classes, i.e. medicines with similar chemical structure of the API;
- Testing different therapeutic classes of pharmaceuticals based on their frequency of use; or
- Testing a mixture of medicines that consumers commonly return to a take-back programs based on medicine sorts.

Medicine sorts, or waste characterization, from medicine take-back programs demonstrate the wide range of household pharmaceuticals that are leftover and unwanted. A 2013 waste characterization of medicines collected in a drop box program at pharmacies and at police stations in San Francisco found pharmaceuticals in more than a dozen therapeutic classes, with more than 500 different APIs.⁹⁴ A study of prescription controlled substances returned to take-back events in six states between 2011-2015⁹⁵, found 66% opioids, 22% sedatives, and 5% stimulants in eight different drug categories.⁹⁶

Real world testing should also focus on product effectiveness with short mixing times and immediate trash disposal, per product directions. Available testing for several products showed a time course of the product's "reaction" with some pharmaceuticals. A "complete" reaction, as assessed by the manufacturer, may take several days, and in a few cases weeks. The products for in-home use instruct users to put the container in the trash immediately, except for the Drug Buster which advises a 2-hour waiting period.

Comprehensive analytical testing of product action. This review identified a range of performance questions about medicine disposal products (see Figure 1 and Section III.A.) In addition to testing real world usage, the design of analytical testing for medicine disposal products needs to examine both of the key product performance claims:

1. whether the product completely transforms pharmaceuticals to deter diversion or, more stringently, whether the transformation is complete and irreversible such that medicines are "non-retrievable", and
2. whether the resulting mixture of product and treated pharmaceuticals is non-toxic, non-hazardous, and appropriate for disposal in the solid waste system (for those products that recommend solid waste disposal).

To address the first question, the analytical assay needs to directly detect the tested pharmaceuticals to determine the extent of their physical sequestration or chemical degradation, or both. Testing of products that chemically degrade pharmaceuticals should characterize the breakdown products as part of assessing the toxicity of the resulting mixture. "Wash out" or liquid extraction tests to assess whether APIs are retrievable need to examine a range of solvents. The

⁹³ Drugs.com Drug Class Database. <https://www.drugs.com/drug-classes.html>

⁹⁴ San Francisco Dept. of the Environment & Teleosis Institute's S.F. Medicine Waste Characterization Study. 2013. <https://sfenvironment.org/download/san-francisco-medicine-waste-characterization-study>

⁹⁵ Jaramillo-Stametz, J.E., Stewart, H., Ochs, L., Payne, K. (2018) Multi-state medication take back initiative: Controlled substances collected from 2011 to 2015, J. Substance Use, 23:1, 36-42. <https://www.tandfonline.com/doi/full/10.1080/14659891.2017.1337821>

⁹⁶ This historical take-back data is valuable because the DEA's 2014 Rule on Final Disposal of Controlled Substances prohibits sorting medicines collected by pharmacies or other authorized collectors, as a diversion control. Law enforcement agencies may still conduct medicine waste sorts under their secure oversight.

effect of physical extraction methods, such as heat, steam, and pressure, should also be tested on products using adsorbent materials. Ultimately the DEA's formal review is needed to determine whether test data support a determination of "non-retrievable" destruction of controlled substances.

To address the second question, a complete waste determination needs to be performed on the product-drug mixture to assess whether APIs can leach out and whether the material is non-hazardous. Tap water extraction does not mimic landfill leaching conditions, rather an appropriate TCLP method or related regulatory assay methodology should be combined with detection of pharmaceutical compounds. Appropriate test methods for waste determination are defined by the EPA, by some state agencies, and may also be defined by local agencies, as overviewed in Section II and further described in Section III.F. It may be challenging for regulatory agencies to approve a medicine disposal product for use with all pharmaceuticals unless a waste determination has been performed with every pharmaceutical.

None of the available product testing examines both issues thoroughly, although the product manufacturers assert their testing is sufficient. Testing the disposal product material alone, without addition of any pharmaceuticals, does not address either question. Testing physical sequestration of medicines by the product does not provide a waste determination analysis. Performing a TCLP provides partial waste determination but does not address whether active APIs are leachable.

Other Recommendations

Improve consumer safety labelling and spill clean-up instructions. Medicine disposal products for in-home use should have clear warnings about avoiding any type of exposure to the product-drug mixture. Almost all of the products have some type of warning label with an emphasis on not ingesting and keeping out of reach of children. Warnings about dermal exposure need to be added because many people are unaware that pharmaceuticals such as opioids in liquid form can be absorbed through the skin in sufficient amounts to cause poisoning.

The products come in pouches or bottles, in liquid form or requiring addition of water, so spills or splashing are likely to occur with some frequency. Spill clean-up procedures should be clearly explained in product instructions, including steps such as using gloves, using a disposable absorbent material to clean up liquid spills, double-bagging the waste, and cleaning the spill area well with detergent.

Medicine disposal products containing ingredients that are chemically reactive, such as oxidizing agents, may create new exposure risks. As noted on a few product labels, foaming or gas production may occur when medicines are mixed with the product, especially if cautions not to add certain types of medicines are ignored. More information is needed on the properties and hazards of undisclosed disposal product ingredients, as well as on the resulting product-drug mixture. In contrast, potentially harmful chemical reactions are not a concern for consumers using a secure medicine take-back program or using inert agents like dirt or kitty litter or coffee grounds to disguise medicines for trash disposal per federal guidelines when no take-back program is available.

Align product use directions with federal disposal guidelines for household medicines. To conform with recommendations of the DEA, FDA, and EPA, medicine disposal products should be recommended and marketed for home use only in situations where a secure medicine take-back program is not available. Product manufacturers should quote complete guidelines of the federal

agencies, which 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. Focusing use of medicine disposal products to areas without authorized collectors and medicine take-back programs would also align with a 2017 report from The President's Commission on Combating the Drug Addiction and Opioid Crisis which recommended encouraging more pharmacies to become authorized collectors and exploring the use of "drug deactivation bags" especially in rural areas where authorized collectors are not nearby.⁹⁷

Across the country, local public health, law enforcement, and solid waste agencies are promoting the use of secure medicine take-back programs. Some local jurisdictions prohibit or discourage residents from disposal of waste pharmaceuticals in the household trash. Current marketing of medicine disposal products may complicate that message. Aligning product marketing with the federal agency medicine disposal guidelines will provide clearer and more consistent messaging to consumers.

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 dirt, kitty litter, or coffee grounds. By encapsulating most of the medicines or making the medicine mixture too unpleasant to ingest, the products may make illicit access to the medicines more difficult even if falling short of stated goals of making APIs fully non-retrievable. Other recommendations in this section on safety precautions and exposure risks for using these products must also be considered.

Suggestions have been made that a medicine disposal product could be used in combination with a secure medicine take-back program. A consumer could mix medicines with one of the in-home use products to prevent misuse or diversion prior to taking the medicines to a secure drop box location or collection event. Arguments against this approach are that it is an unnecessary step that creates greater cost to the consumer for the disposal product, as well as greater cost to the take-back program operator for disposal of the additional weight of the disposal product, which may be in liquid form. Additionally, a take-back program operator may be unwilling to accept medicines that were pre-treated with unidentified agents that may produce a chemical reaction. As an alternative approach, residents seeking additional security can use a reusable medicine lock bag⁹⁸ to transport unwanted medicines to a local take-back program.

Add solidifying agents or absorbents for liquid products. Six of the medicine disposal products reviewed are designed to be in liquid form, or a liquid slurry, after use and when put into the solid waste system: Deterra, Drug Buster, Element MDS, NarcX, The Pill Catcher, Rx Destroyer (if used without hardener). However, the plastic bottles or ziplock pouches are unlikely to ever make it to the landfill intact. They will burst or leak in the household trash can, the garbage compactor truck or during transloading at a transfer station. The pharmaceutical waste mixture may be released onto the street or transfer facility floor, potentially entering storm drains or sewers. Depending on the pharmaceuticals dissolved in the product, the spill may create an exposure hazard for solid waste workers. In this regard, these liquid disposal products are not preferable to solid deterrents like dirt, kitty litter, or coffee grounds.

⁹⁷ Final report of The President's Commission on Combating Drug Addiction and the Opioid Crisis. November 2017. <https://www.whitehouse.gov/ondcp/presidents-commission/>

⁹⁸ A variety of portable locking bags are available from Vaultz, LockMed, and many other vendors.

Free liquids, even if non-hazardous, are typically not accepted in household garbage and municipal landfills. Solidifying or absorbing agents need to be included with the liquid-based medicine disposal products to convert the pharmaceutical-product mixture to solid form. A solid form that does not allow any leaching of APIs under landfill conditions should be the standard.

Somewhat related products are sold to consumers in some states to solidify leftover latex paint for disposal in the household trash. Drying out the paint or using kitty litter are other approaches. Some jurisdictions have latex paint recycling programs which are a better option than landfill disposal. A key difference with pharmaceuticals however is that most modern latex paints designate as non-hazardous, while a mixture of pharmaceuticals has biological activity and may be toxic. The paint comparison also varies depending on the state or municipality. In California, latex (water-based) paint is banned from landfill disposal whether it qualifies as a hazardous waste or not.

Use in healthcare settings for diversion prevention, not final disposal. For healthcare facilities, pharmacies, and other regulated generators of pharmaceutical wastes, the appropriate use of these medicine disposal products depends on the specific pharmaceuticals to be disposed and the specific disposal requirements applicable in the facility's jurisdiction. Regulated generators should take special care to review all applicable regulations prior to solid waste disposal of unused pharmaceutical inventory. For disposal of controlled substance inventory, the DEA's regulations apply, and the DEA has not approved any medicine disposal product as an on-site destruction method that achieves the non-retrievable destruction standard.

Given both federal and state regulatory requirements, it appears most appropriate to use a medicine disposal product in the healthcare setting as a diversion prevention step in management of pharmaceutical wastage, especially for controlled substance wastage that might otherwise be sewered to prevent diversion. Under DEA regulations and the EPA's new conditional exemption for hazardous waste pharmaceuticals that are also controlled substances, pharmaceutical wastage can be collected in a container at a healthcare facility prior to final disposal. In its new rule language, EPA "strongly recommends that any container that is used to collect pharmaceutical wastage that will include DEA controlled substances contain some sort of absorbent or chemical reactant in order to bind or chemically alter the contents and thus deter the diversion of the collection container for controlled substance recovery."⁹⁹

This still leaves the determination of how a container of mixed pharmaceutical wastage should be properly destroyed. If any hazardous waste pharmaceuticals are in the mix, then EPA's regulations require proper hazardous waste disposal under RCRA. State or local disposal requirements may apply even if the pharmaceuticals are non-hazardous, with many states defining additional waste determination criteria or prohibiting solid waste disposal for any type of pharmaceutical. Given the EPA's recommended management of non-hazardous pharmaceuticals, disposing of a used medicine disposal product in the solid waste system should be a last option, and only if allowable under federal, state, and local regulations. Stericycle's CsRx System and Stryker's Cactus Smart Sink are focused on collection of pharmaceutical wastage in the healthcare setting, and these products provide or recommend final disposal by incineration at appropriate facilities.

⁹⁹ EPA Final Rule on Hazardous Waste Pharmaceuticals. Full citation in footnote 17. See page 5901.

Define appropriate regulatory oversight for medicine disposal products. Medicine disposal products represent a new on-site treatment technology that should be regulated to protect human health and environmental quality, as well as to define appropriate standards for effectiveness and performance claims. Some of these products have been on the market for many years, with no apparent regulatory oversight. Recently, marketing and distribution of some products for in-home use has expanded rapidly through partnerships between product manufacturers and major pharmacy chains.

Products for home use currently fall into a federal regulatory gap because home-generated pharmaceutical wastes and disposal of controlled substances by patients are exempted from regulations of the EPA and DEA, respectively. These exemptions were intended to allow residents to dispose of medicines in the household trash when there is no other medicine disposal option available. It is a different issue to extend such regulatory exemptions to disposal products marketed to consumers that promote trash disposal of medicines based on unproven claims of altering pharmaceuticals such that they are inaccessible and safe for trash disposal.

Some federal review appears to be in the works. The 2018 SUPPORT for Patients and Communities Act, an omnibus bill addressing the opioid abuse epidemic, includes a section providing FDA with authority to require that dangerous pharmaceuticals are dispensed with safe disposal packaging or a safe disposal system that renders the drug non-retrievable per the DEA standard.¹⁰⁰ A return mailer would be an example of existing technology providing established non-retrievable disposal. Potentially a medicine disposal product meeting the DEA's strict non-retrievable standard could be such a disposal technology. The law also directs the General Accounting Office (GAO) to submit a report to Congress in 2019 that examines the effectiveness of in-home controlled substance disposal products and packaging technologies, including a review of existing and needed federal oversight of these products.

Local authority should be respected in development of a regulatory framework for medicine disposal products, both for consumer use and healthcare sector use. Federal solid waste disposal regulations, including hazardous waste regulations under RCRA, recognize state, tribal, and local authority to establish and enforce more stringent regulations and waste acceptance policies for their solid waste systems and local needs. Currently, medicine disposal product manufacturers put responsibility for local regulatory compliance on product users and on the government agencies. Statements made by some product manufacturers to the author suggest they are unaware of differing state and local regulatory requirements or are not fully informed about how to perform waste determinations.

Many state and local agencies have questions and concerns about use of medicine disposal products and yet lack sufficient information to make determinations that allow enforcement of local laws or disposal guidances. Until appropriate regulatory authority and standards are defined, medicine disposal product manufacturers and retailers should voluntarily comply with requests of local authorities not to market the products where their use conflicts with local waste acceptance policies or local medicine disposal guidances.

¹⁰⁰ H.R.6 (2018) SUPPORT for Patients and Communities Act. Title III. FDA and Controlled Substances Provisions. Section 3032. Safety-enhancing packaging and disposal features. <https://www.congress.gov/bill/115th-congress/house-bill/6/text>

V. Medicine Disposal Product Profiles

Each product description provides a summary of information available from the manufacturer’s website, promotional materials, and product labels as of February 2019. These sources may have been updated or changed after this date. Additional information provided by manufacturers who responded to the author’s query letter is also summarized. Further summaries and analysis of available product testing is provided in Section III of this report.

Products for Consumers, Healthcare Facilities, and Others

Deterra	56
DisposeRx	65
Drug Buster	69
Element MDS	72
NarcX.....	75
Pill Catcher	79
Pill Terminator	82
Rx Destroyer and Narc Gone HD	85

Products for Healthcare Facilities Only

Cactus Smart Sink.....	89
CsRx System.....	91

Deterra

deterrasystem.com

Verde Technologies, Inc.
12900 Whitewater Drive, Suite 200, Minnetonka, MN 55343
(612) 568-1128

Product Overview

Manufacturer’s website FAQ states, “Each patented Deterra pouch contains a water-soluble inner pod containing proprietary MAT12® activated carbon. Once the drugs are placed in the pouch, warm water is then added, which dissolves the inner pod releasing the activated carbon. Deterra works on pills, patches and liquids, allowing them to be adsorbed by the carbon, rendering them inert and non-retrievable.”

Directions

1. Put unused medications in pouch.
2. Fill pouch halfway with warm tap water and wait 30 seconds.
3. 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.”

If the user exceeds the recommended number of pills, liquids, or patches, Deterra states “deactivation of additional drugs will still occur but at reduced efficiency.”

Size	Maximum Pills	Maximum Liquid	Maximum Patches	Unit Cost
SP	15	60 mL (2 oz)	2	\$4.99; sold in 3-pack
MP	45	180 mL	6	\$5.99; sold in 3-pack
LP	90	360 mL	12	\$6.99; sold in 3-pack
XL	450	1.8 L	60	~ \$34.99
3.5	1,800	6.0 L	185	
5.0	2,000	9.5 L	265	

Deterra was originally marketed by Verde as Medsaway.

Label Safety Warnings

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

FAQs state, “As an additional safety precaution, it is important to keep Deterra out of the reach of children and pets as the medication is deactivated.”



Intended Users

Home and Healthcare.

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

Manufacturer List Price

\$4.99-\$6.99 per unit for consumer sized pouches. Approximately \$34.99 for XL size (see chart).

Contact Deterra for pricing for 6 L and 9.5 L sizes, or bulk purchase prices.

How Product Sold or Distributed

Manufacturer’s website

Amazon.com

Pharmacies

Medical supply retailers

Manufacturer's Performance Description

The manufacturer's website states, "Patented, proprietary activated carbon bonds to pharmaceutical compounds, rendering drugs ineffective and safe for disposal." Also, "renders chemical compounds safe for landfills".

Deterra's FAQs state, "With Deterra, the process of deactivation starts immediately, but it takes time to complete. Some highly soluble drugs will dissolve and adsorb rapidly, while other less soluble drug types will take longer to dissolve and adsorb. The deactivation period varies based on volume and type of medication. As an additional safety precaution, it is important to keep Deterra out of the reach of children and pets as the medication is deactivated."

Product Ingredients

Activated carbon: patented MAT₁₂® Molecular Adsorption Technology. The carbon is in a water-soluble polyvinyl alcohol pod inside a pouch.

Deterra's website provided a MSDS from Norit Americas Inc. for Activated Carbon.¹⁰¹ Under toxicological and ecological information this MSDS states "This material is non-toxic in its original state. Used activated carbon may exhibit characteristics of the absorbed material."

Packaging: Black plastic pouch with single ziplock-type seal. 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 described as a "recycled material". Verde's letter to the author states they plan to shift to a plant-based packaging in 2019 that is 70% biobased and USDA certified.

Mechanism of Action

Verde Technologies describes Deterra's mechanism of action as physical adsorption of pharmaceuticals to activated carbon. Verde states, "Pharmaceuticals are not chemically transformed" and "pharmaceuticals are physically bound to the internal surfaces of activated carbon by intermolecular London Dispersion forces (a form of Van Der Waal's forces)", in a response letter to the author. Verde's letter also describes adsorption as "permanently deactivating, destroying, and disposing of" the pharmaceuticals.

In their test descriptions, publications, and marketing materials, the authors of Deterra's publications use the term "deactivated" to refer to the adsorption of pharmaceuticals to activated carbon.¹⁰²

Test Results

Product testing information on Deterra is organized and summarized in this section to assist readers in assessing what is known about product performance. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. Review of the complete technical reports or publications, where available, will provide additional details. The product manufacturer may have additional test information that was not known to the author in this review.

Analyses of Deterra's performance in adsorbing pharmaceuticals were conducted by Verde

¹⁰¹ Norit. Activated Carbon. Material Safety Data Sheet. Available from Deterra website in March 2017.

¹⁰² 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. <https://www.mdpi.com/1999-4923/8/4/31>

Technologies’ scientific staff and by researchers in the laboratory of Dr. Ajay Banga, Chair and Professor of Pharmaceutical Sciences, Mercer University (Atlanta) through funding from a National Institute of Drug Abuse (NIDA) Small Business Innovation Research grant to Verde. Three of four peer-reviewed journal publications on Deterra, as well as two unpublished poster presentations, resulted from the NIDA grant research. In response to the author’s query letter, Verde provided a letter of explanation as well as hard copies of all studies and publications available from its website.

Test methods: Carbon adsorption and desorption were measured by detecting free pharmaceutical in the liquid “phase” of the pouch using high performance liquid chromatography (HPLC) and ultraviolet-visible spectroscopy (UV/Vis) at the API’s signature wavelength, or by UV/Vis alone. The spectroscopic peak size was typically compared to a standard curve determined by measurements on pure API (not dosage form) and the amount expressed as the percentage adsorbed of the total amount of API. In these studies, the authors commonly use the term “deactivated” to refer to the adsorption of pharmaceuticals to Deterra’s activated carbon.

The following tables provide summaries of Verde’s NIDA grant report followed by summaries of 2 unpublished studies and 4 publications in chronological order.

Deterra Test	Grant Report to NIDA - In-Home Deactivation System for Psychoactive Drugs	
Date	September 2016	
Analysis By	Verde Technologies staff scientists and Mercer University researchers. Funded by a NIDA Small Business Innovation Research grant.	
Scientific Report Availability	Full grant report available from Deterra website; not peer-reviewed. Report includes experimental data, standard curves, and HPLC validation data for Mercer University’s studies. Data from Verde’s scientists is presented only as a summary table and Verde’s letter states no further analytical data is available. https://deterrasystem.com/wp-content/uploads/2018/03/NIDA-Final-Report.pdf	
Drugs & Dosage Forms Tested	20 controlled substances, each medicine tested individually in their common dosage form, including tablets, capsules, films, patches, and liquids.	
	alpraxalone (10 tablets; 2 mg ea.) buprenorphine (10 films, 8 mg ea.) dextroamphetamine (10 tablets, 10 mg ea.) diazepam (10 tablets, 10 mg ea.) Endocet (10 tablets, 10 mg oxycodone/ 325 mg acetaminophen ea.) fentanyl (2 patches, 1.38 mg ea.) fluoxetine (10 tablets, 20 mg ea.) hydromorphone (10 tablets, 4 mg ea.) ketamine (10 mL liquid, 500 mg API) lorazepam (10 tablets, 2 mg ea.)	loxapine (10 tablets, 200 mg ea.) meperidine (10 tablets, 50 mg ea.) methadone (10 tablets, 10 mg ea.) methylphenidate (10 tablets, 20 mg ea.) morphine (20 mL containing 300 mg API) OxyContin (10 tablets, 10 mg ea.) quetiapine (10 tablets, 100 mg ea.) temazepam (10 capsules, 30 mg ea.) tramadol (10 tablets, 50 mg ea.) zolpidem (10 tablets, 5 mg ea.)
Test Protocol Summary	<p>Adsorption Test: Each of 20 medicines, tested separately, were added to Deterra SP pouches (15 g carbon) with 50 mL warm tap water and shaken 5 times. Amount free API measured in samples taken at 8 hours, and 1, 2, 4, 7, 14, 21, 28 days.</p> <p>Desorption (Wash-Out) Test: After 28 days, each pouch washed with 200 mL tap water, with rocking for 1 hour, followed by standing for 23 hours, then shaking before a sample was taken. The pouch contents were then washed with 250 mL 30% ethanol, with rocking for 1 hour, then standing for 23 hours, then shaking before a sample was taken.</p> <p>API Detection Method: Mercer University researchers used HPLC with UV/Vis at each API’s signature wavelength with quantitation based on standard curves from measurements of pure API. Verde scientists used UV/Vis alone.</p>	

Deterra Test	Grant Report to NIDA - In-Home Deactivation System for Psychoactive Drugs
Test Results Summary	<p>Adsorption Results: After 8 hours, adsorption of the 20 APIs ranged from 46.3% (diazepam) to 99.9%, with an average of 89.1% for all drugs. After 1 day, adsorption ranged from 50.8% (diazepam) to 100%, with an average of 99.6%. After 28 days, 100% adsorption was observed for 16 of the 20 medicines tested. 4 medicines showed detectable “free” API, slightly less than 100% adsorption: diazepam (99.3%), fluoxetine (94.4%), quetiapine (99.6%), and temazepam (99.3%).</p> <p>Fentanyl Patch Adsorption Results: Patches described as a "special case" because the sticky patch could adhere to the pouch or to itself, interfering with the "deactivation process". Patch’s sticky side had to be covered with a Kimwipe tissue. Observed 100% of fentanyl adsorbed after 1 day. Wash-out of the treated patch after 28 days did not release detectable fentanyl.</p> <p>Desorption (Wash-Out) Results: Tap water wash of the Deterra pouches released small amounts of oxycodone (0.1%), methadone (0.2%), lorazepam (0.3%), and diazepam (1.0%). A second 30% ethanol wash released additional amounts of 15 of the 20 APIs tested, from 0.1% for buprenorphine to high values of 6.5% for ketamine and 9.4% for dextroamphetamine.</p>

Deterra Test	Deterra System Deactivation of Unused Drugs: Comparison between Deterra Ingredients and Others Recommended in Federal and SmartRx Disposal Guidelines.														
Date	Oct. 2012 (updated in 2017 to call product Deterra instead of MedsAway)														
Analysis By	Verde Technologies scientist (Fowler)														
Scientific Report Availability	Summary linked from Deterra website, but complete technical report not available. Verde’s letter explains that this study was not published and "additional analytical data are not available." https://deterrasystem.com/wp-content/uploads/2017/01/White-Paper-updated-1-3-17.pdf														
Drugs & Dosage Forms Tested	<p>12 medicines, tested individually, in tablet or coated tablet dosage forms:</p> <table border="0"> <tr> <td>amoxicillin (10 tablets, 250 mg ea.)</td> <td>naproxen sodium (10 tablets, 220 mg ea.)</td> </tr> <tr> <td>aspirin (10 enteric coated tablets, 250 mg ea.)</td> <td>omeprazole magnesium (10 enteric coated tablets, 20.6 mg ea.)</td> </tr> <tr> <td>dexamethasone (10 tablets, 4 mg ea.)</td> <td>venlafaxine HCl (10 tablets, 75 mg ea.)</td> </tr> <tr> <td>diphenhydramine (10 tablets, 25 mg ea.)</td> <td>generic Vicodin (10 tablets; 10/325 mg ea.)</td> </tr> <tr> <td>duloxetine HCL (10 enteric coated tablets, 60 mg ea.)</td> <td>generic Percocet (10 tablets, 5/325 mg ea.)</td> </tr> <tr> <td>ibuprofen (10 tablets, 200 mg ea.)</td> <td></td> </tr> <tr> <td>ketoprofen (10 tablets, 75 mg ea.)</td> <td></td> </tr> </table>	amoxicillin (10 tablets, 250 mg ea.)	naproxen sodium (10 tablets, 220 mg ea.)	aspirin (10 enteric coated tablets, 250 mg ea.)	omeprazole magnesium (10 enteric coated tablets, 20.6 mg ea.)	dexamethasone (10 tablets, 4 mg ea.)	venlafaxine HCl (10 tablets, 75 mg ea.)	diphenhydramine (10 tablets, 25 mg ea.)	generic Vicodin (10 tablets; 10/325 mg ea.)	duloxetine HCL (10 enteric coated tablets, 60 mg ea.)	generic Percocet (10 tablets, 5/325 mg ea.)	ibuprofen (10 tablets, 200 mg ea.)		ketoprofen (10 tablets, 75 mg ea.)	
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ibuprofen (10 tablets, 200 mg ea.)															
ketoprofen (10 tablets, 75 mg ea.)															
Test Protocol Summary	<p>Adsorption Test: Each of 12 medicines, separately, were added with 80 mL tap water to Deterra pouches (15 g carbon), and to pouches containing 15 grams each of coffee grounds, cat litter (Roundy’s brand), and sawdust. Blank pouches contained drugs without any adsorbent material. Pouches were shaken once per day; samples taken after 7 days.</p> <p>Desorption (Wash-Out) Test: For 9 of the medicines (not the 3 medicines with enteric coated tablets), contents of each pouch washed with 250 mL tap water with 1 hour of mixing. Samples taken the next day.</p> <p>API Detection Method: UV/Vis at each API’s signature wavelength. Complete methodology, experimental data, and standard curves are not reported.</p>														
Test Results Summary	<p>Adsorption Results: The summary provides “deactivation” results in percentages, without any raw data, that may represent a combination of the results of the adsorption and wash-out tests. Deterra carbon: 98.7% average adsorption for 9 APIs, with a range from 94.3% to 100%. 3 enteric coated dosage forms (aspirin, duloxetine, and omeprazole) were 99.5% adsorbed on average.</p> <p>Coffee grounds: 16.0% average adsorption for 9 drugs, with range from 0% to 49.2%.</p> <p>Cat litter: 25.5% average adsorption for 9 APIs, with range from 0% to 83.6%.</p>														

Deterra Test	Deterra System Deactivation of Unused Drugs: Comparison between Deterra Ingredients and Others Recommended in Federal and SmartRx Disposal Guidelines.
	Sawdust: 27.7% average adsorption for 9 APIs, with range from 0% to 67.7%. Diphenhydramine and venlafaxine (Effexor) were much better adsorbed by all materials, with cat litter adsorbing 83.6% of the diphenhydramine and 87.4% of the Effexor. Ketoprofen and dexamethasone also somewhat better adsorbed by all materials.
Deterra Test	Deterra Activated Carbon Retention of Pharmaceuticals Using the TCLP Extraction Solution.
Date	2013
Analysis By	Verde Technologies scientists (Fowler and Anderson)
Scientific Report Availability	Summary linked from Deterra website, but complete technical report not available. Verde's letter explains that this summary was not published and "additional analytical data are not available." https://deterrasystem.com/wp-content/uploads/2018/03/Deterra-with-TCLP-Extraction-Solution.docx.pdf
Drugs & Dosage Forms Tested	3 OTC pain relievers, tested individually, in tablet form. acetaminophen (6 tablets, 500 mg ea.) ibuprofen (10 tablets, 200 mg ea.) naproxen sodium (10 tablets, 220 mg ea.)
Test Protocol Summary	<u>Adsorption Test:</u> Each of 3 medicines, tested separately, added to Deterra pouches (size not stated, but appears to be 15 g carbon pouch) with ~ 50 mL warm tap water. After 5 days, samples taken for analysis of free APIs in liquid "phase", then the carbon was dried. Portland Cement, in "paste" form, was solidified with each of the 3 medicines individually, for same time period, then crushed. <u>Desorption (Wash-Out) Test:</u> The dried Deterra carbon (15 g) and crushed Portland cement (100 g) were each extracted with ~300 mL 0.1 N acetic acid (pH 4.93) with rocking for 18 hours. This weak acid solution is the same as Extraction Fluid #1 of TCLP Method 1311; however, the EPA TLCP method was not fully followed. <u>API Detection Method:</u> UV/Vis at each API's signature wavelength. Complete methodology, experimental data, and standard curves are not reported.
Test Results Summary	<u>Adsorption Results:</u> Author reports 99.7% adsorption of acetaminophen, and 100% adsorption of ibuprofen and naproxen by Deterra after a 5 day incubation. <u>Desorption (Wash-Out) Results:</u> Washing the Deterra carbon with weak acid released no detectable acetaminophen or ibuprofen. Weak acid released 0.21% of naproxen. Washing the crushed Portland cement released 65.4% to 88.8% of each API, which is explained as result of "direct exposure of the drug when the cement cracks." Verde's letter to the author also states they have unpublished data (not provided in this summary) that warfarin, a hazardous pharmaceutical, "is retained by Deterra when exposed to the TCLP extraction solution."
Deterra Test	Development of disposal systems for deactivation of unused/residual/expired medications. Herwadkar A., Singh N., Anderson C., Korey A., Fowler W., Banga A.K. Pharmaceutical Research 2015. 33(1):110-24.
Date	2015
Analysis By	Mercer University researchers and Verde Technologies scientists. Funded by Travanti Pharma, now owned by Teikoku Pharma.
Scientific Report Availability	Published in Pharmaceutical Research, peer-reviewed publication of the American Association of Pharmaceutical Scientists. Abstract linked from Deterra website; journal access needed for full article. Deterra website provides related preliminary data in two unpublished posters by Herwadkar <i>et al.</i> and Singh <i>et al.</i> from the 2012 conference of the

Deterra Test	Development of disposal systems for deactivation of unused/residual/expired medications. Herwadkar A., Singh N., Anderson C., Korey A., Fowler W., Banga A.K. Pharmaceutical Research 2015. 33(1):110-24.
	American Association of Pharmaceutical Scientists. https://www.ncbi.nlm.nih.gov/pubmed/26264512
Drugs & Dosage Forms Tested	4 pure APIs and 3 dosage form drugs tested individually. Pure API tested were 250 mg each in 100 mL of water: amoxicillin, dexamethasone sodium phosphate, ketoprofen (solubilized with NaOH), and metformin. Dosage forms tested were: amoxicillin (30 capsules, 250 mg ea.); dexamethasone (30 tablets, 4 mg ea.), and Duragesic patches (12.5 ug/hour containing 2.1 mg fentanyl).
Test Protocol Summary	<p><u>API Adsorption Test:</u> Separately tested adsorption or degradation of 250 mg of 4 pure APIs in pouch with 100 mL water by each material:</p> <ul style="list-style-type: none"> • two Verde activated carbons (Carbon 1 and Carbon 2; tested 1, 2, and 3 g each), • zeolite (adsorbent rock/minerals; tested 1, 2, and 3 g), • sodium percarbonate (3 g; oxidizer), • sodium carbonate (3 g; hydrolyser), • percarbonate with 3g Carbon 1 or 3 g Carbon 2, • dry cat litter (45 g, Roundy's brand, containing zeolite), and • dry coffee grounds (45 g). <p>Samples taken after 1 hour, 1 day and 7 days incubation with shaking.</p> <p><u>Dosage Form Adsorption Test:</u> Separately tested adsorption of dexamethasone tablets or amoxicillin capsules in 240 mL warm water for 7 days with 45 grams of 4 adsorbents: the Verde carbons (2 samples), or dry kitty litter, or dry coffee grounds. Control pouches contained 5 pills or capsules of each medicine in water without any adsorbent material</p> <p><u>Desorption (Wash-Out) Test:</u> Pouch contents washed by adding distilled water to 3,800 mL volume, with 4 hours shaking and "overnight" standing.</p> <p><u>Fentanyl Patch Adsorption Test:</u> Tested Verde's Contra Patch product (a carbon fabric not on market) for treatment of a fentanyl patch. Amount of fentanyl remaining in the patch after removal from the Contra Patch system was measured at 8, 24, 48, and 96 hours, and compared to a control patch in 250 mL water alone.</p> <p><u>API Detection Method:</u> HPLC with UV/Vis at API's signature wavelength. Did not attempt to characterize any chemical breakdown products produced by the oxidizing or hydrolyzing agents tested.</p>
Test Results Summary	<p><u>Pure API Adsorption Results:</u> Verde Carbon 1 with larger pore size was more efficient than Carbon 2. After 7 days incubation with 3 g Carbon 1, no detectable ketoprofen or dexamethasone, and less than 0.5% amoxicillin remained free in the liquid "phase". Metformin was not well adsorbed by Carbon 1, with 84% unadsorbed after 1 day and 60% unadsorbed after 7 days. The authors conclude that metformin's molecular properties cause it to prefer the water phase to adsorbing on the carbon. Combining Carbon 1 with sodium percarbonate was more effective in reducing the amount of unadsorbed metformin to 12% after 7 days.</p> <p>The oxidizing agents sodium percarbonate and sodium carbonate were not effective in "deactivating" 3 of the 4 APIs which remained almost entirely in the liquid "phase" after 7 days. Amoxicillin was oxidized by both agents with no detectable API after 1 day. Zeolite partially adsorbed 2 of the 4 APIs, with 20% of the ketoprofen and 12% of the amoxicillin still detectable after 7 days. Zeolite did not adsorb any metformin and 60% of the dexamethasone was still free/unadsorbed after 7 days.</p> <p><u>Dosage Form Adsorption Results:</u> After 7 days, pouches with 30 dexamethasone pills showed no detectable soluble API in the carbon samples, 15% in coffee grounds, and 18% in cat litter. After 7 days, treatment of 30 amoxicillin capsules showed less than 0.018% soluble API in the carbon samples, 16% in the coffee grounds, and 18% in the cat litter. However, the dexamethasone tablets and amoxicillin capsules did not completely dissolve</p>

Deterra Test	Development and validation of an HPLC-UV Method of Analysis of Methylphenidate Hydrochloride and Loxapine Succinate in an Activated Carbon Disposal System. Bakshi, P., Korey, A. Fowler, W. Banga, A.K. J. Pharmaceutical Analysis 2018. 8: 349-356.
Analysis By	Mercer University researchers and Verde Technologies scientists. Funded by Verde Technologies under NIDA grant.
Scientific Report Availability	Full article is linked from the Deterra website and in the open access, peer reviewed Journal of Pharmaceutical Analysis, a publication of the Xi'an Jiaotong University (China). https://doi.org/10.1016/j.jpha.2017.12.002
Drugs & Dosage Forms Tested	2 controlled substance medicines, tested individually, in tablet and capsule form. loxapine succinate (10 capsules; 20 mg ea.), and methylphenidate hydrochloride (10 tablets; 20 mg ea.).
Test Protocol Summary	<u>Adsorption Test:</u> Each medicine tested separately in the Deterra small pouches (15 g carbon) with 50 mL warm tap water. Samples taken at 8 hours and 1, 2, 4, 7, 14, 21, and 28 days. Pouch shaken before a sample was taken. <u>Desorption (Wash-Out) Test:</u> After 28 days, pouch contents washed with 200 mL tap water, with rocking for 1 hour, followed by standing for 23 hours. Pouch shaken before a sample was taken. Pouch contents then washed again with 250 mL 30% ethanol, with rocking for 1 hour, then standing for 23 hours. Pouch shaken before a sample was taken. <u>API Detection Method:</u> HPLC with UV/Vis at API's signature wavelength. Quantitation based on standards prepared from pure API.
Test Results Summary	<u>Adsorption Results:</u> Time course showed 96.9% of the loxapine was adsorbed by 8 hours and 100% by 14 days. 99.9% of the methylphenidate was adsorbed by 8 hours and 100% by 1 day. <u>Desorption (Wash-Out) Results:</u> No detectable amount of either API was measured in the tap water wash. The second 30% ethanol wash also did not release detectable amounts of loxapine, but 1% of the methylphenidate was released. <u>API Detection Method Validation:</u> HPLC-UV/Vis. The article focuses on method validation showing representative chromatograms, standard curves, and experimental detection limits. The authors state that inactive ingredients (excipients) in the dosage forms do not interfere with detection of API.

Deterra Test	Evaluation of an activated carbon-based deactivation system for the disposal of highly abused opioid medications. Gao X., Bakshi P., Ganti S.S., Manian M., Korey A., Fowler W., Banga A.K. Drug Development and Industrial Pharmacy 2018. 44(1):125-134.
Date	2018
Analysis By	Mercer University researchers and Verde Technologies scientists. Funded by Verde Technologies under NIDA grant.
Scientific Report Availability	Published in Drug Development and Industrial Pharmacy, a peer-reviewed journal. Abstract linked from Deterra website; journal access needed for full article. https://doi.org/10.1080/03639045.2017.1386199
Drugs & Dosage Forms Tested	4 controlled substance medicines, tested individually, in tablet and liquid form. hydromorphone HCl (10 tablets, 4 mg ea.) methadone HCl (10 tablets, 10 mg ea.) meperidine HCl (10 tablets, 10 mg ea.) morphine sulfate (20 mL liquid, 300 mg)
Test Protocol Summary	<u>Adsorption Test:</u> Individually tested 4 medicines in Deterra small pouches (15 g carbon) with 50 mL warm tap water. Samples taken at 8 hours and 1, 2, 4, 7, 14, 21, and 28 days. <u>Desorption (Wash-Out) Test:</u> After 28 days, pouch contents washed with 200 mL tap water, with rocking for 1 hour, followed by standing for 23 hours, then a sample was taken. Pouch contents were then washed again with 250 mL 30% ethanol, with rocking for 1 hour, then standing for 23 hours, then a sample was taken. Authors state duplicate pouches were used "in case of any spillage during handling of the pouches or accidental rupture of the pouch".

Deterra Test	<p>Evaluation of an activated carbon-based deactivation system for the disposal of highly abused opioid medications. Gao X., Bakshi P., Ganti S.S., Manian M., Korey A., Fowler W., Banga A.K. Drug Development and Industrial Pharmacy 2018. 44(1):125-134.</p>
Test Results Summary	<p><u>API Detection Method:</u> HPLC with UV/Vis at API's signature wavelength. Standards for each medicine prepared from purified API in distilled water. This article provides example chromatograms for each API tested.</p> <p><u>Adsorption Results:</u> Results show 99.99% adsorption of each of the 4 APIs by 28 days; with maximum adsorption achieved by 4 days. Morphine and hydromorphone were adsorbed faster than methadone and meperidine.</p> <p><u>Desorption (Wash-Out) Results:</u> Washing with tap water released a small percentage methadone (0.20%), and none of the other APIs. Washing with 30% ethanol released an additional 0.52% of morphine, 0.25% of methadone, 0.50% of hydromorphone, and 1.4% of meperidine. Authors describe these desorption conditions as representative of landfill leaching, but do not comment on pH or other differences with landfill conditions.</p>
Product Capacity Determination	<p>Deterra directions state a medicine capacity limit for each product size, for example: 15 pills or 2 oz liquid or 2 patches for the SP pouch. In response to author's query letter, Verde states the product capacity was determined by internal study results that 15 g of activated carbon was sufficient to "deactivate" 20 pills with API content ranging from 4-325 mg per tablet, or 2 ounces of "common household liquid medication", or 2 transdermal patches. Stated directions for the Deterra SP pouch containing 15 g carbon were adjusted to 15 pills. Capacities for other sizes of Deterra were scaled to this determination. Further detail not provided.</p>

This profile of Deterra is based on descriptions from the manufacturer's website and promotional materials as of February 14, 2019, and additional materials provided by Verde Technologies, Inc in December 2018.

DisposeRx Inc.
503 Carthage Street, Suite 202, Sanford, NC 27330
(844) 456-1600

Product Overview

Manufacturer’s website states, “DisposeRx packets contain a blend of patented and proprietary solidifying materials that provide a safe solution for the disposal of unused or expired medications. When water and the DisposeRx powder are added to drugs in the prescription vial and shaken, the drugs are dissolved and then chemically and physically sequestered in a viscous polymer gel made from materials that are FDA approved for oral medications.”

Directions

- Open prescription vial.
- Add warm tap water until vial is up to 2/3 full.
- Add DisposeRx powder to prescription drug vial.
- 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”

Package states, “Local medication disposal regulations may vary. The average pill count is 25 pills or 1/3 vial per packet depending on the pill or vial size. For large vials consider using additional packets of DisposeRx.”

Label Safety Warnings

Packet states, “Do not ingest or inhale. Not for use with sharps. Keep out of reach of children and pets.”

Manufacturer’s Performance Description

Manufacturer’s website states, “DisposeRx treatment both chemically and physically sequesters medications in a viscous gel, which eliminates the opportunity for drug diversion and prevents the pollution of water supplies.”

The website’s Education section states, “We have developed a powder that contains cross-linking polymers that when combined with water, renders drugs unavailable and unusable for practical purposes”, then describes the DEA’s non-retrievable standard for the disposal of controlled substances.

Product Ingredients

DisposeRx materials describe the active ingredient as a “patent



Intended Users

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

Manufacturer List Price

- Box of 6 single-use packets \$9.85
 - Box of 30 packets \$33.40
 - Box of 100 packets \$127.04
 - Box of 600 packets - \$646.00
- Prices above from Wal-Mart online as of early Feb. 2019.

How Product Sold or Distributed

Wal-Mart
Distributed with opioid prescriptions through contractual agreements with Wal-Mart, Rite Aid, Kroger, and Humana (as of Dec. 2018 per DisposeRx press releases).

pending cross-linking polymers". The packet label states, "Contains 2 g. (0.071 oz) of non-toxic polymers." A response letter from DisposeRx states the ingredients are proprietary, but "every ingredient in DisposeRx powder is on the *FDA Inactive Ingredient* list and is approved for use in oral medications and food." The "Pharmacists One Sheet" material also states DisposeRx is "made of components often used in manufacturing drugs and in food."¹⁰³

The DisposeRx patent application for disposal of medicaments¹⁰⁴ provides a general description of cross-linking polymer agents that will form a gel or mass and states that an acid or base might also be added to degrade the medicine. Examples of potentially sequestering polymers are polyvinyl alcohol, carrageenans, alginates, and chitosans.

Packaging: Individual plastic packets of DisposeRx are sold in a cardboard box. Manufacturer's website states some sizes of the product are provided in "biodegradable bags".

Mechanism of Action

The DisposeRx website and materials state the product "chemically and physically sequesters medications in a viscous gel." Manufacturer's documents state that "DisposeRx cannot be rehydrated and will become stronger as it dries, allowing the pharmaceutical contained in it to completely degrade within the polymer network".

The DisposeRx "Scientific Testing Summary" also references microbial breakdown of the mixture: "Because of their biological origin, these components serve as a medium for the growth of molds and bacteria found in the air and in landfills. Within weeks to months, molds or bacteria promote the biodegradation of the gel and the drug contents, resulting in the release of harmless gases such as carbon dioxide as the components dry up."

Test Results

Product testing information on DisposeRx is organized and summarized in this section to assist readers in assessing what is known about product performance. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. Review of the complete technical reports or publications, where available, will provide additional details. The product manufacturer may have additional test information that was not known to the author in this review.

DisposeRx's "Corporate One Sheet" materials states: "Several independent laboratories have provided third-party, independent validation of the science of DisposeRx as an efficient drug disposal solution that will not harm the environment.", but these test results are not provided on the DisposeRx website.

In response to the author's query letter, DisposeRx's Director of Training and Science explained that test results are proprietary but provided a 5-page "DisposeRx and the Environment" document and a 3-page "Scientific Testing Summary" document. These provide brief non-technical descriptions of waste determinations on the DisposeRx product alone without any medicines, and as well as some

¹⁰³ In 2017 the DisposeRx website stated the mixture of medicines and polymer are "safe if accidentally ingested with or without sequestered drugs" and that the mixture would be excreted in the feces. As of February 2019, these statements were no longer on the DisposeRx website.

¹⁰⁴ U.S. Patent Application Number US20180001357A1 "Disposal of medicaments". 2016, patent pending. <https://patents.google.com/patent/US20180001357A1>

testing of whether pharmaceuticals can be extracted from the DisposeRx gel. These tests are summarized below based on those descriptions.

DisposeRx Test	EPA Toxicity Characteristic Leaching Procedure (TCLP) on DisposeRx Product (No Medicines)
Date	Unknown.
Analysis By	Elemental Analysis Inc.
Scientific Report Availability	No, proprietary information.
Drugs & Dosage Forms Tested	None. Test was on the DisposeRx material alone.
Test Protocol Summary	DisposeRx sample was processed per EPA TCLP Method 1311 and tested for presence of metals per EPA Method 6010C, mercury per EPA Method 7470, and VOCs per EPA Method 8260C. ¹⁰⁵
Test Results Summary	Testing of DisposeRx material (without pharmaceuticals) found “no leachable VOCs or metals”.

DisposeRx Test	Washington State Hazardous Waste Designation Bioassay on DisposeRx Product (No Medicines)
Date	Unknown.
Analysis By	Unidentified “independent laboratory”
Scientific Report Availability	No, proprietary information.
Drugs & Dosage Forms Tested	None. Test was on the DisposeRx material alone.
Test Protocol Summary	Non-technical summary states a 96-hour Static Acute Fish Toxicity Test was conducted to determine the toxicity of waste material under WA State’s Dangerous Waste Regulations, WAC 173-303. ¹⁰⁶ Fish species tested was not identified.
Test Results Summary	Dispose Rx material (without pharmaceuticals) found to be “non-toxic and non-hazardous.”

DisposeRx Test	California Fathead Minnow Hazardous Waste Screen Bioassay on DisposeRx Product (No Medicines)
Date	Unknown.
Analysis By	Unidentified “independent laboratory”
Scientific Report Availability	No, proprietary information.
Drugs & Dosage Forms Tested	None. Test was on the DisposeRx material alone.
Test Protocol Summary	A non-technical summary references the Fathead Minnow Bioassay specified in CCR Title 22 ¹⁰⁷ to determine aquatic toxicity of a material.
Test Results Summary	Dispose Rx material (without pharmaceuticals) classified as a non-hazardous waste material.

¹⁰⁵ EPA Test Methods for analyzing waste are online at: <https://www.epa.gov/hw-sw846/sw-846-compendium>. See Section III.F. of this report for an overview of the TCLP assay.

¹⁰⁶ WA State Department of Ecology. Biological Testing Methods 80-12 For the Designation of Dangerous Waste. Part A. Static Acute Fish Toxicity Test. <https://fortress.wa.gov/ecy/publications/documents/8012.pdf> See Section III.F. of this report for an overview.

¹⁰⁷ CA Dept. Fish and Game. Water Pollution Control Laboratory. Static Acute Bioassay Procedures for Hazardous Waste Samples. Polsini & Miller, 1988.

https://www.dtsc.ca.gov/HazardousWaste/upload/HWMP_bioassay_report.pdf See also Section III.F. of this report for an overview.

DisposeRx Test	Extraction of Pharmaceuticals from DisposeRx
Date	Unknown
Analysis By	NMS Labs, an FDA registered pharmaceutical testing laboratory.
Scientific Report Availability	Analytical report not disclosed. Non-technical summary provided by DisposeRx.
Drugs & Dosage Forms Tested	Alprazolam and oxycodone, amounts not stated. Other medicines and amounts tested were not identified, but described as “frequently abused drugs...(e.g. opioids such as oxycodone, benzodiazepines such as alprazolam, muscle relaxants such as carisoprodol, and various formulations of Oxycontin™).”
Test Protocol Summary and Results	Non-technical summary describes washing of the DisposeRx-drug gel with water, vinegar, vodka, and buffered solutions at pH 1, pH 6, and pH 8. The extraction and detection protocols are not stated. Percent recovery for oxycodone is shown in a summary graph as 0.02% for each of the buffered solutions. The summary document states “It was concluded that a <i>de minimus</i> quantity of pharmaceutical can be extracted in a laboratory setting within as little as 30 minutes after using DisposeRx - well over 90% of the drug remains unavailable using DisposeRx.”
How Product Capacity Determined	The manufacturer does not state a specific limit for the number of pills or patches or liquid that can be treated by adding a packet of DisposeRx powder to a prescription drug vial. The Dispose Rx package states “The average pill count is 25 pills or 1/3 vial per packet depending on the pill or vial size. For large vials consider using additional packets of DisposeRx.” A letter from DisposeRx states it is “effective in inactivating all drug formulations, including pills, tablets, capsules, suppositories, liquids and patches.” The manufacturer did not provide an explanation of how the product capacity was determined or testing of all these dosage forms.

This profile of DisposeRx is based on descriptions from the manufacturer’s website and promotional materials as of February 6, 2019, and additional materials provided by DisposeRx in January 2019.

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.
64 ounce bottle for approximately 1500 pills; wall mount available.

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."

Label states: Do not overfill. In some cases foaming may occur.

Online direction footnotes state:

* 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.

Label Safety Warnings

Keep out of reach of children; will induce vomiting, may be harmful if swallowed.

Performance Descriptions

The manufacturer's website states, "The Drug Buster® medication disposal system deactivates and contains the active ingredients in non-hazardous medications." The product label states, "Helps contain the active ingredients of the medication to deter it from leaching into soil & water supplies."



Intended Users

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

Home health/hospice.

Product marketing emphasizes use by healthcare staff for disposal of non-hazardous pharmaceuticals.

Manufacturer List Price

4 oz - \$9.95
16 oz - \$15.99
64 oz - \$34.99
per Amazon list prices.
Medline does not list manufacturer price.

How Product Sold or Distributed

Medline
Amazon
Medical supply retailers

Marketing materials state that the product-drug mixture becomes “an environmentally inert slurry that, if consumed, would induce vomiting.” Product directions state product is for non-hazardous unused pharmaceuticals and recommends consulting local regulations on disposal. Website states “safe and effective for use on tablets, capsules, creams and more”.

Medline’s product website states in the FAQ section: “Drug Buster drug disposal system complies with non-retrievable DEA standards for controlled substances. Drug Buster also advocates for FDA and EPA efforts for responsible drug disposal. Please refer to the link to ensure proper compliance with EPA laws and regulations <http://www2.epa.gov/home/health-and-environmental-agencies-us-states-and-territories>.” A related FAQ quotes the DEA’s definition of “non-retrievable” in a 2014 letter to DEA registrants.¹⁰⁸

Product Ingredients

Activated charcoal, water, surfactants, and neutralizing agents.

Medline provides a MSDS that lists carbon 25% by weight (CAS 7440-44-0).¹⁰⁹ The MSDS Hazards Classification states: EYE DAMAGE/IRRITATION - Category 2B; SENSITIZATION - SKIN - Category 1B; SKIN CORROSION/IRRITATION - Category 3. The MSDS description lists the product as including Diethanolamine and Cocamide DEA, which are noted as IARC potential human carcinogens.

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

Mechanism of Action

Medline’s letter to the author describes the product’s mechanism of action as rendering the pharmaceuticals “physically non-retrievable through the use of activated charcoal. The activated charcoal is intended to absorb the active ingredient in the drug, while the remaining solution creates an undesirable slurry.”

Test Results

No product testing reports on Drug Buster are publicly available from the manufacturer. In response to the author’s query letter, Medline provided a one-page letter with brief information about testing and a statement that “testing details, facilities and reports are proprietary”. Product testing information on Drug Buster is described below to the extent possible given limited information. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. The product manufacturer may have additional test information that was not known to the author in this review.

Drug Buster Test	Tests “based off of the USP <731> standard, which included HPLC Assay testing and efficacy testing”
Date	Unknown
Analysis By	Unknown
Scientific Report Availability	Not available. Medline’s letter states testing information is proprietary.

¹⁰⁸ DEA letter to practitioners. Full citation in footnote 27.

¹⁰⁹ Medline. Safety Data Sheet. Drug Buster Drug Disposal System. https://www.medline.com/media/catalog/Docs/MSDS/MSD_SDS0138.pdf

Drug Buster Test	Tests “based off of the USP <731> standard, which included HPLC Assay testing and efficacy testing”
Drugs & Dosage Forms Tested	Unknown. Medline description did not address what pharmaceuticals were tested.
Test Protocol Summary and Results	Medline’s letter states Drug Buster passed tests “based off of the USP <731> standard, which included HPLC Assay testing and efficacy testing”. USP <731> ¹¹⁰ is a “loss on drying” quality assurance test defined by the United States Pharmacopeia. It is used to measure the amount of water and volatile material that can be driven off a sample at a given test temperature. Without further information, the author cannot assess what “testing based off the USP <731> standard” would determine about the efficacy of Drug Buster in making drugs non-retrievable or safe for solid waste disposal.
How Product Capacity Determined	Medline’s website lists pill capacities for each product size. Medline’s response letter states the pill limit per product is “a recommendation as pill size can vary.” The website states “Continue to add medication until it is one (1) inch from the bottle opening, then discard...” This capacity determination appears to be based on volume. No capacity limit is defined for liquids or other dosage forms.

This profile of Drug Buster is based on descriptions from the manufacturer’s website and promotional materials as of February 12, 2019, and additional materials provided by Medline Industries, Inc. in December 2018.

¹¹⁰ Physical Tests <731> Loss on Drying from website of the U.S. Pharmacopeial Convention Herbal Medicines Compendium. <https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c731.pdf>

Element MDS

elementmds.com

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 transdermal patches, FAQs state Element MDS "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."

Label Safety Warnings

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..."; and "Wash with soap and water after handling".

Manufacturer's Performance Description

Element MDS's press kit info sheet says, "The Element MDS product accepts medication, whether in solid or liquid form, and



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, and funeral homes. 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

On Amazon: single 17 oz unit - \$8.99

How Product Sold or Distributed

Manufacturer's website
Amazon

renders it undesirable.”¹¹¹ The product packaging and a video linked from the website¹¹² states “Element MDS® is in compliance with the EPA’s recommendation of disposing medication in a trash receptacle after rendering the medication undesirable.” Product packaging states “Element MDS can be used for the disposal of controlled substances.”

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.

Product Ingredients

V23 describes Element MDS as an “organic, plant-based powder”. 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 about swallowing, eye contact or inhalation.

Packaging: Not described, but product is sold in an opaque plastic jug bottle which is probably polyethylene or polypropylene. The bottle’s screw cap is tamper-evident in that its seal will break if the cap is reopened.

Mechanism of Action

The Element MDS website FAQs describe the mechanism of action as “the structure and texture of the medication is altered within minutes, rendering it undesirable.” The Element MDS Press Kit information sheet says that mixing the MDS powder packet with water and medicines “holds the medication in suspension and forms a solid gel making the medication undesirable.”

Other statements on the product’s website describe making pharmaceuticals “undesirable” but do not describe the product as neutralizing or degrading the pharmaceutical compounds. FAQs for patches: “When a patch is mixed with the Element MDS Powder Packet and water, it is bathed in the gel-like substance. This does not make the patch unusable, but it certainly makes it less desirable.”

Test Results

No product testing information on Element MDS is publicly available from the manufacturer. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. The product manufacturer may have additional test information that was not known to the author in this review.

Element MDS Test	None available. The manufacturer’s website does not provide any test results to support the description of the product’s performance. V23 LLC did not respond to a query letter and other communications from the author.
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¹¹¹ Element MDS Press Kit Info Sheet. <https://elementmds.com/wp-content/themes/ABC-basic/images/Element%20Press%20Kit.pdf>

¹¹² Element MDS-Medication Disposal video on YouTube. <https://www.youtube.com/watch?v=GW89X6XngiQ&feature=youtu.be>

How Product Capacity Determined	The manufacturer's directions state an approximate limit of 500 tablets for a 17 oz bottle of Element MDS. The product website describes use for other dosage forms, including liquids and patches, but does not state their capacity limit. The manufacturer did not respond to a query letter about how product capacity was determined.
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This profile of Element MDS is based on descriptions from the manufacturer's website and promotional materials as of February 12, 2019.

NarcX, Inc.
523 E 1750 N, Suite 300, Vineyard, UT 84057
844-793-4776

Product Overview

Manufacturers' website states, "The proprietary blend of ingredients in NarcX dissolves tablets, capsules and liquids to make them immediately non-retrievable and indigestible.", and "Our unique and patent-pending product, NarcX™, is the ONLY liquid solution that immediately renders tablets and capsules non-retrievable—and the only on-site method of medication destruction that is DEA compliant."

- 16 ounce bottle for ~100 pills
- 32 ounce bottle for ~250 pills
- 64 ounce jug for ~500 pills
- 1 Gallon jug for ~1,000 pills
- 5 Gallon container for ~5,000 pills
- 30 Gallon drum for ~ 30,000 pills
- 55 Gallon drum for ~55,000 pills

Directions

Label directions on 16 oz size:
Open the cap and add tablets, pills, capsules, gelcaps, or liquids until solution reaches indicated fill level. DO NOT OVERFILL.
Replace cap to reseal solution between each use.
Apply tamper-proof cap to depleted solution for disposal.

Product label states not for use with antacid medications, Fentanyl, Butrans, or any patch that may contain narcotics.
Website states NarcX is not effective or recommended for medication patches such as Fentanyl or Butrans. A letter from NarcX states creams should not be disposed.

Product label states, "NarcX products do not require incineration or pickup by a DEA reverse distributor. Depleted solution can be discarded in the trash, returned through an authorized NarcX vendor or retrieved by your contracted waste management provider." NarcX's letter describes a contract with Univar ChemCare for general pickups anywhere in the U.S. for NarcX's largest sizes and weights.

Label Safety Warnings

Product label (16 oz size) states, "Do not tamper. Do not ingest. Solution will induce vomiting." Graphic warnings include a skull and crossbones.



Intended Users

- Individuals at home.
- Medical facilities, pharmacies, hospice, assisted living centers, hospitals, reverse distributors.
- Law Enforcement Agencies.
- Government or tribal take-back programs.

Manufacturer List Price

- \$9.99 – 16 oz bottle (plus \$8.50 for shipping)
 - \$18.99 – 32 ounce bottle
 - \$34.99 – 64 ounce jug
 - \$64.99 – 1 Gallon jug
 - \$324.99 – 5 Gallon container
- Prices not stated for 30 and 55 gallon drums.

Additional shipping fees apply.

How Product Sold or Distributed

Manufacturer's website

Manufacturer's Performance Description

Website states, "NarcX is the only liquid solution and on-site disposal option that meets DEA policy and the Code of Federal Regulations." Also, "NarcX is effective for destruction of all narcotic and non-narcotic substances, including amphetamines, opiates and non-opiate medications. NarcX is only approved for medication disposal, as natural agents in the solution make it indigestible and will cause immediate vomiting."

Other performance statements on the website include:

- Non-retrievable – Tablets and capsules begin to dissolve immediately and become fully neutralized in under 2 hours
- Eco-Friendly – Our products are environmentally safe, meaning you can toss depleted solution right into the trash

Letter from NarcX states, "as soon as the pill, tablet, capsule, liquid, etc. is placed in NarcX that it is immediately "Non-Divertible". Most importantly, based on the volume disposed of in NarcX it is "Non-Retrievable within two hours, if not almost immediately based on volume."

The NarcX website includes a recommendation that community medicine take-back programs can use the 30 gallon or 55 gallon drum size: "For robust collection needs, our 55-gallon NarcX drum meets the demands of high-intake hospitals, military facilities, law enforcement agencies, DEA-registered reverse distributors and government or tribal take-back programs for disposal of collected and warehoused narcotics, opiates or amphetamines awaiting an affordable, mass disposal solution."¹¹³

Product Ingredients

NarcX's website states it is a liquid with a proprietary blend of ingredients. In response to the author's query, NarcX stated the ingredients are patent pending and cannot be disclosed but include "a specialized version of activated carbon" and agents that help the activated carbon "render drugs quickly non-retrievable", as well as ingredients that act as catalysts and pH and surface tension adjusters. NarcX's test data identifies the liquid as basic.

Packaging: Website states NarcX bottles and drums are made from "heavy-gauge plastic" with a tamper-resistant cap.

Mechanism of Action

The NarcX website states, "The proprietary blend of ingredients in NarcX dissolves tablets, capsules and liquids to make them immediately non-retrievable and indigestible."

In response to the author's query, a letter from NarcX stated "NarcX uses a mixture of compounds that help breakdown the organic material and enhance the adsorption of drugs into the matrix of NarcX. The process is ultimately a chemical process, but the NarcX solution has ingredients that help physically transform solid dose drugs, like pills and capsules..."

Test Results

Product testing information on NarcX is organized and summarized in this section to assist readers in assessing what is known about product performance. Key performance questions for medicine

¹¹³ These entities should review requirements of the DEA's Rule for disposal of collected controlled substances by medicine take-back programs (Title 21 CFR Part 1317). DEA has stated that carbon-based disposal products do not render controlled substances non-retrievable. https://www.deadiversion.usdoj.gov/drug_disposal/

NarcX Test	NarcX with Schedule I Illegal Drugs by WY Crime Lab
	<p>heroin, or 1 mL THC oil or 1 mL CBD were each similarly tested separately with 300 mL NarcX liquid for 72-78 hours, then extracted.</p> <p>Similar tests were performed using an acidic version of NarcX which the manufacturer's letter says is designed for use by law enforcement.</p> <p><u>Drug Detection Method:</u> GC-MS analysis (gas chromatography mass spectrometry) to detect drug in the extracted phase.</p>
Test Results Summary	<p>After treatment of drugs individually with 3 mL of NarcX liquid for 24 hours, methamphetamine, cocaine and heroin could be recovered by methylene chloride extraction, but at "diminished" concentration. No THC or CBD were detected.</p> <p>When 200 mL or 250 mL of NarcX was used for 72 hours, a "small amount" of each drug could be recovered by methylene chloride extraction. When 300 mL or 350 mL of NarcX used for 72 hours, no detectable drug could be extracted.</p> <p>WY Crime Lab concludes that the NarcX reaction should be extended to a minimum of 72 hours and the ratio of drug (mg) to volume (mL) of NarcX should be 1:30.</p>

NarcX Test	EPA Toxicity Characteristic Leaching Procedure (TCLP) on NarcX Liquid (No Medicines)
Date	July/August 2018
Analysis By	American West Analytical Laboratories (AWAL), accredited by the National Environmental Laboratory Accreditation Program (NELAP).
Scientific Report Availability	Two tables are provided on the NarcX website showing results for inorganics/metals and related QC data. https://narcx.com/test-data/ The complete analytical report is not public but was released by NarcX to the author.
Drugs & Dosage Forms Tested	None. Test was on product alone without any pharmaceuticals.
Test Protocol Summary	NarcX liquid product alone was processed per EPA TCLP Method 1311. Testing for presence of metals per EPA Method 6020B, mercury per EPA Method 7470A, VOCs per EPA Method 8260C and 8270D, and for pesticides and herbicides per EPA Method 8081B and 8151A. ¹¹⁴
Test Results Summary	<p>Analysis of the NarcX liquid product, without any added pharmaceuticals, found all results below the TCLP maximum contaminant levels and AWAL concluded that the NarcX liquid is not a hazardous material.</p> <p>Trace amounts of arsenic and barium were detected in the NarcX liquid at levels more than 100-fold below the TCLP maximum allowable limits.</p>
How Product Capacity Determined	The manufacturer's directions state an approximate pill limit for each product size. NarcX's letter states the recommended capacity is determined by "a maximum fill volume of the container and not the number of pills or capsules to be disposed of."

This profile of NarcX is based on descriptions from the manufacturer's website and promotional materials as of February 7, 2019, and additional materials provided by NarcX, Inc. in January 2019.

¹¹⁴ EPA Test Methods for analyzing waste are online at: <https://www.epa.gov/hw-sw846/sw-846-compendium>. See Section III.F. of this report for an explanation of the TCLP assay.

Pill Catcher

thepillcatcher.com

The Pill Catcher (F.P.R. Inc.)
P.O. Box 700741 Plymouth, MI 48170-0953
(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."

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 pills 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."

Label Safety Warnings

None.

Manufacturer's Performance Description

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 tests for safe disposal to landfills." "The pharmaceutical waste will remain permanently encapsulated, and cannot be separated from the encapsulating material." "We certify that The Pill Catcher™ is the only drug disposal product that passes all EPA tests for safe disposal to landfills."

Product Ingredients

The active ingredient is bentonite clay.

The bentonite clay in The Pill Catcher is manufactured by Cetco, a manufacturer of ORGANOCCLAY® products for environmental



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).

How Product Sold or Distributed

Manufacturer's website
Amazon.com

remediation.^{115,116,117} F.P.R. Inc. provides a MSDS that lists: Bentonite (CAS # 1302-78-9), containing naturally occurring crystalline silica and Quartz (CAS # 14808-80-7).¹¹⁸ 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.

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

Mechanism of Action

Absorption to bentonite clay. The website’s explanation of The Pill Catcher’s mechanism of action: “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.” F.P.R. Inc’s letter states that bentonite clay is more effective than activated carbon products because it absorbs the drugs rather than adsorbing them on the surface of the carbon.

Test Results

Product testing information on The Pill Catcher is organized and summarized in this section to assist readers in assessing what is known about product performance. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. Review of the complete technical reports or publications, where available, will provide additional details. The product manufacturer may have additional test information that was not known to the author in this review.

Manufacturer’s website states, “The Pill Catcher™ was tested on all classes of drugs, in pill, gel cap, liquid, and patch form. The Pill Catcher™ passed all standard environmental tests as required by law.” The testing provided is an EPA TCLP assay, which is summarized below along with additional information provided by F.P.R. Inc.

Pill Catcher Test	EPA Toxicity Characteristic Leaching Procedure (TCLP) on The Pill Catcher with Mixture of 13 Medicines
Date	2009
Analysis By	TestAmerica (Chicago, IL), accredited by the National Environmental Laboratory Accreditation Program (NELAP). F.P.R. Inc. prepared the test sample of The Pill Catcher with medicines. The sample was shipped to Cetco Environmental and tested under the EPA’s TCLP Method. Cetco then shipped the sample to TestAmerica for further TCLP analysis.
Scientific Report Availability	TestAmerica’s full analytical report is linked from The Pill Catcher website. F.P.R., Inc. identified the medicines tested and described sample preparation in a separate communication to the author. http://www.thepillcatcher.com/files/75371143.pdf
Drugs & Dosage Forms Tested	13 medicines, in pill, capsule, and liquid dosage forms, tested together in a mixture: Pain relievers: Darvocet (1 pill, 100/650 mg), Vicodin (1 pill, 7.5/750 mg pill), Tylenol (1 oz liquid), aspirin (1 pill, 325 mg), ibuprofen (1 gel capsule, 200 mg); Hormones: prednisone (1 tablet, 20 mg), Premarin (1 tablet, 1 mg); Antibiotic: erythromycin (1 tablet, 250 mg); Psychotropics: Ativan (1 tablet, 2 mg), Xanax (1 pill, 2 mg), Neurontin (1 pill, 400 mg), Prozac (1 gel capsule, 20 mg); Statin: Simvastatin (1 tablet, 20 mg).

¹¹⁵ CETCO ORGANOCLAY® <http://www.cetco.com/en-us/Products/Environmental-Products/Organoclays>

¹¹⁶ Personal communication with Clyde Parrott, 12/08/16.

¹¹⁷ U.S. Patent Publication Number US 7918777 B2. “Pill Catcher” <https://www.google.com/patents/US7918777>

¹¹⁸ “Full Disclosure Material Safety Data Sheet” <http://www.thepillcatcher.com/files/94362689.pdf>

Pill Catcher Test	EPA Toxicity Characteristic Leaching Procedure (TCLP) on The Pill Catcher with Mixture of 13 Medicines
Test Protocol Summary	<p>4 ounces of The Pill Catcher mixed for three hours with the 13 medicines, then sent to Cetco and TestAmerica for testing according to EPA TCLP Method 1311.¹¹⁹ Cetco tested for 8 metals and 20 organic pollutants. TestAmerica tested the same sample for the same 20 organic compounds, plus two more organics per EPA Methods 8260B and 8270C.</p> <p><u>API Detection Method:</u> None. The standard TCLP Method does not assay for the presence of pharmaceuticals.</p>
Test Results Summary	<p>Both TCLP analyses found that the 40 regulated organic pollutants were non-detectable, and the metals were below regulatory limits. Lead, which is typically found in trace amounts in bentonite clay, was detected at 0.10 mg/L, under the regulatory limit of 5.0 mg/L.</p> <p>The sample was not assayed for pharmaceuticals. The 13 APIs tested 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.</p>
How Product Capacity Determined	<p>The manufacturer's directions state a limit of the number pills or volume of liquid for each product size. The manufacturer did not provide an explanation of how the product capacity was determined.</p>

This profile of The Pill Catcher is based on descriptions from the manufacturer's website and promotional materials as of February 11, 2019, and additional materials provided by F.P.R. Inc. in December 2018.

¹¹⁹ EPA Test Methods for analyzing waste are online at: <https://www.epa.gov/hw-sw846> See Section III.F. of this report for an explanation of the TCLP assay.

Pill Terminator

pillterminator.com

Combined Distributors Inc.
2360 Lakewood Road 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 mL bottle for 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.

Label Safety Warnings

The product label has warning: "CAUTION! KEEP OUT OF REACH OF CHILDREN".

Manufacturer's Performance Description

The manufacturer's website and product label state 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." Taglines include "Child Safe".

The product website states, "It's an easily disposable product that meets and exceeds EPA/FDA standards, and can be utilized in the home, in hospitals, medical offices, funeral homes, care centers, and much more!" and "Exceeds FDA & EPA guidelines".

Product Ingredients

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



Intended Users

Households.

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

Manufacturer List Price

\$9.95 per single 300 mL bottle.

\$29.85 for 3 single bottles.

\$58.80 for 6 bottles (\$9.80 per unit).

\$24.95 for 1 Gallon Professional Size.

Shipping & handling fees may apply.

How Product Sold or Distributed

Manufacturer's website

Amazon.com

A MSDS¹²⁰ 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 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.

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.¹²¹

Mechanism of Action

Combined Distributors Inc. did not respond to a query letter about the product's mechanism of action. The manufacturer's website describes Pill Terminator's mechanism of action as "denaturing the chemical compounds of the medications as well as rendering them inedible by creating an extremely unpleasant taste." Product label states, "contains inorganic solid solvents that help break down medications."

Calcium hypochlorite is an oxidizing agent. The product's other ingredients, Fuller's earth and an unidentified absorbent polymer, appear to act as absorbents.

Test Results

Product testing information on the Pill Terminator is organized and summarized in this section to assist readers in assessing what is known about product performance. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. Review of the complete technical reports or publications, where available, will provide additional details. The product manufacturer may have additional test information that was not known to the author in this review.

The "Tested and Proven" page on the Pill Terminator website provides three test results that are summarized below: a 2014 analysis by Bureau Veritas Consumer Product Services, Inc (BVCPS) that tested aspirin and two unpublished reports by academic researchers who tested morphine by the same method. Combined Distributors Inc. did not respond to a query letter about any other available product testing information.

Pill Terminator Test	Treatment of Aspirin by Pill Terminator by Bureau Veritas Consumer Product Services, Inc (BVCPS)
Date	July 2014
Analysis By	Bureau Veritas Consumer Product Services, Inc (BVCPS), an analytical laboratory accredited by the American Association for Laboratory Accreditation, the U.S. Consumer Product Safety Commission, and others.
Scientific Report Availability	A summary report is linked from the Pill Terminator's website at https://www.pillterminator.com/pages/tested-and-proven

¹²⁰ Pill Terminator "SDS" <https://www.pillterminator.com/pages/sds>

¹²¹ Marlex HHM 5502BN High Density Polyethylene.

<https://cdn.shopify.com/s/files/1/1000/3902/files/MARLEX-5502BN-Material-Specification.pdf?11981800429654242971>

Pill Terminator Test	Treatment of Aspirin by Pill Terminator by Bureau Veritas Consumer Product Services, Inc (BVCPS)
Drugs & Dosage Forms Tested	Aspirin (302 coated tablets, 325 mg each)
Test Protocol Summary	302 aspirin tablets added to a 300-cc bottle of Pill Terminator with warm water per product directions. Photographs of the product-aspirin mixture were taken at 2 minutes, 60 minutes, and 2 hours. <u>API Detection Method:</u> Visual observation, no chemical detection method.
Test Results Summary	BVCPS concluded that coated aspirin tablets were “destroyed” because the tablets were physically dissolved and made unusable by treatment with Pill Terminator. After 2 hours, the mixture appears to be a loose solid. No chemical analysis was performed to assess if the aspirin was chemically degraded.

Pill Terminator Test	Treatment of Morphine by Pill Terminator by Two Academic Researchers
Date	April 2014 for University of Hertfordshire report. October 2015 for Western New England University report.
Analysis By	Professor Priefer, College of Pharmacy, Western New England University Dr. Matt Traynor, Department of Pharmacy, University of Hertfordshire
Scientific Report Availability	Summary reports, not published or peer-reviewed, are linked from the Pill Terminator’s website. https://www.pillterminator.com/pages/tested-and-proven
Drugs & Dosage Forms Tested	Morphine (pure API in form of sulfate salt, pentahydrate) Morphine amount tested in Traynor study not stated. Priefer tested 10.2 mg morphine.
Test Protocol Summary	<u>Traynor’s Study:</u> Morphine was mixed with a sample of Pill Terminator (exact amounts not stated) and water, stirred for 2 minutes, then rolled for 30 minutes. Samples taken after mixing (0 hours) and after 48 hours. <u>Priefer’s Study:</u> Dr. Priefer replicated Dr. Traynor’s study with brief shaking per Pill Terminator directions, rather than 2 minutes stirring. 10.2 mg morphine mixed with 1.0294 g of Pill Terminator mixture, shaken for 15 seconds, then 8.5312 g water added, and the mixture rolled for 2 hours. Samples taken after mixing (0 hours) and after 48 hours. <u>API Detection Method:</u> Traynor developed a morphine assay using HPLC with UV spectroscopy at morphine’s signature wavelength. Compared to a morphine standard curve. Priefer’s study used Traynor’s HPLC method.
Test Results Summary	<u>Traynor Study Results:</u> Traynor measured 1.55% of the amount of morphine in the 48 hour sample compared to the 0 hour sample taken right after mixing. Traynor concludes 98.45% of the morphine was degraded after 48 hours. <u>Priefer Study:</u> Priefer detected 57% of the original amount of the morphine in the 0 hour sample taken right after the mixing period, then detected 45% of the original amount of morphine after 48 hours. Priefer concludes that Pill Terminator destroys over half of the morphine when briefly mixed (per bottle directions) and stirring is needed to destroy > 98% of the API per Traynor’s test.
How Product Capacity Determined	The manufacturer’s directions state a 300 pill limit for a 300 mL Pill Terminator bottle. This determination appears to be volume-based. The manufacturer did not respond to a query letter about how product capacity was determined.

This profile of Pill Terminator is based on descriptions from the manufacturer’s website and promotional materials as of February 11, 2019.

Rx Destroyer

rxdestroyer.com

and Narc Gone®HD

narcgone.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.

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

Website states uses for “All non-hazardous medications (DEA-controlled & Non-controlled)” and lists dosage forms for the All Purpose formula as “Pills, Capsules, Tablets, Liquids, Lozenges, Transdermal Patches, Fentanyl Lollipops, Suppositories.”

The Rx Destroyer product line includes a funnel and a locking wall or countertop mount called RxLockBox for larger size bottles. Rx Destroyer also comes in a Liquids formulation for only liquid medications. A “hardener” packet to convert the Rx Destroyer liquid to a gel-like substance is provided with the Liquids formula and may be purchased separately for the All Purpose formula.

Narc Gone®HD: C2R Global Manufacturing also markets an activated carbon product called Narc Gone HD for disposal of Schedule I – V drugs by law enforcement that appears similar or identical to Rx Destroyer. Narc Gone®HD is marketed in larger sizes, 64 oz to 5 gallon drum, with packets of a “liquid hardener”.

Directions

Load medications into bottle.

Tightly replace cap.

Gently shake to mix solution over medications.

Store in a safe and secure location...use until full.

Bottle is full when contents are within 2” from cap - DO NOT OVERFILL.

Discard bottle and its contents into common trash or according to business process and regulations.



Intended Users

Healthcare facilities, health-care providers, pharmacies, long-term care facilities.

Consumers.

Law Enforcement .

Manufacturer List Price

4 oz. All Purpose - \$6.29 at Walgreens.com

16 oz - case of 12 \$108.95 (\$9.08 ea.) from C2R Global via Amazon.com

64 oz - \$34.76 from C2R Global via Amazon.com

1.0 gallon - \$60.00 from Health Care Logistics Inc.

Available in 5 and 30 gallon drums.

Prices not stated on manufacturer’s website.

How Product Sold or Distributed

Walgreens –4 oz size

Amazon.com

Distributed by McKesson, Cardinal Health, and other drug distributors and medical supply retailers.

Always follow institutional policies, local, state, tribal and federal 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

Website also states, “Do not add gassing items such as effervescent, antacid medications, syringes (hardware) or drugs known to react with one another such as sodium bicarbonate and aspirin.”

Disposal by Medical Waste Hauler and Mail-Back Program: In 2017, a disposal options section was added to the Rx Destroyer website, www.rxdestroyer.com/masswastedisposal/, which lists garbage disposal, medical waste hauler, or mail-back disposal options, with a description of differing regulatory requirements. A search function is provided to find waste haulers in each state that can be contracted to pick-up and dispose of Rx Destroyer bottles by incineration. An affiliated company called Rx Waste Systems provides a mail-back option for used Rx Destroyer bottles for “state compliant” destruction at additional cost, e.g. \$165 for mail-back of a 1 gallon Rx Destroyer jug.

Label Safety Warnings

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

Manufacturer’s Performance Description

RxDestroyer.com website states, “DEA & EPA COMPLIANT Rx Destroyer™ minimizes drug diversion and abuse as well as protects our environment’s water supply. Rx Destroyer™ formula is 100% natural and meets DEA definition of Non-Retrieveable.” The product label states: “Independent Lab Tested: Medications Deemed Non-Retrieveable. Exceeds Federal Drug Disposal Guidelines.”

The website also states, “Rx Destroyer™ brands are landfill friendly supporting EPA and FDA 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, tribal and or federal regulations.”

Narc Gone HD is described as a high capacity version of Rx Destroyer in a testing summary linked from the Rx Destroyer website. Narc Gone HD is marketed to law enforcement for disposal of illicit and prescription drugs, including for medicines collected in take-back programs.¹²² Narc Gone HD’s website states it “meets and exceeds the Federal Guidelines for the DEA’s definition of chemical destruction” and “meets current EPA standards for Solid Waste Disposal”.

Product Ingredients

Activated carbon and other agents that are not identified.

The manufacturer provides Safety Data Sheets (SDS) for Rx Destroyer and Narc Gone¹²³, which do not identify ingredients but state the product is a mixture consisting of “non-regulated material”. A separate SDS for the hardening agent lists sodium acrylate (2-propenoic acid, homopolymer sodium salt), an absorbent that polymerizes, used in products like baby diapers. Sodium acrylate is a skin and

¹²² Law enforcement agencies should review requirements of the DEA’s Rule for disposal of collected controlled substances (Title 21 CFR Part 1317). DEA has stated that carbon-based disposal products do not render controlled substances non-retrieveable. https://www.deadiversion.usdoj.gov/drug_disposal/

¹²³ Rx Destroyer. Product and Hardener Safety Data Sheets. As of Feb. 9, 2019, available from <https://www.rxdestroyer.com/downloads/> and <https://narcgone.com/documents/SDSNarcGone.pdf>.

eye irritant and a potential respiratory irritant. A website FAQ states “Some medications, drugs or combinations may not be compatible with Rx Hardener™ due to their chemical composition.”

Packaging: Manufacturer states bottle is manufactured with “recyclable plastics”; however, the bottle is designed to be disposed in the solid waste system, not recycled.

Mechanism of Action

Rx Destroyer’s website describes the mechanism of action as adsorption to carbon, stating “Active medication ingredients are adsorbed or neutralized by activated charcoal. Adsorption time varies depending on additive and existing contents.”

The Narc Gone HD website describes the product’s mechanism of action as an “activated carbon chemical digestion” technology.

The Test Data section of the Rx Destroyer website states, “Drug will not be retrievable, because it is tightly bound in the micropores. It takes commercial reactivation, furnace at 1700°F to restore carbon.”, citing Dr. Henry Nowicki of PACS Lab, Inc.

Test Results

Product testing information on Rx Destroyer, and the related Narc Gone HD product, is organized and summarized in this section to assist readers in assessing what is known about product performance. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. Review of the complete technical reports or publications, where available, will provide additional details. The product manufacturer may have additional test information that was not known to the author in this review.

The manufacturer’s website provides some test results which are summarized below, however complete test reports are not available and several of the documents are memos which do not describe direct testing of the product. C2R Global Manufacturing did not respond to the author’s query letter requesting further information.

Narc Gone Test	Methamphetamine Adsorption by Narc Gone
Date	Summary dated May 1, 2017.
Analysis By	Unidentified lab described as DEA certified.
Scientific Report Availability	1-page summary linked from Rx Destroyer website. C2R Manufacturing did not respond to requests for additional testing information. https://www.rxdestroyer.com/wp-content/uploads/narcgone-dea-cert-lab-test-report-2017.pdf
Drugs & Dosage Forms Tested	Methamphetamine, pure Schedule II illicit drug, 50% solution tested.
Test Protocol Summary	<u>Adsorption Test:</u> Methamphetamine solution added to Narc Gone 16 ounce liquid product, shaken for 10 seconds, and shaken again for 10 seconds after 1.5 hours. Time course samples taken at 2 and 24 hours, and at 4 and 7 days after shaking the mixture for 10 seconds then settling for 30 minutes. No wash out or desorption test described. <u>Drug Detection Method:</u> GC-MS (gas chromatography mass spectrometry). Complete methodology and standards not described.
Test Results Summary	<u>Adsorption results:</u> Treatment of 5 g methamphetamine with 16 oz Narc Gone resulted in 65% adsorbed in 2 hours, 86% adsorbed in 24 hours, 94% adsorbed in 4 days and 100% in 7 days.

Rx Destroyer Analysis	5 Memos from Dr. Henry Nowicki, activated carbon consultant.
Date	Two memos are dated February 2015, one is dated April 2015, and the others are undated.
Analysis By	Dr. Nowicki, president of PACS Professional Analytical and Consulting Services (pacslab.com).
Scientific Report Availability	The five memos are provided under Test Data on the Rx Destroyer website, https://www.rxdestroyer.com/test-data/ No novel analytical testing provided.
Drugs Tested	None. PACS Lab did not conduct any direct testing of Rx Destroyer with pharmaceuticals.
Analysis Summary	<p>Two of Dr. Nowicki's memos describes characterization of the activated carbon used in Rx Destroyer (Sample EE-541) by a gravimetric adsorption energy distribution method (GAED) to determine its pore size and adsorption potential in comparison to other commercial grade activated carbons. No medicines are tested. The test concludes the Rx Destroyer sample has a high pore volume level that is theoretically sufficient to adsorb all pharmaceuticals. Dr. Nowicki's memos states "Typically there will be a small trace amount of drug ingredients remaining in the liquid phase at completion."</p> <p>In two other memos, Dr. Nowicki describes the activated carbon properties in general and provides theoretical calculations for drug capacity of Rx Destroyer bottle sizes. Nowicki references work of other researchers - including Dr. David Cooney, and Dr. Bert McCarthy - on activated carbon adsorption of other organic compounds, such as pesticides.</p> <p>The fifth memo, in sections labeled Appendix C and D, provides Dr. Nowicki's review of unattributed results for pharmaceutical adsorption with activated carbon. The tables appear to be identical to the internal unpublished studies by Dr. Fowler of Verde Technologies on Deterra, except that the name "Deterra" has been replaced with "Rx Destroyer". The data tables show less than 100% adsorption of controlled substances and other APIs by the carbon. Dr. Nowicki concludes that "the test results can be applied to the activated carbon used in Rx Destroyer and there is no need to recreate the study."</p>

Hardener Packet Test	SW-846 Paint Filter Liquids Test on Rx Destroyer Hardener Pouch
Results Statement	<p>Product description for the Rx Destroyer Liquid Hardener Pouch¹²⁴, active ingredient sodium acrylate (2-propenoic acid, homopolymer salt), states that it converts liquid Rx Destroyer to a solid gel meeting the SW-846 Test Method (paint filter liquids test). No further information on this testing is provided.</p> <p>EPA's SW-846 Test Method 9095B defines a waste sample as solid if no liquid from the material passes through a paint filter within 5 minutes.</p> <p>Website also states, "Some medications, drugs or combinations may not be compatible with Rx Hardener™ due to their chemical composition."</p>
How Product Capacity Determined	<p>Rx Destroyer directions state a pill number limit for each product size. A website FAQ states the capacity is based upon a 200 mg Advil tablet. The determination appears to be based on volume to fill container to within 2" of opening.</p> <p>Narc Gone® HD's stated product capacity also appears to be volume based. The website states it has a shelf life of 3 years and can be used until the contents reach two inches from the top of the container.</p>

This profile of Rx Destroyer, and the related product Narc Gone HD, is based on descriptions from the manufacturer's website and promotional materials as of February 8, 2019.

¹²⁴ Rx Destroyer Hardener Pouch product description online at <https://www.rxdestroyer.com/rxdestroyer-hardener-6-pack/> as of February 11, 2019.

Cactus Smart Sink

www.stryker.com, search for Smart Sink

Stryker
2825 Airview Boulevard, Kalamazoo, MI 49002
(269) 385-2600

Product Overview

The manufacturer's¹²⁵ website states, "The battery powered Cactus Smart Sink System conveniently mounts on a wall or countertop in minutes and can be used anywhere medications are dispensed or administered by healthcare professionals. The innovative controlled substance waste disposal system accepts unused pharmaceuticals in both liquid and solid forms, including patches. It incorporates two types of cartridges, one for liquid waste and one for solid waste. Both cartridges have the ability to render the remaining portions of controlled substance waste into an unrecoverable and unusable form and securely store them until they can be disposed of per regulatory guidelines."

Solids cartridge capacity: approximately 1.7 L, or 500-1500 tablets/capsules.

Liquids cartridge capacity: approximately 3.0 L.
Cartridges are designed to last 90 days.

Stryker's Cactus product line includes smaller units – called Cactus Pharma Lock and Pharma Lock O.R. – designed to be mounted to anesthesia carts or used in EMS vehicles.

Directions

The self-contained, locking unit mounts onto a wall or countertop. It has two openings for medicines: 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 indicate when internal cartridges are full or have expired after 90 days. Removing cartridges requires a key, and other attempts to access trigger an alarm.

Stryker recommends disposal of full cartridges through an authorized pharmaceutical waste management company in accordance with federal, state, tribal, and local disposal regulations, depending on whether disposed pharmaceuticals are hazardous or non-hazardous wastes.

¹²⁵ Shortly after the first version of this report was released in 2017, Stryker Corporation acquired Cactus LLC.

Intended Users

Healthcare professionals in medical facilities.
Not marketed to consumers.

Manufacturer List Price

Price quotes can be requested from Stryker.

How Product Sold or Distributed

Stryker

Cactus Smart Sink is not intended for: chemotherapy wastes, nuclear medicine wastes, and sharps.

Manufacturer's Performance Description

The manufacturer's website states, "Stryker's Cactus Smart Sink securely captures partially administered or unused controlled substances and renders them non-retrievable and unusable."

The FAQ documents states, "When liquid waste is introduced it is automatically filtered through a proprietary mixture of chemicals and deterrents and it is converted to a semi-solid state within fifteen seconds, rendering waste unusable and non-recoverable. Solids (tablets, capsules and patches) are captured through a one-way pill maze and patch slot, secured and rendered unusable and non-recoverable with a proprietary liquid mixture."

An FAQ document states the Cactus Smart Sink® meets the DEA requirements for controlled substance waste disposal of "partially administered and remaining portions of controlled substances."

Stryker recommends use of an authorized pharmaceutical waste management company for final disposal of the full cartridges, and states "Always follow all federal, state, tribal and local disposal regulations for RCRA hazardous waste. If RCRA hazardous waste is introduced into the Cactus Smart Sink System, the appropriate RCRA guidelines for labeling, tracking and disposal should be followed."

Product Ingredients

Stryker does not identify the cartridge's proprietary mixture or provide a MSDS.

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.

Mechanism of Action

Stryker's website and materials do not identify the mechanism of action beyond describing how the proprietary chemicals convert liquids to solid form and make solid dosage forms "unusable and non-recoverable".

Test Results

No product testing information on the Cactus Smart Sink is publicly available from the manufacturer. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. The product manufacturer may have additional test information that was not known to the author in this review.

Cactus Smart Sink Test	Not publicly available. The manufacturer's website does not provide any test results to support the description of the product's performance. Stryker responded to the author's query letter by providing the FAQ document and product manual, stating other information is confidential.
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How Product Capacity Determined	No product capacity information provided on Stericycle's website. Capacity appears to be based on volume of container.
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This profile of the Cactus Smart Sink is based on descriptions from Stryker's website and promotional materials as of February 13, 2019.

CsRx System

www.stericycle.com, search for CsRx

Stericycle Inc.
4010 Commercial Avenue, Northbrook, IL 60062
866-338-5120

Product Overview

Stericycle's website states, "CsRx™ is a safe and secure solution to dispose of your controlled substance waste and help you mitigate diversion risk while protecting your patients, staff and the environment."

A Stericycle video¹²⁶ shows a plastic jug with a one-way disposal path for controlled substance waste disposal. Jugs can be secured to a locking wall bracket. The jug contains a deactivating substance and a deterrent. For final disposal, a solidifying agent is added to the jug and full containers are shipped to Stericycle and destroyed by incineration.

CsRx is available in 1.4 quart, 1 gallon, and 3 gallon sizes.

Directions

Add water to the container to activate the deactivating agent and the deterrent. Add pharmaceutical waste through the one-way lid until jug is full. Full containers are treated with a "fast-acting solidifier" and returned in a prepaid shipping box for incineration at a permitted Stericycle facility.

Stericycle states the "CsRx Service is for controlled substances that have been dispensed to a patient at the registrant's location and need to be wasted at that location. This is NOT for disposal of controlled substances brought in by patients."

CsRx is marketed for use with tablets, capsules, liquids and patches. Stericycle's website states, "Only non-controlled drugs and schedule II, III, IV and V controlled substances can be accepted in CsRx containers."

Manufacturer's Performance Description

Stericycle's website describes the action of the material in the CsRx container as:

Non-Retrieveable Elements: Reduces Risk

- Acts immediately to deactivate controlled substance

¹²⁶ RxInsider Virtual Pharmacy Trade Show. Stericycle CsRx video.
http://www.rxshowcase.com/trade_show_print_booth.php?booth=1781

Intended Users

Staff at healthcare facilities for disposal of controlled substance pharmaceutical wastage.

Manufacturer List Price

Service is marketed as a flat monthly fee. Price quotes can be requested from Stericycle.

How Product Sold or Distributed

Stericycle

- waste in the container
- Deterrent to prevent ingestion of the liquid while in use
- Solidification of waste prior to shipping secures content and prevents diversion
- Meets Drug Enforcement Administration (DEA) non-retrievable requirement*

*Per DEA guidance letter, hospitals are not required to meet the non-retrievable requirements once a controlled substance is dispensed to a patient.

Product Ingredients

Stericycle’s website and materials do not identify the ingredients in the CsRx System, describing them as a “deactivating agent-deterrent, which will require water be added to activate.”¹²⁷ A solidifying agent is also provided to add to a full container.

The unidentified mixture may include activated carbon. An RxInsider healthcare publication from Summer 2018 describes CsRx’s active ingredient as activated carbon.¹²⁸ An older Stericycle CsRx marketing material dated 2016¹²⁹ that is not on Stericycle’s website, but still available from a healthcare-related business, states “Deactivation agent supplied by Verde Technologies”. Verde Technologies markets Deterra, an activated carbon product reviewed in this report.

Packaging: The product is provided in rigid plastic jugs.

Mechanism of Action

Stericycle’s materials state that the “deactivating agent permanently alters the substance’s chemical condition rendering the substance unavailable and unusable, including pill, patches, tablets, and IV solutions. The deactivating agent also works as a precautionary measure deterring the improbable occurrence of someone attempting to ingest the liquid.”

Test Results

No product testing information on the CsRx System is publicly available from the manufacturer. Key performance questions for medicine disposal products are summarized in Section I and examined in more detail in Section III of this report. The product manufacturer may have additional test information that was not known to the author in this review.

CsRx Test	Not publicly available. Stericycle does not provide any testing information about the agents used in CsRx on its website and did not respond to the author’s query letter.
How Product Capacity Determined	No product capacity information provided on Stericycle’s website, but capacity appears to be based on volume of container.

This profile of the CsRx System is based on descriptions from Stericycle’s website and promotional materials as of February 13, 2019.

¹²⁷ Stericycle CsRx System description available from RxInsider Virtual Pharmacy Trade Show.

http://www.rxshowcase.com/trade_show_print_booth.php?booth=1781

¹²⁸ RxInsider. 20Ways Publication. Summer 2018 “Stericycle’s CsRx Service Makes Disposing of Controlled Substance Waste Easy”. http://www.rxinsider.com/20ways/articles/9_stericycle_20wayssummer18_way.pdf

¹²⁹ Stericycle CsRx System handout dated 2016, online at

[http://www.fawks.com/PDFs/Hazardous%20waste/STC-CsRx%20Slick_2016-03%20Final%203-16\).pdf](http://www.fawks.com/PDFs/Hazardous%20waste/STC-CsRx%20Slick_2016-03%20Final%203-16).pdf), as of Feb. 13, 2019.

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 sources cited, including manufacturers' websites, product materials, and product labels, as of February 2019. 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. In February 2019, a sample of DisposeRx was purchased from Wal-Mart and a sample of NarcX was purchased from the manufacturer's website.

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.

Questions about this Report may be directed to:

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