There are no uniform protocols in the United States for safe, environmentally acceptable disposal of controlled substances by patients. In addition, there are conflicting protocols used by various institutions for the disposal of narcotic medications. Although the US Drug Enforcement Administration oversees the prescribing, acquisition, and distribution of controlled substances and works to prevent the illegal diversion of these products, it stops short of recommending specific mechanisms for consumers to dispose of unused medications. The lack of specific regulations in this area increases the risk of illegal diversion of prescription medications and other controlled substances. The authors review and examine the dilemma posed by an ill-defined set of guidelines for disposal of controlled substances by patients and institutions not registered with the US Drug Enforcement Administration. The authors encourage public officials to update and reform ambiguous policies regarding opioid disposal by consumers and allied healthcare workers.

Consider the following scenarios:

- A patient who was given a prescription for an opioid analgesic after her surgery makes a faster-than-expected recovery. What should the prescribing physician advise the patient regarding the disposal of unused medication?
- A patient with metastatic prostate cancer who is being cared for in a hospice setting dies 2 weeks after a 1-month supply of opioids was ordered for him. How should the hospice team dispose of the unused medication in a way that meets federal relations in an environmentally friendly manner?

Scenarios like these play out every day across the United States, with physicians, other healthcare providers, and patients puzzling over what to do with unused opioids and controlled substances. Unfortunately, US health authorities have not provided clear and consistent direction for the safe and environmentally friendly disposal of such substances.

Opioid analgesics are an important component of pain management for many patients. The World Health Organization (WHO)1,2 developed its three-step Pain Relief Ladder to guide physicians prescribing opioids and nonopioids for the management of cancer pain. The WHO’s Pain Relief Ladder, which is now used for pain management with other clinical conditions (eg, refractory severe low back pain), recommends adjunctive opioid therapy in cases where nonopioids and other analgesics do not provide adequate pain relief. Medications are to be administered orally using the following escalating sequence, as necessary, until the patient is free of pain:

- nonopioids (eg, acetaminophen, aspirin, nonsteroidal anti-inflammatory drugs)
- mild opioids (eg, codeine)
- strong opioids (eg, morphine)1,2

Although millions of patients use opioids properly under the direction of their physicians, the abuse and diversion of these medications is a major problem. In the United States, approximately 11 million people used opioids in 2002 for nonmedical purposes.3

The US Drug Enforcement Administration (DEA)4 defines the diversion of medications as “the redirection of narcotic drugs and psychotropic substances from the legitimate distribution chain of medical and scientific use into illicit channels.” There are more than 1 million potential sources for drug diversion, including theft, fraud, and illegal sales involving physicians, pharmacies, hospitals, and nursing homes.4 Among the most common narcotics included in drug diversion are codeine, hydrocodone, hydromorphone, methadone, and oxycodone.4 Proper disposal of these medications is crucial in countering this illegal activity.

The DEA, however, has not developed clear guidelines regarding the proper disposal of unused narcotic medications by patients, long-term care facilities, or other unregistered entities.5,6 Furthermore, there is no uniformity among local guidelines for disposal of unused opioid medications admin-
istered by such institutions as hospices, nursing homes or extended-care facilities, pharmacies, and urgent-care settings or clinics (eg, drug detoxification centers). It is also important to note that different government agencies publish different and conflicting guidelines regarding the proper means of disposing controlled substances (eg, flushing into sewage systems vs incineration via traditional curbside waste disposal).5,7

The present article addresses the issue of nonuniformity in government regulations for opioid disposal by patients, long-term care facilities, hospices, and other entities not registered with the DEA. Various guidelines issued through different regulatory agencies are reviewed, and recommendations are proposed.

Current Consumer Practices
A comprehensive search of both the biomedical and popular literature was conducted. The biomedical literature was searched using the US National Library of Medicine’s PubMed database, with various combinations of the following search terms: opioid(s), controlled substances, disposal, and regulation(s). Literature published between January 1965 and December 2005 was included in the search.

Because of a paucity of articles on this topic in the biomedical literature, we also used Internet search engines (eg, Google) to locate other relevant articles on the disposal of controlled substances.

A 1996 survey performed by Kuspis and Krenzelok8 examined the behaviors of pharmacies and patients regarding disposal of controlled and uncontrolled medications. The survey, which involved 100 pharmacies, demonstrated that 97% of these businesses had formal procedures in place to dispose of their own supplies of unneeded medications.8 However, only 5% of these pharmacies regularly offered recommendations to their customers on how best to dispose of unused or expired medication.8

Of the 500 patients surveyed by Kuspis and Krenzelok,8 the vast majority (89%) disposed of their medications either in the trash (54%) or down the toilet or sink (53.4%). The remaining patients did not dispose of such medications (7.2%), consumed all medications before expiration (2%), or returned these products to pharmacies (1.4%).8

Seehusen and Edwards9 conducted a survey in 2006 of 301 patients at one outpatient pharmacy regarding disposal of controlled and uncontrolled drugs. Their results illustrated the fact that more than half of patients surveyed stored unused and expired medications at home or flushed them down the toilet, with about 23% returning uncontrolled drugs to the pharmacy.9 Less than 20% of patients said they had been given advice about drug disposal by a healthcare provider. The survey found a strong association between such previous advice and returning unused and expired drugs to the pharmacy, suggesting the importance of healthcare workers counseling patients about drug disposal.9

Current Guidelines and Regulations
The WHO has published the following statement regarding the proper disposal of controlled substances:

Controlled substances must be destroyed under supervision of a pharmacist or the police depending on national regulations. Such substances must not be allowed into the public domain as they may be abused. They should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.10

There is little else in the literature about regulations for disposal of pharmaceutical products and other controlled substances. Great Britain’s Environmental Protection Act of 1990 mandates that controlled substances not be disposed into wastewater systems, but the legislation provides little further guidance.11

Australia’s National Health and Medical Research Council considers incineration, when possible, to be the most appropriate method of disposal.12 Pharmacies in Australia are able to return unsold or expired medications to some pharmaceutical companies through a system of reverse distributors.12

Australia and Canada have implemented measures to assist consumers in proper disposal of unused medications: the Return Unwanted Medications Program and the Medications Return Program, respectively.12-14

In Canada, the National Association of Pharmacy Regulatory Authorities guides pharmacists on proper ways to accept expired, unused, and discontinued medications—including controlled substances—from consumers.13 These guidelines facilitate proper disposal of these substances and prevent their illegal diversion.13 Health Canada14 issued detailed guidelines for that nation’s citizens, and similar information and guidelines have been released in several European nations.12

Many countries in Latin America have regulations for the public regarding the disposal of unused opioid medications. For example, Argentina, Colombia, Cuba, Mexico, and Peru allow—or, in some cases, require—patients to dispose of unused opioid medications by returning them to such healthcare institutions as hospitals, pharmacies, and government health agencies.15

The United States, however, has no federal system of guidelines or requirements for the proper disposal of controlled substances by consumers—though there are well-defined guidelines for pharmacists. Pharmacists may dispose of expired, damaged, or unwanted pharmaceutical products once per calendar year, provided that the pharmacies follow strict DEA regulations, including obtaining prior written approval.8 The specific method chosen for disposal must also be in accordance with local environmental regulations, which are not specified in the DEA guidelines.5

The US Department of Justice, which oversees the DEA,
forbids pharmacists and physicians from accepting opioids or other controlled substances from consumers and patients.\textsuperscript{5,6} Similarly, long-term care facilities are prohibited from returning controlled substances to pharmacies, even if the substances are unexpired and unused by the patients for whom they were prescribed.\textsuperscript{6} The only exception to this rule would be in the case of a drug recall or a pharmacy dispensing error.\textsuperscript{5,6} The inability of patients or long-term care facilities to return unused medications is a result of the fact that there are no regulations in the Controlled Substances Act\textsuperscript{16} or the Code of Federal Regulations\textsuperscript{17} that allow for entities not registered with the DEA to return unused narcotic medications to entities that are registered.\textsuperscript{5}

**Available Means of Opioid Disposal**

Physicians and government agencies may give widely varying directives to patients for the proper disposal of unused opioid medications. These directives may include flushing unused medications down the toilet, throwing them away in the trash, or incinerating them.

Most patients would have access to incineration only if there is a local entity that facilitates this procedure, such as a reverse distributor or a community-based “take-back” program.\textsuperscript{18} Many environmentalists consider incineration the most environmentally friendly means of disposing of these products.\textsuperscript{12}

**Community Take-Back Programs**

In the United States, most local entities—including hazardous-waste collection programs, reverse distributors, and take-back programs—cannot accept controlled substances directly from consumers because of federal regulations. As previously mentioned, individuals and institutions that are not registered with the DEA are not allowed to return controlled substances to DEA registrants.\textsuperscript{5,6} This regulation is the primary reason that most community take-back programs cannot accept unused, unneeded, or expired controlled substances directly from consumers.

In some communities and states, innovative pilot programs to address medication disposal, including disposal of opioids, have been implemented or proposed. One such program was implemented in Clark County, Wash, in 2003.\textsuperscript{19,20} This program, which was recognized with an award from the North American Hazardous Materials Management Association, takes advantage of the fact that federal regulations permit the collection of controlled substances by law enforcement officials.\textsuperscript{19,20} The program involves the collection of controlled substances from consumers by the Clark County Sheriff’s Office. The medications that are collected for disposal are documented, sealed in plastic bags, and stored at a secure location until they can be incinerated.\textsuperscript{19,20} Federal regulations require law enforcement officials in the United States to turn over controlled substances directly to licensed waste incinerators; law enforcement officials cannot give controlled substances to reverse distributors.\textsuperscript{21}

Another initiative for collecting unused and unwanted pharmaceutical products from consumers was carried out in Franklin County, Mass, as a pilot program in 2004.\textsuperscript{22} This program was a collaboration between the county and the Northeast Recycling Council.\textsuperscript{22} As with the Clark County program, the participation of law enforcement officials was necessary in the Franklin County program.\textsuperscript{22} Unfortunately, the effectiveness of the Franklin County program was limited by a lack of appropriate marketing. The program’s organizers expressed concern that excessive advertising might have the effect of attracting “participants” who might want to obtain drugs for nonmedical purposes.\textsuperscript{22}

In 2005, Maine implemented the Unused Pharmaceutical Disposal Program, administered by the Maine Drug Enforcement Agency, to collect consumers’ unused pharmaceutical products.\textsuperscript{23} Additional states and counties can be expected to launch similar programs, typically involving the participation of law enforcement agencies for collection and incineration.\textsuperscript{18,21,24}

**Disposal in Wastewater Systems**

As previously noted, flushing unused medications down the toilet is the method of disposal most often recommended to patients by healthcare providers and regulators in the United States.\textsuperscript{25-27} For example, VITAS Hospice Services, LLC, of Miami, Fla, the largest provider of hospice services in the United States, notes in its policy manual that unneeded controlled substances in the homecare setting are to be flushed down the toilet after documentation of the medications to be disposed.\textsuperscript{25} In addition, one of the two methods of drug disposal advocated by the North Carolina Board of Pharmacy Investigations and Inspections is flushing into sewer systems.\textsuperscript{26}

The Kentucky Board of Medical Licensure states that if a patient brings unused medications to a physician, he or she must destroy the medications in the presence of the patient.\textsuperscript{27} The physician is instructed to first dissolve any tablets in hot water and then flush them down the toilet.\textsuperscript{27} If the medication is not in tablet form, it can be flushed directly down the toilet.\textsuperscript{27} According to the Kentucky Board of Medical Licensure, physician-owned controlled substances cannot be disposed of in trash or sewer systems. Instead, these substances must be taken to any of a small number of selected substance-disposal companies in that state where the products will be disposed of for a small fee.\textsuperscript{27}

As previously noted, physicians in the United States cannot take possession of medications returned by patients because such an action would be a violation of federal law, which forbids DEA registrants from accepting controlled substances from nonregistrants.\textsuperscript{3} Ideally, a physician and patient should each sign a legal statement to prevent allegations of drug diversion by either party.

Unfortunately, the disposal of medications into sewer systems promotes the ready entry of potentially harmful substances into the environment.\textsuperscript{28} Because the effects of many
pharmaceutical compounds on the environment are not fully understood, many environmentalists consider sewage-mediated disposal to be the least desirable means of disposal.28

In a search of the literature conducted at the time of this investigation, we were unable to locate studies that demonstrated the contamination of public water supplies by opioids. Though that paucity of data may have been the result of the fact that no studies had been performed on this exact topic at that time, earlier this year such reports began to appear in the public media.29 Nevertheless, none of the articles we reviewed concerning contamination of water systems made specific mention of opioids or other controlled substances as agents of contamination. However, various nonsteroidal anti-inflammatory drugs, which are not controlled substances, have been found in the environment. For example, ibuprofen and aspirin, which are key ingredients in some opioid combination medications, have both been detected in surface waters.29,30 Thus, many environmental experts recommend that consumers not flush excess or outdated medications into sewer systems.

**Municipal Solid Waste Disposal**

Patients may also choose to dispose of their unused medications in the trash. This method is recommended by government entities in many states.7,24,31

For example, in the absence of community household hazardous-waste collection programs, the Michigan Department of Environment Quality considers landfill trash disposal the best option for unused medications.24,31 However, the department also advises consumers to keep each medication in its original container, adding water to solid drugs and absorbent materials to liquid suspensions, and double-pack the unused portion of the product in its original packaging to prevent identification or breaking.30,31

Similarly, the California Integrated Waste Management Board recommends that residents unable to access community take-back programs dispose of such medications in the trash.7

**Disposal Dilemma**

The lack of unambiguous federal regulations and consistent state directives regarding appropriate procedures for disposal of unused opioids and other controlled substances has caused a dilemma for patients and healthcare providers. How are they, without clear and consistent guidance, to know the most appropriate and most environmentally friendly method for disposing of opioids and other controlled substances?

Although flushing medications into sewer systems is a recommendation commonly made to consumers, it is important to note that most municipal sewage treatment plants are not equipped to extract pharmaceutical compounds from wastewater.7 The physiologic and ecologic effects of pharmaceutical chemicals in the environment are not known because there are few adequate studies on this topic.7

Similarly, throwing medications away in the trash may result in the unintended and potentially harmful distribution of these substances to other people (eg, children,32 people with substance abuse problems33), pets, and wild animals. Still other concerns about disposing medications in the trash include issues related to patient privacy, especially if pharmaceutical products are thrown away in containers bearing identifying information.

Federal regulations prohibit patients from regularly returning unused or expired medications to pharmacies,16 and, aside from law enforcement officials, no one else is currently authorized under federal law to accept controlled substances from patients and healthcare institutions.21

So what can patients and healthcare institutions do about this dilemma?

**Proposals for the Future**

We propose several ways of resolving the many problems related to the effective and environmentally acceptable disposal of controlled substances. Some of these proposals have been previously suggested by researchers and experts:

- Create a national protocol for disposal of controlled substances involving a system of reverse distributors similar to those enacted in other countries.
- Allow pharmacies to accept controlled substances from patients and institutions not registered with the DEA for the explicit purpose of product disposal. However, pharmacies should be required to document all medications received for this purpose.
- In an effort to minimize possible unused doses, physicians and other licensed healthcare providers should be asked to write prescriptions for controlled substances in smaller amounts,33 particularly when modifying opioid dosages for pain management.
- Consider municipal recycling programs for unused pharmaceutical products, allowing redistribution of “reclaimed” medications to individuals who cannot afford to purchase them. However, because precautions must be taken to identify expired or tampered medications, such a program may be relevant only for medications in tamper-resistant (eg, blistered) packaging.34 Thus, this program would be most effective if all controlled substances were economically packaged in tamper-resistant packaging.
- Enlist the cooperation of regional law enforcement agencies in communities throughout the country for periodic scheduled collections of controlled substances by officers. Such programs may prove to be attractive options because they are the only legal means of collection for controlled substances from consumers and institutions not registered with the DEA.
- Provide economic incentives (eg, extensions of company drug patents) to pharmaceutical companies that take extra steps to ensure the safe disposal of the medications they produce.

(continued)
Implement public education programs about the potential dangers of disposing medications into the environment through sewer systems and the trash. Such programs would require that acceptable alternative methods of disposal be presented to the public.

Provide financial incentives to counties and municipalities that offer controlled-substance collection drives for their residents.

Consider financial incentives for waste-management companies that provide drug-incineration services.

In May 2005, the DEA initiated a novel approach for the disposal of pharmaceutical products at long-term care facilities. This approach involves allowing the facility to use an automated dispensing system (ADS) provided by the pharmacy for the distribution of patient medications. The ADS is similar to a vending machine in that it is programmed to record the dispensing of each single dose provided to patients. Until the controlled substance is dispensed, it is considered part of the pharmacy’s stock and, hence, remains in the control of the pharmacy, which is a DEA registrant.

This single-dose ADS system for patients prevents excess ordering of controlled substances. Thus, fewer medications leave the DEA system, relieving some of the drug-disposal dilemma that results from common prescribing practices. However, the use of this system depends on states amending their laws to allow off-site pharmacies to place ADS systems in long-term care facilities, as certain states, or clarifying their laws to allow off-site pharmacies to place

징

used in the trash after making sure the following three steps are taken:

Medications should be made unusable by adding water to pills; and cat litter, bleach, or some other appropriate substance to liquid suspensions.

Unused medications should be kept in their original packaging with all identifying information obscured or removed.

The original packaging should be concealed by placing the product within plain outer packaging such as sealable plastic bags.

References


In answer to the questions of how long have you been teaching this discovery, and what books are essential to the study? I will say I began to give reasons for my faith in the laws of life as given to men, worlds and beings by the God of nature, June, 1874, when I began to talk and propound questions to men of learning.

I thought the sword and cannons of nature were pointed and trained upon our systems of drug doctoring.

Andrew Taylor Still, MD, DO
“When I Became an Osteopath” from Philosophy of Osteopathy (1899)