

**DRUG WASTE AND DISPOSAL: WHEN
PRESCRIPTIONS BECOME POISON**

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DRUG WASTE AND DISPOSAL: WHEN PRESCRIPTIONS BECOME POISON

WEDNESDAY, JUNE 30, 2010

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:03 p.m. in room SD-106, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl [presiding], Casey, Corker, and Collins.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good afternoon. We appreciate you all being here today.

Our hearing today is about what happens to drugs that are prescribed but never taken and how we can do a better job of making sure that they do not cause unintended harm or even death.

Odds are that many of us have half-empty bottles of medicine lying around our houses. Some of us may have thought we were doing the right thing by flushing them down the toilet or throwing them away with our trash. But these disposal methods can have a damaging effect on our environment.

A 2002 U.S. Geological Survey of 139 bodies of water across the country found that over 80 percent of the water samples were contaminated by prescription drugs, which have been shown to harm fish and our wildlife. While we don't yet know what impact this has on humans, we can all agree that it is disturbing to think about leftover drugs tainting our drinking water.

Environmental harm is only one side of the issue. Though improper disposal of prescription drugs can be risky, lack of disposal can be deadly. Prescription drugs from the medicine cabinet may be just as harmful as illegal drugs purchased off the street if they were not prescribed for you, for a particular need, at a particular time, by a professional.

One of the best strategies to tackle the problem of drug disposal is to make sure drugs are not wasted in the first place. We need to explore innovative ways to improve patient care and reduce waste through programs like medication therapy management, improved compliance, and patient education.

For example, many doctors prescribe several months' supply of a medication before it has been determined whether the patient will respond well to it. A program in Maine aims to reduce waste by limiting initial prescriptions for a list of drugs that are known to provoke adverse reactions in some individuals. Once the patient

and their doctor decide to continue with the medication, it is then dispensed in larger quantities.

Not surprisingly, reducing waste also reduces costs. The initiative also saves Maine's Medicaid program money—nearly a quarter of a million dollars in projected savings for 2010.

Since we cannot eliminate all waste, we need to find better ways to dispose of unwanted medications. We need to expand programs such as the one in Wisconsin that collects leftover drugs and incinerates them, turning them into an energy source; or like the one that we will be hearing about from Senator Collins in her home State of Maine, which has successfully implemented a comprehensive drug mail-back program.

Unfortunately, current DEA guidelines concerning who can handle the most dangerous types of drugs create a barrier for many drug disposal initiatives. While we understand there is a risk that drugs can fall into the wrong hands on their way to a drug disposal collection point, the fact is that the risk of that happening in the home is even greater. We need the DEA to update its regulations to allow safe, comprehensive take-back programs across our country.

We also need to provide Americans with better information about what to do with their leftover medications. Contradicting guidelines put forth by the DEA, FDA, EPA, and the U.S. Fish and Wildlife Service need to be reconciled.

Americans deserve a safe and effective way to get drugs away from their homes and keep them out of our drinking water. I will be working with my colleagues to develop a comprehensive package of legislative reforms that reduce waste and ensure safe disposal.

We thank you again for your willingness to be here today, and we will now turn to the ranking member, Senator Corker, for his statement.

OPENING STATEMENT OF SENATOR BOB CORKER

Senator CORKER. Mr. Chairman, thank you. I very much appreciate you calling the hearing.

Prescription drug misuse in Tennessee is a big issue. So not only am I concerned about this from the standpoint of having appropriate national policy to deal with diversion issues, to deal with disposal issues, knowing that prescription drugs are expensive, and sometimes people are wary to let go of them. So, they end up being around medicine cabinets and other places far longer than they should.

So I look forward to hearing the testimony today, and I thank you very much for calling this hearing and thank our witnesses for being here.

The CHAIRMAN. Thank you, Senator Corker.
Now we will hear from Senator Collins.

STATEMENT OF SENATOR SUSAN COLLINS

Senator COLLINS. Thank you, Mr. Chairman.

First, let me thank you and the ranking member for calling this hearing to examine the challenges associated with the safe disposal of unused or expired prescription drugs.

An estimated 40 percent of drugs that are dispensed outside of our Nation's hospitals go unused. That generates approximately 200 million pounds of pharmaceutical waste each year. These unused drugs, as the chairman has pointed out, are prime candidates for diversion and also are a potential source of both safety and environmental problems.

While many rural States, including Tennessee and Wisconsin, are experiencing serious problems associated with diverted or misused prescription drugs, no State has been harder hit than mine, the State of Maine. Since 1997, when I first came to the Senate, the number of the accidental deaths from drugs in Maine has increased almost tenfold, jumping from 19 to 179 last year, and most of these deaths were due to prescription drugs.

Moreover, prescription drug abuse is the second most-common form of illicit drug abuse among our Nation's teenagers behind only marijuana use. Nearly 1 in 5 of Maine's high school seniors say that they have abused prescription drugs. Many of these drugs were found in medicine cabinets, dresser drawers, or trash cans of their unsuspecting parents or grandparents.

The vast majority of Americans currently dispose of unwanted medicines by throwing them in the trash or by flushing them down the toilet or sink. This has raised concerns about the potential environmental impact of these disposal methods and in particular about the effect on our Nation's water supply. These concerns have led a number of local communities and States, including Maine, to initiate drug take-back programs to collect unused or unwanted medications for disposal.

Mr. Chairman, I am particularly grateful that you have invited one of my constituents, Dr. Stevan Gressitt—and I apologize if I have mispronounced his name—to testify about the Safe Medicine Disposal for ME program, which I believe could be used as a national model. Our mail-back program in Maine uses prepaid mailing envelopes addressed to the Maine Drug Enforcement Agency that individuals and families can use for the disposal of unused medications.

These envelopes are available for pickup throughout the State at pharmacies, doctor's offices, and post offices. All the drugs collected by the program are disposed of through the same high-heat incineration process that is used for Maine's law enforcement drug seizures.

Since the program was established in 2007, it has prevented more than a ton of unused, unneeded, or expired drugs from falling into the hands of our children or being diverted to criminals. At the same time, it has kept these medications out of our water supply and landfills.

So, again, Mr. Chairman, thank you very much for focusing the Senate's attention on this issue.

The CHAIRMAN. Thank you very much, Senator Collins.

At this time, we will turn to our witness on the first panel, who is R. Gil Kerlikowske, the Director of National Drug Control Policy. There, he oversees all Federal drug control programs, as well as the President's national drug control strategy. Previously, Mr. Kerlikowske served 9 years as the chief of police for Seattle, WA.

We welcome you here, sir, and we look forward to your testimony.

**STATEMENT OF HON. R. GIL KERLIKOWSKE, DIRECTOR,
WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY,
WASHINGTON, DC.**

Mr. KERLIKOWSKE. Chairman Kohl, Ranking Member Corker, and Senator Collins, thank you very much for the opportunity to address prescription drug abuse and disposal.

I am also very encouraged and very pleased about the committee's focus on this topic. Prescription drug abuse, proper methods of disposal have been a major factor for us at ONDCP since my arrival, and I have directed the National Drug Control Program agencies to address these vital issues in our drug control efforts.

Let me begin by describing the growing problem—and Senator Collins, you certainly elaborated on that also—of drug abuse in this country, of prescription drug abuse. This abuse has increased dramatically in the last several years. In recent years, the number of individuals who, for the first time, consumed prescription drugs for a nonmedical purpose exceeded the number of first-time marijuana users. This increase has had tragic consequences.

In 2006, more than 26,000 Americans died from unintentional drug overdoses, and prescription drugs, particularly the opioid painkillers, are considered a major contributor to the total number of drug deaths. The extreme threat and abuse of prescription drugs comes from their widespread availability.

Well, how are they obtained? Well, for instance, in 2007–2008, among persons aged 12 or older who used these pain relievers non-medically in the last 12 months, about 70 percent obtained the pain relievers from a friend or a relative. Further troubling, an estimated 1.9 million adults, aged 50 or older, or 2.1 percent of adults in that age range, used pharmaceutical drugs nonmedically in the past year.

The problem doesn't lend itself to traditional interventions. These drugs are originally dispensed for legitimate purposes. Too often the public's perception is that they are safe for uses other than for which they were prescribed.

Well, we must change public perception so the societal norm shifts to one where unused or expired medications are disposed of in a timely, safe, and environmentally responsible manner. To address the growing problem, the national drug control strategy outlines specific steps to address prescription drug abuse.

The first is to encourage individuals to dispose of expired or unused drugs through increased prescription drug take-back programs or disposal programs. We know that legitimate prescriptions from the family medicine cabinet are most often the source of the drugs that get abused.

To counter this, law enforcement professionals and grassroots organizations have held take-back days where residents can dispose

of their unwanted prescriptions. These events have already been a success in many States, but more can be done.

It is important to remember that all take-back programs must be conducted consistent with the regulations of the Controlled Substances Act. Under current rules, the DEA special agent-in-charge must approve the take-back events when controlled substances are accepted. Therefore, if Congress were to amend the CSA to ease restrictions on drug take-back programs, it would be an important step in combating this problem by decreasing the supply of prescription drugs that may be misused.

Another step the strategy promotes is more training and education for physicians about opiate painkiller prescribing. Through the Physician Clinical Support System Program, the Substance Abuse and Mental Health Services Administration will train prescribers on how to instruct patients in the use and proper disposal of painkillers, observe signs of dependence, and use prescription monitoring programs to detect doctor shopping. We are also working with our Federal partners to identify other ways to increase prescriber education.

Our strategy promotes the expansion of prescription drug monitoring programs and establishing the information sharing between States. The strategy also calls for ONDCP, along with the DEA, to continue to work with State, local, and tribal officials to give more assistance to States that are targeting doctor shopping and pill mills. This is an extremely difficult problem for State-level law enforcement to handle and due to resource constraints and difficulties navigating these cases across multiple State, local, and tribal jurisdictions.

Lastly, the strategy focuses on driving illegal Internet pharmacies out of business and also shutting down rogue pain clinics that do not follow appropriate prescription practices. ONDCP is working with the DEA, the FDA, and EPA, and Congress to further refine Federal laws and regulations to foster an expansion of comprehensive, cost-effective prescription drug take-back programs across the country.

Unless take-back programs are consumer friendly, large quantities of unneeded prescription drugs will remain in the community, subject to diversion and misuse. I look forward to continuing to work with this committee to address these challenging important issues, and I know that we could not accomplish what we all want to for the Nation from the executive branch without the support of Congress.

Thank you for the opportunity to testify, and I look forward to answering your questions.

[The prepared statement of Mr. Kerlikowske follows:]



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

**“Drug Waste and Disposal: When Prescriptions
Become Poison”**

Senate Special Committee on Aging

June 30, 2010

2:00 p.m.

106 Dirksen Senate Office Building

Written Statement of
Director R. Gil Kerlikowske
Director of National Drug Control Policy

Chairman Kohl, Ranking Member Corker, distinguished members of the Committee, thank you for providing me the opportunity to appear before you today to address prescription drug abuse and disposal. I am encouraged by your Committee's focus on this topic. Prescription drug abuse and proper methods of disposal have been a major focus for ONDCP since my arrival, and I have directed National Drug Control Program agencies to address these vital issues in our drug control efforts.

The Growing Problem of Prescription Drug Abuse

Prescription drug abuse is the fastest-growing drug problem in the United States and is a serious public health concern. In recent years, the number of individuals who, for the first time, consumed prescription drugs for a non-medical purpose, exceeded the number of first-time marijuana users.¹ Monitoring the Future, a study of youth attitudes and drug use, shows that seven of the top ten drugs reported abused by 12th graders are prescription drugs.² From 1997 to 2007, there was a 400 percent increase in treatment admissions for individuals primarily abusing prescription pain killers.³ According to a Department of Defense survey in 2008, one in eight (12%) active duty military personnel reported past month illicit drug use, largely driven by the misuse of prescription drugs (reported by 11%).⁴

Between 2004 and 2008, the estimated number of emergency department visits linked to the nonmedical use of prescription pain relievers has more than doubled. The dramatic rise in emergency department visits associated with nonmedical use of these drugs occurred among men and women of all age groups.⁵

1 SAMHSA 2009 Results from the 2008 National Survey on Drug Use and Health: National Findings.

2 University of Michigan 2009 Monitoring the Future: A Synopsis of the 2009 Results of Trends in Teen Use of Illicit Drugs and Alcohol.

3 Highlights for 2007 Treatment Episode Data Set (TEDS) Table 1b Admissions by primary substance of abuse: TEDS 1997-2007 Percent distribution, <http://www.drugabusestatistics.samhsa.gov/TEDS2k7highlights/TEDSHighl2k7Tbl1b.htm>

4 Bray et al., 2008 Department of Defense Survey of Health Related Behaviors Among Active Duty Military Personnel. (2009). Research Triangle Institute, Research Triangle Park, NC.

5 Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs — United States, 2004–2008. June 18, 2010.

Further troubling, an estimated 1.9 million adults aged 50 or older, or 2.1 percent of adults in that age range, used prescription-type drugs non-medically in the past year. Intentional misuse of prescription drugs among those 65 and older is more pervasive than marijuana use. This is the only age group for which this is so.⁶

The Substance Abuse and Mental Health Services Administration's Treatment Episode Data Set (TEDS) reveals that between 1992 and 2008 the proportion of substance abuse treatment admissions involving older Americans (aged 50 and older) nearly doubled -- from 6.6 percent of all admissions in 1992 to 12.2 percent in 2008. For the same timeframe, the proportion of admissions among this age group due primarily to prescription drug abuse rose from 0.7 percent to 3.5 percent.⁷

Among persons aged 12 or older in 2007-2008 who used pain relievers non-medically in the past 12 months, 55.9 percent got the pain relievers they most recently used from a friend or relative for free. Another 8.9 percent bought them from a friend or relative, and 5.4 percent took them from a friend or relative without asking. Nearly one-fifth (18.0 percent) indicated they got the drugs they most recently used through a prescription from one doctor. About 1 in 20 users (4.3 percent) got pain relievers from a drug dealer or other stranger, and 0.4 percent bought them on the Internet. These percentages are similar to those reported in 2006-2007.⁸ Most distressingly, more than 26,000 Americans died from unintentional drug overdoses in 2006, and prescription drugs—particularly opioid painkillers—are considered a major contributor to the total number of drug deaths.⁹

As these statistics demonstrate, the misuse of controlled substances and more broadly pharmaceuticals is a problem of ever-increasing concern, and the problem does not lend itself to traditional interventions. These drugs are dispensed for legitimate purposes and too often, the public's perception is that they are safe for uses other than those for which they are prescribed. We must change public perception so the societal norm shifts to one where unused or expired

⁶ NSDUH Report, "Illicit Drug Use Among Older Adults," December 29, 2009.

⁷ SAMHSA 2009 The TEDS Report - Changing Substance Abuse Patterns among Older Admissions: 1992 and 2008.

⁸ SAMHSA Results from the 2008 National Survey on Drug Use and Health: National Findings, 2008.

⁹ CDC, National Center for Health Statistics, "National Vital Statistics Report", 2009.

medications are disposed of in a timely, safe, and environmentally responsible manner. We envision a future where disposal of these medications is second-nature to most Americans, in much the same way as proper and responsible recycling of aluminum cans has become. Creating a method for disposal of expired or unused prescription drugs is essential to public health, public safety, and the environment.

While these realities demand action, any policy response must be approached thoughtfully, as it must strike a balance between our desire to minimize misuse of pharmaceuticals and the need to maximize their legitimate benefits. As science has successfully developed valuable medications to alleviate suffering, such as opioids for cancer patients and benzodiazepines for anxiety disorders, it has also led to the unintended consequence of increased pharmaceutical abuse.

Last month, the Obama Administration released its inaugural *National Drug Control Strategy*. This *Strategy* is balanced and comprehensive and recognizes that prevention, treatment, and enforcement are all essential components of an effective approach to addressing drug use and its consequences. The *2010 National Drug Control Strategy* is the result of a nine-month consultative effort with Congress, Federal agencies, State and local partners, and hundreds of individuals across the country. It serves as a bold call to action for all Americans who share in the desire and the responsibility to keep our citizens -- especially our vulnerable youth -- safe, healthy, and protected from the terrible costs of substance abuse, while ensuring our seniors, as well as those who are ill or vulnerable, have access to the prescription drugs they need to reduce pain, mitigate disease, and preserve life.

The *Strategy* sets specific goals by which we will measure our progress. Over the next five years, working with dozens of agencies, departments, Members of Congress, State and local organizations, and the American people, we intend to make significant reductions in illicit drug use and its consequences.

Our efforts are balanced, incorporating science and smarter strategies to better align policy with the realities of drug use and its consequences in communities throughout this country. Research shows addiction is a complex, biological, and psychological disorder. It is chronic and

progressive, and negatively affects individuals, families, communities, and our society as a whole. In 2008, over 23 million Americans ages 12 or older were estimated to need treatment for an illicit drug or alcohol use problem. However, only 10 percent were estimated to have received the necessary treatment for their disorders.¹⁰

The 2010 National Drug Control Strategy Addresses Prescription Drug Abuse

The *Strategy* specifically acknowledges that prescription drug abuse is the fastest-growing drug problem in the United States, and therefore outlines an approach to address the unique issues surrounding the growing problem. The following are specific steps outlined in the *Strategy*:

Increase Pharmaceutical Return/Take-Back and Disposal Programs

One aspect of our *Strategy* relates directly to the focus of today's hearing. Increasingly, many of the abused prescription drugs are found in the family medicine cabinet (e.g., the pain pill prescription that was never finished, the tranquilizers that are used occasionally). Yet, the difficulty in disposing of such medications in a fashion that is simple, legal, and environmentally responsible is a challenge. In some communities, law enforcement professionals in conjunction with grassroots organizations have held "take-back days" in which such medications are safely collected. At the Federal level, Congress is exploring legislative proposals to facilitate the establishment of pharmaceutical take-back programs around the country, and EPA has awarded two grants for pilot pharmaceutical take-back programs. However, a statutory change to the Controlled Substances Act (CSA) is required before the Drug Enforcement Administration (DEA) can fully implement the legitimate take-back of frequently abused prescription drug products containing controlled substances. These grassroots, legislative, and agency efforts will be intensified as part of the Administration's effort to combat prescription drug abuse. The private sector will be engaged as a potential partner in take-back programs. These efforts will also be complemented by activities of several other Federal partners, including the work done by the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to educate patients and family members on the most appropriate methods of disposal when take-back programs are not available.

¹⁰ Results from the 2008 National Survey on Drug Use and Health: National Findings, Substance Abuse and Mental Health Services Administration (SAMHSA), 2008, <http://www.oas.samhsa.gov/hsduh/2k8nsduh/2k8RResults.cfm>

The Closed System of the Controlled Substances Act

These steps are all temporary approaches until Congress acts to amend the Controlled Substances Act (CSA) (P. L. 91-513) to permit promulgation of more systematic policy responses. Currently, the CSA establishes a closed system of distribution to provide security and accountability for the Nation's controlled substance supply. Under this system, all controlled substances used in legitimate commerce may be transferred only between persons or entities who are DEA registrants or who are exempted from the requirement of registration, until they are dispensed to the ultimate user. After a DEA-registered practitioner, such as a physician or a dentist, issues a prescription for a controlled substance to a patient (i.e., the ultimate user), the patient can fill that prescription at a retail pharmacy. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants to participate in the process.

Under the CSA, if an individual has been prescribed a controlled substance, he or she cannot legally transfer the controlled substance to a pharmacist or to another non-law enforcement person for any reason, even if the person intends to dispose of the drug. Consumers, therefore, often retain unused controlled substances in their homes, which can lead to diversion and abuse of the prescription drug. As already discussed, the 2009 Monitoring the Future Study found that, among 12th graders surveyed, 7 of the top 10 drugs abused by youth were prescription drugs, with a majority of the youth surveyed saying that they had obtained the drug from a friend or relative.

Community-based Efforts to Control Prescription Drug Abuse

We know that legitimate prescriptions from the family medicine cabinet are often the source of drugs that get abused. Proper disposal of unused or expired medications must be made easier. Disposing of unused or expired medications in a fashion that is simple, legal, and environmentally responsible is a challenge. Currently, the Federal government advises controlled substance users to dispose of controlled substances in one of three ways – throw them in the trash, after taking proper precautions; flush them down the toilet, in limited cases of very dangerous drugs; or participate in a take-back event. Only exceptionally dangerous drugs should

be flushed down the toilet. The FDA advises this because it has determined that the misuse of these prescription drugs creates a high risk of immediate harm, and so their potential danger outweighs the potential environmental impact. These prescription drugs are very dangerous and can be lethal if used improperly, especially by youth.

Take-back or community drug disposal events are community-based activities that accept prescription drugs. If controlled substances such as Vicodin or OxyContin are accepted, the events must be conducted in accordance with DEA guidelines, with the permission of the DEA Special Agent in Charge for the region, and under the supervision of authorized and certified law enforcement officials. Any methods utilized to destroy the collected controlled substances must comply with all applicable Federal and State laws and regulations, including, but not limited to, laws and regulations relating to public health and the environment.

Currently, there are three types of take-back programs designed to assist in the disposal and destruction of prescription drugs. All require a waiver from the DEA if they accept controlled substances. Programs range from permanent sites where unused medication is received; one day events at various locations, such as pharmacies or hazardous waste collection sites; and in Maine, a mail/ship back program where ultimate users send their unused drugs to a central location using a pre-issued label or through a private carrier, such as UPS or FedEx.

EPA has awarded two grants for pilot take-back programs. From January to December 2008, the Regional eXcess Medication Disposal Service (RxMEDs) project managed by the Area Resources for Community and Human Services (ARCHS) in St. Louis collected more than 10,000 bottles of over-the-counter and non-controlled prescription drugs during collection days held at pharmacies.¹¹ In addition, through a mail-back return envelope system, the Safe Medicine Disposal for Maine (SMDME) program collected more than 2,300 lbs of drugs, including controlled substances.¹²

¹¹ Prudent Disposal of Unwanted Medications (RxMEDS): Final Report, 2009, <http://www.epa.gov/aging/grants/winners/rx-meds-technical-report508.pdf>

¹² Executive Summary: Reducing Prescription Drug Misuse Through the Use of a Citizen Mail-Back Program in Maine, 2010, <http://www.epa.gov/aging/RX-report-Exe-Sum/>

Several States and many localities have organized one-day take-back events in coordination with appropriate law enforcement officials. In 2009, New Jersey held Operation Medicine Cabinet. Throughout all of New Jersey's 21 counties, over 440 local police departments and sheriff departments hosted collection sites. Over 9,000 pounds of prescription drugs (both controlled and non-controlled substances) were collected at the one day take-back event. This event was organized through the Special Agent in Charge DEA New Jersey Division, the New Jersey Office of the Attorney General (OAG), and the Partnership for a Drug-Free New Jersey.

In March of this year, Oregon organized a statewide Prescription Drug Turn-In Day. More than 2,300 individuals took part, turning in more than 4,000 pounds of pills, tablets, and other drugs. The event was coordinated by the Oregon Medical Association Alliance, Community Action to Reduce Substance Abuse, and the Oregon Partnership. Several other States, including Montana and Missouri, have conducted similar take-back days.

Just as the Federal government, along with national partners, took on the challenge of changing societal attitudes about wearing seat belts, so, too, does this Administration, along with national, State, and local partners, need to change societal attitudes about proper and timely disposal of prescription drugs.

Beyond the issue of disposal of excess medications, ONDCP is also focused on other effective measures which can be implemented to curtail prescription drug abuse and its consequences. The following are some examples of initiatives currently underway by Executive Branch Departments and Agencies.

Educate Physicians about Opiate Painkiller Prescribing

The FY 2011 Budget proposes for SAMHSA, through the Physician Clinical Support System (PCSS) program, to train prescribers on how to instruct patients in the use and proper disposal of pain killers, observe signs of dependence, and use prescription monitoring programs to detect doctor shopping. FDA, the agency responsible for reviewing and approving drug applications for prescription pain medications, plays an important role in providing effective information about the proper use and disposal of opioids through approved product labeling. Furthermore,

Federal agencies that support their own healthcare systems, such as the Department of Veterans Affairs, will increase continuing medical education for their prescribers on proper prescribing and disposal.

Expand Prescription Drug Monitoring Programs and Promote Links among State Systems and to Electronic Health Records

Prescription drug monitoring programs (PDMPs) are State-level, controlled substance prescription data collection systems which allow authorized users (such as prescribers, pharmacists, regulatory and law enforcement entities, and professional licensing agencies) access to the data under certain conditions and with varying restrictions. PDMPs gather controlled substance prescription data from pharmacies within their states on regular intervals (1, 2 or 4 times monthly).

Generally, PDMPs can generate two different kinds of reports: solicited and unsolicited. With most PDMPs, authorized users can query or obtain information from the PDMP system for information about controlled substance prescriptions for individuals. ONDCP believes that all PDMPs should also produce and disseminate unsolicited reports. These unsolicited reports can be generated when certain thresholds are reached which might indicate abuse of a controlled substance, doctor shopping, or errant prescribing practices. Different States and Federal agencies are experimenting with different thresholds. For instance, the SAMHSA's Center for Substance Abuse Treatment (CSAT) proposes that unsolicited reports be sent to prescribers when any individual that has filled six or more controlled substance prescriptions from six different prescribers, or six different dispensers in a State, within a six month period.

There are currently two Federal funding programs for PDMPs. The Harold Rogers Prescription Drug Monitoring Program, administered by DOJ's Bureau of Justice Assistance, has been operating since 2003 and competitively funds State PDMP planning, implementation, and enhancement, and also can and does fund research, training, and technical assistance. The National All Schedules Prescription Electronic Reporting Act (NASPER) program, administered by SAMHSA's CSAT, has been funding PDMP programs since 2009 and awards funds to States with operational programs based on a formula applied annually.

Criminal activity does not respect State borders, and it is critical that State PDMPs share information across State lines. This is currently being done on an *ad hoc* basis between States. The Department of Justice has invested considerable resources to develop the technology for states to share PDMP data via a hub (currently located at the Ohio Board of Pharmacy). Kentucky and Ohio have shared test data via this hub (transactions occurred within 30 seconds) and currently have a memorandum of understanding in place to exchange real data. It is anticipated this will start occurring regularly by the end of 2010. ONDCP has also invested resources in ensuring other States have the technology needed on their end to be able to interact with the hub and also begin engaging in interstate information sharing.

Currently, prescription drug monitoring programs are authorized in 42 States, but only 34 have operational programs. The PDMP authorizing legislation in each State determines where and how the PDMP in that state functions or will function. In some States, this is done by regulation. Recently, Wisconsin's Governor Doyle signed PDMP authorizing legislation making Wisconsin the 42nd State with such authority. ONDCP supports the establishment of PDMPs in every State.

PDMPs can be effective at decreasing prescription drug abuse and the Administration is seeking to ensure new and existing PDMPs are effectively using the data they acquire. A study sponsored by DOJ indicated that PDMPs reduce the amount of prescription pain relievers and stimulants available for diversion, thus reducing the probability of abuse. The evidence also suggests that States which are proactive in their approach to regulation are more effective in reducing the per capita supply of prescription pain relievers and stimulants than states which are reactive in their approach.¹³ PDMPs can and should serve a multitude of functions including: a tool for patient care, drug epidemic early warning system (especially when combined with other data), drug diversion investigative tool (although PDMP data cannot be used as evidence in court), and insurance fraud investigative tool.

Assist States to Address Doctor Shopping and Pill Mills

Criminal organizations have established a thriving business of transporting individuals from

¹³ Ronald Simeone and Lynn Holland, "An Evaluation of Prescription Drug Monitoring Programs." Simeone Associates, Inc. [2006] <http://www.simeoneassociates.com/simeone3.pdf>

States with strong prescription-monitoring programs to States with less monitoring and regulation. Areas with little regulation are often populated by “pill mills”, which distribute prescriptions indiscriminately. This is an extremely difficult problem for State-level law enforcement to handle, due to resource constraints and difficulties navigating cases across multiple State, local, and tribal jurisdictions. It also creates significant problems for prescribers trying to determine whether a patient is doctor shopping. ONDCP, through our High Intensity Drug Trafficking Area Program (HIDTA) Program, and DEA continue to work with State, local, and tribal officials to suppress this aspect of the drug trade through training provided by the National Methamphetamine and Pharmaceuticals Initiative (NMPI) and DEA’s Tactical Diversion Squads.

Drive Illegal Internet Pharmacies Out of Business

Proper and safe prescribing of medications rests on a triangle of responsibility comprising the patient, the prescriber, and the pharmacist. However, those internet pharmacies that sell prescription pharmaceuticals without a valid prescription and/or personal contact between a patient and a physician are a threat to public health and a source of significant criminal revenue. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 requires that all internet pharmacies, unless exempted by statute, must obtain a modification of their DEA pharmacy registrations in order to operate online, must include certain declarations on their website designed to provide clear assurance that it is operating legitimately, and must not provide pharmaceuticals to individuals who have not had at least one face-to-face evaluation by a prescribing medical practitioner. The Act requires that internet pharmacies report to the DEA monthly and include all controlled substances dispensed by any means, not just controlled substances over the internet, unless the pharmacy does not meet the threshold of either (A) 100 or more prescriptions for controlled substances filled by the pharmacy or (B) 5,000 or more total dosage units of controlled substances dispensed. DEA will continue to partner with international, State, and local law enforcement agencies to further suppress these sources of prescription drug diversion and abuse.

Crack Down on Rogue Pain Clinics that Do Not Follow Appropriate Prescription Practices

In recent years, pain management clinics that operate outside the scope of acceptable medical

practices have increased. Currently, these “rogue pain clinics” are now a major source of controlled substance pharmaceuticals for drug seekers. Although rogue pain clinics are operating throughout the United States, DEA has identified three major hubs where these illegal schemes are flourishing: the Houston, TX, area; the Los Angeles, CA, area; and, most significantly, the tri-county area of South Florida (Palm Beach, Broward, and Miami-Dade counties).

The vast majority of “patients” who visit these clinics come from out-of-State. The opiate-based pharmaceutical controlled substances most frequently illegally dispensed at the clinics in the Texas and California regions are a combination of hydrocodone and alprazolam (Xanax®). In the South Florida region, oxycodone products are most frequently dispensed. DEA, in coordination with other Federal, State, and local agencies, will investigate these rogue clinics through expanded Tactical Diversion Squads and will shut down these rogue operations, via criminal, civil, or administrative actions, when they violate Federal prescribing and dispensing requirements and endanger the American public.

State legislative approaches, like the law recently enacted in Florida, can also play an important role in reining in rogue pain management clinics. The Florida law mandates greater regulation of pain clinics by the Florida Department of Health and allows the Department to shut down clinics if they violate established standards. The Florida law also allows the Florida Department of Health to prevent felons and disciplined physicians from owning and operating pain management clinics, and allows law enforcement to be informed of possible “doctor shopping” and potential criminal conduct by practitioners.

Conclusion

Prescription drug take-back programs play an important role in a comprehensive effort to reduce prescription drug abuse. ONDCP is working with DEA, FDA, EPA, and Congress to further refine Federal laws and regulations to foster an expansion of comprehensive and cost-effective prescription drug take-back programs across the country. To be effective, prescription drug take-back programs must be consumer friendly. Unless take-back programs are easy to access and

regularly occur, large quantities of unneeded prescription drugs will remain in the community, subject to diversion, misuse, and abuse.

The National Drug Control Strategy provides the blueprint for reducing prescription drug abuse, primarily by: focusing on prescriber education; limiting controlled substance prescriptions to those who have the greatest potential for abuse; and reducing, through take-back programs, the quantity of unused and expired prescription controlled substances from remaining accessible in homes and long term care facilities.

I look forward to continuing to work with the Committee to address these challenging and important issues, while balancing the safety of the public with the protection of the environment. I recognize that none of the many things ONDCP and my Executive Branch colleagues want to accomplish for the Nation are possible without the active support of Congress. Thank you very much for the opportunity to testify and for the support of the Committee on these vital issues.

The CHAIRMAN. Thank you, Mr. Kerlikowske.

Mr. Kerlikowske, your Web site directs consumers to FDA in order to obtain a list of flushable medications. Yet the EPA and the U.S. Fish and Wildlife Service have expressed concerns about flushing any medication. These conflicting recommendations are confusing. Is there a straightforward, comprehensive guide for Americans wishing to dispose of their medications in a safe and environmentally responsible way?

Mr. KERLIKOWSKE. Along with the information about what should be disposed of, according to the FDA, through flushing it down the drain, we have a series on our Web site of how other drugs can be disposed of. The drugs—the small number of drugs that are listed by the FDA are those that are clearly deemed as absolutely the most dangerous kinds of drugs, drugs that can be actually absorbed through skin contact and need to be disposed of in a way that they never can be misused.

But I am in complete agreement that a simple, straightforward set of guidelines is imperative, and we are working very hard to do that, Senator.

The CHAIRMAN. What is your timetable on that?

Mr. KERLIKOWSKE. The timetable has been that we are working with two members on the Senate side, two members on the House side for a drug take-back program. The other important thing would be that the recommendation that the Attorney General be given some latitude in administrative rulemaking when it comes to this area. So I am very hopeful that some proposed legislation will be forthcoming shortly, and we will do everything we can to foster that through the administration.

The CHAIRMAN. All right. Thank you so much.

Senator Corker.

Senator CORKER. Mr. Chairman, thank you.

I just have one question. Again, thank you for your testimony.

I know that there has been concern about prescription drugs and the water supply. I am just wondering if the guidance that has been given is one that is based on scientific evidence, if we know enough about it, if it is more of a cautionary kind of issue?

But I know it is something that many citizens are concerned about, and I just wondered if you could educate us as to whether there has actually been enough evidence to know that it is of concern? Or are we basically saying that its out of more of caution until we find out more about the issue?

Mr. KERLIKOWSKE. Senator, I think your question is an excellent one, and I think there are two things, and particularly having come from Seattle. I mean, the Nation is becoming such an environmentally conscious nation, in so many ways. So, there are two things that have come about, and one is that the ability to test such minute amounts, to detect such minute amounts of a substance in the water system or the sewer system, those things have greatly increased.

The second part of this is that a lot of what has been disposed of or is now in the different systems isn't always as a result of flushing the individual substance down the toilet. It is also through human waste. I think that these are questions that need to be answered.

On the other hand, we have a nation that is very concerned about the environment, and figuring out a way to dispose of these in a safe manner that doesn't have environmental effects is part of our work with the EPA. By the way, we couldn't be more pleased with the support that Lisa Jackson and EPA have given us as we kind of work through this myriad of difficulties.

Senator CORKER. So, I guess, do we know? I mean, are we doing things necessary to figure out, first of all, if those levels are of concern and, secondarily, how they are actually entering our drinking water today?

Mr. KERLIKOWSKA. The testing is continuing on, and I would be happy to provide information that I can obtain and others from the EPA on some of the most recent. Unfortunately, I do not have those specifics, but I think your point is right on the mark.

Senator CORKER. OK. So you don't really yet personally have an opinion. Well, we look forward to following up and getting additional information.

Thank you.

Mr. KERLIKOWSKA. Thank you, Senator.

The CHAIRMAN. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Director, I know that your office does recommend that consumers take advantage of community take-back programs, such as the very successful program that we have in Maine. I described it during my opening statement. It has been very popular. It has prevented more than a ton of unused or expired drugs from being dumped into water supplies or diverted.

There are some organizations, however, including, I am told, PhRMA, who have raised concerns about these kinds of mail-back programs. They argue that they create a greater potential for drug diversion because the mailer obviously contains drugs. It is addressed to the Maine Drug Enforcement Agency. It is clear what is inside.

But I will tell you that it is my understanding that in my State at least, there have been no examples of a single package even being diverted for criminal use. What is your judgment? Since you come from a law enforcement background, do you see any potential for diversion through these take-back, mail-back programs?

Mr. KERLIKOWSKA. You know, I am only slightly familiar with the program in Maine, and I would tell you that I think by far the greater danger is the drug staying in the medicine cabinets, the potential for abuse or misuse while they are there and no longer necessary for the patient that had them. So I also clearly recognize that what may work in New Jersey, which was a large take-back in perhaps more urban areas of that State, is not particularly effective in a State like Maine that we want people to dispose of these safely.

So I would tell you that I think that the potential for diversion is minimal in the take-back program that you have described in Maine and that by far the greater danger is letting these things pile up in the medicine cabinets.

Senator COLLINS. I agree. Thank you.

The CHAIRMAN. Thank you so much, Mr. Kerlikowski.

Mr. KERLIKOWSKA. Thanks.

The CHAIRMAN. At this point, we are happy to welcome our second panel who will testify here today. Our first witness on the second panel will be Joseph Rannazzisi, who is Deputy Assistant Administrator for the Office of Diversion Control at the U.S. Drug Enforcement Agency, where he oversees drug investigations and serves as liaison to various outside industries and agencies.

Next, we will hear from Mary Hendrickson, who is Director of Quality and Regulatory Affairs for Genco Pharmaceutical Services in Milwaukee, WI. At this position, Dr. Hendrickson is responsible for the regulation of one of the largest reverse pharmaceutical distribution sites in our country.

Next, we will be hearing from Bernard Strain. Mr. Strain currently works for Pennsylvania State Treasurer Rob McCord, and previously, he served as Deputy Finance Director for the city of Philadelphia.

After that, we will be hearing from Dr. Steve Gressitt, who is faculty associate at the University of Maine Center on Aging and Founding Director of the Maine Institute for Safe Medicine. In addition, he is Associate Professor of clinical psychiatry at the University of New England College of Osteopathic Medicine.

Our fifth witness is from Tennessee.

Senator CORKER. Mr. Chairman, if it is OK, I will introduce him. I first want to welcome all of you, but I especially welcome a native of our State, Mr. Bruce Behringer from Johnson City. He had been working as Executive Director of the Office of Rural and Community Health and Community Partnerships at East Tennessee State University for the better part of two decades.

Through his work, East Tennessee has been helping to build a curriculum to educate new pharmacists and practitioners regarding prescription drug use in small mountain communities, and his vast knowledge of the topic and firsthand experience makes him amply qualified to share his expertise with us today.

It is also my pleasure to congratulate him and Dean Calhoun and all of their colleagues at East Tennessee State University Gatton College of Pharmacy for receiving full accreditation this last Monday. I know they have worked hard. They have done an excellent job also in educating primary physicians, No. 1 in the country.

So, Mr. Behringer, I thank you for being here. I thank you for your work and certainly for sharing your expertise here today.

Thank you.

The CHAIRMAN. Thank you all.

We will start with Mr. Rannazzisi.

STATEMENT OF JOSEPH RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE, WASHINGTON, DC

Mr. RANNAZZISI. Chairman Kohl, Ranking Member Corker, Senator Collins, good afternoon. On behalf of Acting Administrator Michele Leonhart and nearly 10,000 men and women of the Drug Enforcement Administration, I am honored today to appear before you and provide testimony concerning the disposal of pharmaceutical controlled substances.

Let me begin by saying that the overwhelming majority of dispensed pharmaceuticals in the United States are not controlled substances. They are noncontrolled or legend drugs that are not subject to the provisions of the Controlled Substances Act. DEA's authority under the CSA is limited to controlled substances.

So why is DEA concerned with collection and disposal processes? In carrying out its enforcement and regulatory obligations, DEA must monitor pharmaceutical take-back programs because, in all likelihood, any organized collection of unwanted or unused pharmaceuticals will also include the collection of controlled substances.

The percentage of controlled substances collected during take-back programs may be small, but DEA has a statutory mandate to ensure that all controlled substances are collected and disposed of in a manner that protects public health and safety and prevents the reintroduction of these drugs into illicit or the illicit market.

The diversion and abuse of pharmaceutical controlled substances has reached alarming levels in the United States. There are many contributing factors to this increase, but one source for abused pharmaceuticals is right in our own home, the medicine cabinet. Household medicine cabinets provide free and easy access to controlled substance by drug seekers and nonmedical users, such as teenagers, and increase the risk of accidental ingestion and poisoning of children and the elderly.

Additionally, the improper disposal of medications may pose risks to the environment. States, counties, and municipalities have tried to develop pharmaceutical collection and disposal programs to address the problems resulting from unwanted and unused medications in household medicine cabinets. These programs are beneficial in many ways, but the Controlled Substances Act only provides for collection and disposal of controlled substances under very limited circumstances.

Specifically, the Controlled Substances Act provides for a closed system of distribution with stringent procedures on procurement, distribution, and possession of controlled substances. As part of this closed system, all persons who possess a controlled substance must be registered with the Drug Enforcement Administration or exempt from registration.

The Controlled Substances Act exempts ultimate users or patients from the requirement of registration when they possess a controlled substance for a legitimate medical purpose. However, there is no exception that allows ultimate users or long-term care facilities to distribute controlled substances for any purpose, even to dispose of unwanted or unused drugs. Simply stated, it is illegal for ultimate users to distribute controlled substances.

Congress has proposed legislation in both chambers to address this issue—specifically, in the House of Representatives, H.R. 1359, the Secure and Responsible Drug Disposal Act of 2009, and H.R. 1191, the Safe Drug Disposal Act of 2009. In May 2009, the Department of Justice issued a views letter in support of H.R. 1359. In May 2010, the National Association of Attorneys General also issued a letter in support of 1359.

H.R. 1359 and its companion measures, Senate 1292 and Senate 3397, allows the Attorney General discretion to promulgate regulations and provides the requisite flexibility to address this impor-

tant issue. It provides a means by which ultimate users may distribute pharmaceutical controlled substances to other persons for disposal.

It also contains a provision authorizing the Attorney General to promulgate regulations that authorize long-term care facilities to dispose of pharmaceutical controlled substances on behalf of their patients who are ultimate users. This provision is necessary because nursing homes and other long-term care facilities often come into possession of controlled substances that are no longer needed or used by the patients for whom they are prescribed.

1359 is straightforward and establishes the necessary framework to address this issue through DEA's rulemaking process. DEA regulations would be implemented uniformly throughout the Nation and would allow a wide variety of disposal methods that are consistent with effective controls against diversion. 1359 would also give DEA the flexibility to allow by regulation new methods of disposal if and when they are developed in the future.

In conclusion, the collection, removal, and safe disposal of unwanted or unused medications from households and long-term care facilities will eliminate the potential avenue of drug diversion, limit the availability of medications to drug seekers and abusers, and decrease the potential for accidental ingestion and poisoning.

We look forward to working with Congress to establish a solid foundation for take-back disposal programs that minimize any potential avenue for diversion while protecting the public health and safety.

I thank the committee for the opportunity to appear today and welcome any questions you may have.

[The prepared statement of Mr. Rannazzisi follows:]



Department of Justice

STATEMENT FOR THE RECORD OF
JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ENTITLED
"DRUG WASTE AND DISPOSAL: WHEN PRESCRIPTIONS
BECOME POISON"

JUNE 30, 2010

**Statement for the Record
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
United States Department of Justice**

**U.S. Senate Special Committee on Aging
“Drug Waste and Disposal: When Prescriptions Become Poison”
June 30, 2010**

Chairman Kohl, Ranking Member Corker, and distinguished Members of the Committee, on behalf of Acting Administrator Michele Leonhart and the more than 9,600 men and women of the Drug Enforcement Administration (DEA), I am honored to have the opportunity to appear before you today to provide testimony concerning the disposal of pharmaceutical controlled substances.

The desire to provide the public with effective means to dispose of unused pharmaceutical controlled substances is based on two main concerns: (1) protecting the safety and welfare of the American people by preventing the diversion of such drugs into either licit or illicit channels for the purpose of abuse or profit; and (2) developing drug disposal methods that help prevent contamination of the nation's water supplies.

Potential Source of Diversion

The diversion of pharmaceutical controlled substances is a significant problem in the United States, as all reliable indicators show that the abuse (non-medical use) of these drugs has reached alarming levels in recent years. (These indicators include, but are not limited to; the National Survey on Drug Use and Health, Monitoring the Future Study, Partnership Attitude Tracking Study, and Drug Abuse Warning Network (DAWN) data.) One factor that may contribute to the increased abuse is the availability of these drugs in household medicine cabinets. In many cases, dispensed controlled substances remain in household medicine cabinets well after medication therapy has been completed, thus providing easy access to non-medical users for abuse, accidental ingestion, or to sell for profit. Accidental ingestion of medication, including a controlled substance, by the elderly and children, is more likely when the household medicine cabinet contains unused medications that are no longer needed for therapy. The medicine cabinet also provides ready access to persons, especially teenagers, who seek to abuse medications. For example, the 2009 Partnership Attitude Tracking Study (PATS) noted that 62 percent of those surveyed believe that most teens get prescription drugs from their own family's medicine cabinets.¹ The Administration recognizes the issue of prescription drug abuse as described in the 2010 National Drug Control Strategy. One of the action items set forth in the Strategy is to increase prescription return/take-back and disposal programs.²

¹ Partnership for a Drug-Free America, The Partnership Attitude Tracking Study (PATS) Teens 2009 Report. February 25, 2010.

² 2010 National Drug Control Strategy, p. 32

Statistics concerning the abuse of pharmaceutical controlled substances and prescription medication also reveal disturbing trends. As recently as June 18, 2010, the Centers for Disease Control and Prevention released a morbidity and mortality report that showed increasing morbidity associated with non-medical use of pharmaceutical controlled substances.³ Persons between the ages of 12 and 17 abuse prescription drugs more than cocaine, heroin, and methamphetamine combined.⁴ In this age group, prescription drug abuse is second only to marijuana use.⁵ The ease of access to prescription medication is a contributing factor in this growing trend of abuse.

Another factor that may contribute to the overall upward trend of abuse is that teenagers and young adults believe that prescription medications are safer than other drugs of abuse such as heroin, cocaine, marijuana and methamphetamine. The 2008 PATS study noted that 41 percent of teenagers mistakenly believe that prescription medications are “much safer” than illegal drugs.⁶ Prescription medications are surrounded by a false sense of security because they are manufactured by pharmaceutical companies, prescribed by physicians and other medical professionals, and dispensed by pharmacies. This false sense of security can end in tragedy. In 2008, 4.7 million teens admitted to abusing prescription drugs at some point in their lives.⁷

In conjunction with the increased abuse of prescription medication, there has been an increase in the number of poisoning deaths related to prescription drug abuse. For the period 1999 to 2004, the Centers for Disease Control and Prevention reported a 55 percent increase in unintentional poisoning deaths involving narcotics and hallucinogens that is mainly attributed to prescription painkillers.⁸ The 2009 Monitoring the Future study reported that Vicodin, a brand name pain reliever containing the narcotic hydrocodone, is one of the most commonly abused drugs among 12th graders: in 2009, 1 in 10 reported non-medical use in the previous year.⁹ On average, every day, 2,500 12-17 year olds abuse a prescription pain reliever for the first time.¹⁰

Potential Source of Contamination

Recent studies by EPA and others have detected pharmaceutical drugs in varying concentrations in our nation’s water supplies. While drugs in waterways also result from normal excretion routes and metabolic process, there has been an increasing interest among the public in developing methods to dispose of unused pharmaceuticals to reduce their introduction into the water supply. The overwhelming majority (approximately 90 percent) of pharmaceuticals dispensed in the United States are non-controlled substances, which are not subject to the

³ Centers for Disease Control and Prevention, *Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs – United States, 2004-2008*, June 18, 2010.

⁴ Substance Abuse and Mental Health Services Administration. Results from the 2008 National Survey on Drug Use and Health.

⁵ *Ibid*, p. 20.

⁶ Partnership for a Drug-Free America, 2008 Partnership Attitude Tracking Study, Key Findings.

⁷ Partnership for a Drug-Free America, 2008 Partnership Attitude Tracking Study, p. 18.

⁸ Centers for Disease Control and Prevention, 2007 Unintentional Poisoning Deaths, United States, 1999-2004. February 9, 2007. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5605a1.htm>

⁹ 2009 Monitoring the Future Study. University of Michigan, Ann Arbor. December 2009 Press Release.

¹⁰ Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (October 18, 2007). The OAS Report: A Day in the Life of American Adolescents: Substance Use Facts. Rockville, MD.

provisions of the Controlled Substances Act (CSA).¹¹ Any organized collection of unused pharmaceuticals will, in all likelihood, involve the collection of both pharmaceutical controlled substances and non-controlled substances, as the public is generally unaware of the distinctions between controlled and non-controlled substances. As explained below, when controlled substances are involved, the CSA provides stringent limitations on the circumstances in which it is lawful to procure, distribute and possess such drugs.

Current Statutory Requirements

Under the CSA, Congress established a "closed system" of distribution designed to prevent the diversion of controlled substances.¹² In furtherance of the closed system, no controlled substance may be transferred between two entities unless the entities are DEA registrants or exempt from registration. In addition, DEA registrants must maintain copious records of all transactions involving controlled substances. The closed system is monitored by a DEA system that accounts for all controlled substances received, stored, distributed, dispensed, or otherwise disposed.

To maintain the closed system, every entity that distributes controlled substances, or proposes to engage in the distribution of any controlled substance, must obtain a DEA registration authorizing such activity. 21 U.S.C. § 822(a). "The term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance . . ." 21 U.S.C. § 802(11). "The terms 'deliver' or 'delivery' means the actual, constructive, or attempted transfer of a controlled substance . . . , whether or not there exists an agency relationship." 21 U.S.C. § 802(8).

"Ultimate users" are exempt from the requirement of registration if the ultimate user lawfully obtained the substance, and possesses the controlled substance for a specified purpose, i.e., for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household. 21 U.S.C. §§ 802(27), 822(c)(3). Most important, this statutory exception does not allow a patient to deliver a controlled substance to any another entity for any purpose, including disposal of the drug.

To summarize, the CSA specifically allows ultimate users to obtain and possess controlled substances for personal use only. The statute does not contemplate that ultimate users may need to dispose of unused pharmaceutical controlled substances. Under current law, an ultimate user is not authorized to deliver or distribute controlled substances for purposes of disposal. Any such distribution by an ultimate user, regardless of the purpose, is illegal.

As an interim measure, DEA has utilized existing federal regulations to assist law enforcement agencies to conduct community "take-back" programs that collect unused pharmaceutical controlled substances. Procedures set forth in 21 C.F.R. § 1307.21 provide that local law enforcement agencies may obtain written guidance from the DEA Special Agent in Charge in their jurisdiction to operate such programs. These "take-back" programs involve duly authorized law enforcement officials collecting unused controlled substances from ultimate

¹¹ Source: IMS Health.

¹² H.R. Rep. No. 91-1444 at 3 (1970).

users. Upon receipt, the authorized law enforcement agency must maintain custody of the controlled substances up to and including destruction. The manner of destruction must comply with applicable federal and state laws including those related to the public health and environment.

In April 2009, a law enforcement collection program was conducted in North Carolina that included several local sheriffs' offices and the North Carolina State Bureau of Investigation. "Operation Pill Crusher" collected more than 144,000 dosage units of expired and unused prescription medications from local residents. All pills collected were hand-counted, recorded, and transported to an incineration unit for destruction.

In November 2009, DEA's Newark Field Division Office, in conjunction with state and local municipalities, conducted a state-wide take-back program entitled "Operation Medicine Cabinet". More than 440 municipalities in all of New Jersey's 21 counties participated in the event. Over 9,000 pounds of pharmaceuticals were collected and properly destroyed.

Though these programs were successful, they are only a stop-gap measure due to the current statutory constraints.

Current Guidance

On February 20, 2007, the U.S. Office of National Drug Control Policy (ONDCP) announced guidelines for the disposal of ultimate user medications, including dispensed controlled substances. The guidelines were published by ONDCP in conjunction with the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA).¹³ The guidelines advise the public to flush medications only if the prescription label or accompanying patient information specifically states to do so. For all other medications, ONDCP recommends mixing the drug product with an undesirable substance (e.g. coffee grounds or kitty litter) prior to disposal in common household trash or at community pharmaceutical "take-back" programs. The press release announcing the guidelines stated:

The new Federal guidelines are a balance between public health concerns and potential environmental concerns. "While EPA continues to research the effects of pharmaceuticals in water sources, one thing is clear: improper drug disposal is a prescription for environmental and societal concern," said EPA Administrator Stephen L. Johnson. "Following these new guidelines will protect our Nation's waterways and keep pharmaceuticals out of the hands of potential abusers."

Due to concerns about public safety, the U.S. Food and Drug Administration has currently identified a small number of drug preparations which contain one of 10 controlled substances that retain a recommendation of disposal by flushing. Primarily narcotics, these preparations have life-threatening capabilities if improperly handled or improperly ingested.

Regulatory Action

¹³ Office of National Drug Control Policy, Executive Office of the President. Proper Disposal of Prescription Drugs. February 2007. http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf

On January 21, 2009, DEA published an Advance Notice of Proposed Rulemaking in the Federal Register entitled *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*. Through this Notice, DEA sought information from all interested members of the public concerning the safe and responsible disposal of controlled substances. A variety of interest groups were solicited including ultimate users; state and local law enforcement agencies; concerned interest groups; long-term care facilities; hospices and in-home care groups; pharmacies; reverse distributors,¹⁴ state regulatory agencies; and other interested parties.

The public comment period expired on March 23, 2009. DEA received 158 comments from a wide variety of sources including: the general public; the pharmacy community; hospitals; long-term care facilities; and reverse distributors. The DEA cannot move forward with a regulatory proposal without legislation such as those described below.

Problems that the Public is Experiencing in Handling Substances to be Destroyed

Because the CSA currently does not authorize ultimate users to dispose of controlled substances, except under limited circumstances, the distribution of a controlled substance by an ultimate user to another person, regardless of the purpose, violates the CSA. At this time, most U.S. communities do not offer programs to properly dispose of excess controlled substances or waste medication. Many consumers keep the drugs in their possession because they do not know how to dispose of them.

Legislative Proposals

DEA strongly supports legislation that authorizes DEA to address this issue through its rulemaking authority. DEA notes that Congress has offered proposed legislation in both chambers. The legislative intent appears consistent: to provide DEA the regulatory authority to give citizens lawful means to safely dispose of controlled substances that prevents their diversion, while also allowing the destruction of those substances in an environmentally safe manner that is consistent with EPA objectives.

In May 2009, the Department of Justice issued a views letter in support of H.R. 1359, the Secure and Responsible Drug Disposal Act of 2009.¹⁵ DEA has concerns about the complexity of the regulatory scheme called for in H.R. 1191 as well as the fact that this legislation confused responsibility for environmental considerations in implementing take back disposal programs. We have been encouraged by conversations with the bill sponsor regarding these concerns. Additionally, we are hopeful that the Energy and Commerce committee, which has jurisdiction over both H.R. 1359 and H.R. 1191, will work toward finding a compromise approach to this important issue. If DEA is given the necessary statutory authority, it will be in a position to promulgate regulations that set forth a comprehensive framework for communities and regulated entities to use as guides to establish secure disposal programs for unused controlled substances.

¹⁴ Reverse distributors are registered by DEA and authorized to accept controlled substances for destruction only from other DEA-registered persons or companies.

¹⁵ The Senate companion bill is S-1292.

Conceivably, a variety of models will be able to operate under the established regulatory framework.

H.R. 1359, and its companion measures, S.1292 and S.3397, affords the Attorney General discretion to promulgate regulations and provides the requisite flexibility to address this important issue in a comprehensive manner. It would provide a means by which ultimate users may distribute controlled substances to other persons for disposal. It would do so by amending section 302 of the Act (21 U.S.C. § 822), to clearly state that an ultimate user who has lawfully obtained a controlled substance may, without being registered, deliver the controlled substance to another person for the purpose of disposing of the controlled substance. The person receiving the controlled substance must be authorized under the CSA to engage in such activity. The disposal must take place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances. This provision is necessary because the CSA currently does not allow for ultimate users to deliver controlled substances to others for the purposes of disposal.

This proposed legislation would also amend section 302 of the CSA to add a new provision (section 302(g)(2)) authorizing the Attorney General to promulgate regulations that authorize long-term care facilities, as defined by the Attorney General to dispose of controlled substances on behalf of ultimate users. The disposal would occur in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety. This provision is necessary because nursing homes and other long-term care facilities sometimes gain possession of controlled substances that are no longer needed by patients, but the CSA currently does not allow such facilities, which are usually not registered under the Act, to deliver controlled substances to others for the purposes of disposal. Addressing the unique nature of long-term care facilities is consistent with the numerous regulations promulgated by DEA to address the needs of ultimate users in these facilities.

For consistency with the foregoing amendments, the legislation also amends section 308(b) of the Controlled Substances Act (21 U.S.C. 828(b)) to make clear that the written order form requirement, which is generally a prerequisite under the Act for distributing a schedule I or II controlled substance, does not apply to the delivery of a controlled substance for the purpose of disposal by an ultimate user or long-term care facility acting in accordance with new section 302(g) of the Act.

The authority proposed to be afforded to DEA in H.R. 1359 and its companion measures is straightforward, the ensuing regulations can be implemented uniformly throughout the nation, and the regulatory scheme is envisioned to allow a wide variety of disposal methods that are consistent with effective controls against diversion. In addition, H.R. 1359 and its companion measures would give DEA the flexibility to allow, by regulation, new methods of disposal if and when they are developed in the future.

Conclusion

DEA has the vital statutory responsibility of promulgating and enforcing regulations that will minimize the availability of pharmaceutical controlled substances to non-medical users and

preserve the integrity of the closed system of distribution. The collection, removal, and safe disposal of unused medication from households and long-term care facilities is one method of preventing these drugs from getting into the hands of the non-medical user. DEA also supports EPA's mission to dispose of these substances in a manner that is consistent with federal, state, and local environmental laws and regulations. It removes a potential avenue of diversion, limits the availability of medications to drug seekers/abusers and decreases the potential for accidental ingestion/poisoning. It is a priority for this Administration.

Chairman Kohl, Ranking Member Corker, and distinguished Members of the Committee, I thank you for the opportunity to appear before you today to discuss this important issue and welcome any questions that you may have.

The CHAIRMAN. Thank you, Mr. Rannazzisi.
We will now hear from Ms. Hendrickson.

**STATEMENT OF MARY HENDRICKSON, PHARM.D., DIRECTOR
OF QUALITY AND REGULATORY AFFAIRS, GENCO PHARMA-
CEUTICAL SERVICES, MILWAUKEE, WI**

Dr. HENDRICKSON. Thank you, Chairman Kohl, Ranking Member Corker, and Senator Collins for holding this important hearing on prescription drug disposal. I appreciate the opportunity to provide this testimony today representing Genco Pharmaceutical Services.

As a pharmacist, I have been a witness to the surplus of unused medications in long-term care facilities, as well as witnessed the destruction method utilized. Many facilities have limited resources to destroy product and may not be familiar with the best standards of practice or environmental regulations for discarding pharmaceuticals.

I have also observed unused medications in people's homes within the general population. Unfortunately, as we know, in some instances, these unused medications can fall into the wrong hands, creating situations of misuse, abuse, and accidental poisonings.

After working in reverse pharmaceutical distribution, I have a very different perspective of how unused medications can be managed. Currently, the reverse pharmaceutical industry receives unused product, including controlled substances, from other business entities such as pharmacies and drug wholesalers.

After the product is processed, an environmentally responsible destruction method is utilized. The product is segregated into non-hazardous or hazardous waste and is sent to incineration. Over 90 percent of the waste that we generate is nonhazardous and is shipped to a waste energy facility. The product combustion process generates steam, which spins turbines, resulting in the generation of electricity.

Reverse pharmaceutical distribution is an extremely regulated industry, inherently making the process not only more complicated, but it also produces an industry with a high level of safety, security, and accountability. Reverse distributors' core business function is drug take-back, but primarily from other business entities as opposed to consumers.

Our primary barrier to entry into consumer take-back is the Controlled Substances Act, or CSA, as this act only allows for transfer of controlled substances among DEA registrants. Since patients are not DEA registrants, we cannot accept these products from patients, with only a few exceptions, which I will present.

The cost of consumer take-back has also been considered a potential barrier to a successful program. However, we believe that a resolution may exist, based on multiple customer requests we have had for a program, including from large pharmacy chains and manufacturers.

Consumer take-back is not new to us. In 2008, we conducted a small feasibility pilot to determine if consumers in two counties in Wisconsin would utilize a ship-back program for their unused medications, except for controlled substances. We ended the test program after 6 months but determined that consumers would uti-

lize this method, as we received over 15,000 medication returns during this time.

Despite the numerous requests we have received to manage consumer take-back, we have not continued a program. While we did our best to educate individuals on the definition of controlled substances, we found that consumers still incorrectly sent these products to us.

We reported receipt of that product to DEA, however ended our program as a result to ensure that we were compliant with the CSA. Our discontinuation of this program puts us at a disadvantage to those operating other prescription take-back programs that allow consumers to send back their unused or expired medications.

Despite the challenges with the CSA for consumer returns, the DEA has been very helpful in providing some clarifications or variances to reverse distributors. First, a clarification provided by the DEA to us for take-back of one particular controlled substance with the trade name Actiq was questioned.

The dangerous—the appearance of the product, along with it being a powerful narcotic, make it potentially dangerous to children. In the clarification, we learned that we could accept consumer returns for this product since we are the manufacturer's agent.

The second clarification mentioned and currently used is for reverse distributors and manufacturers to receive controlled substances from non-DEA registrants in the event of a patient-level recall.

Third, a variance was provided by the DEA, although not widely used at the time it was issued, as an exemption for reverse distributors to accept controlled substances from long-term care facilities located in the State of Kentucky. As a result of these clarifications, we are allowed to take back controlled substances from non-DEA registrants, but only in a very limited circumstance. We would welcome the opportunity to expand our part in take-back of unused consumer product.

To finalize, our primary recommendation is a change to the Controlled Substances Act to allow for take-back of controlled substances from non-DEA registrants. Reverse distributors' core business function essentially is drug take-back, and we have systems in place to adhere to the highly regulated industry, plus use an environmentally safe method to dispose of medications.

To close, we recognize the significant problem of unused consumer medications in the U.S. We believe with changes to the Controlled Substances Act, Genco, along with our customers and other reverse distributors, can have a significant impact on reducing the unused medications in homes across the U.S. As a result, we anticipate the occurrence and prevalence rates of misuse, abuse, and accidental poisonings from prescription products will decrease.

Finally, we also believe that it will minimize the contribution of pharmaceutical contamination in our environment.

Thank you for holding this hearing. I look forward to your questions.

[The prepared statement of Dr. Hendrickson follows:]

**Statement of
Mary L. Hendrickson, PharmD, MBA, RAC
Director of Quality & Regulatory Affairs
Capital Returns Inc., d/b/a Genco Pharmaceutical Services**

Before

**The Special Committee on Aging
United States Senate**

**Hearing on
Prescription Drug Disposal**

June 30, 2010

Thank you Chairman Kohl, Ranking Member Corker and Members of the Committee for holding this important hearing on prescription drug disposal. Consumer drug disposal is a significant issue in the United States and we applaud the committee for its focus on the topic.

General Background

I appreciate the opportunity to provide this testimony today representing Capital Returns / Genco Pharmaceutical Services. Capital Returns was founded in 1991 by a pharmacist and business person and is now part of Genco, a 112 year old privately held third party logistics management company. I have been employed as the director of quality & regulatory affairs by Capital Returns / Genco Pharmaceutical Services (GPS) for the past 5 years. I am also a pharmacist and have worked in multiple pharmacy practice areas, including over 11 years in long-term care pharmacy operations.

I have been a first-hand witness to the surplus of unused medications in long-term care facilities as well as witnessed the destruction method utilized by these facilities. In my experience many facilities have limited resources to destroy products like controlled substances. They are frequently not familiar with the best standards of practice or environmental regulations for discarding pharmaceuticals. As a result many of these products are destroyed by flushing them down the drain or toilet. While the science has not determined what sources of medications have contributed to pharmaceutical contamination in our environment, it is clear based on the findings of the U.S. Geological Survey that pharmaceuticals are present in our waterways. Flushing medications down the toilet or drain, while not the single cause of pharmaceuticals in our environment, is certainly a contributing factor. Long term care facilities need a secure method to send back their unused controlled substances to minimize their contribution to pharmaceuticals in the environment and allow the facility staff to spend more time focusing on the care of their residents as opposed to the destruction of unused medications.

In addition to the long term care population I have observed unused medications in people's homes within the general population. I have heard individuals rationalize that they may have a potential need for the medication in the future or they simply do not know how to dispose of the medications properly. Unfortunately, in some instances these unused medications can fall into the wrong hands creating situations of misuse, abuse, and accidental poisonings.

After working in reverse pharmaceutical distribution I have a very different perspective of how unused medications can be managed. Currently, the reverse pharmaceutical distribution industry receives unused, expired, or recalled pharmaceutical product, including controlled substances from other business entities such as pharmacies and drug wholesalers. These unused medications are processed for potential credit from the manufacturer. Depending on the manufacturer's returns policy the product is sent back to the manufacturer or to incineration.

While a summarized description of the process is relatively straight-forward, reverse pharmaceutical distribution is an extremely regulated industry inherently making the process not only more complicated, but also producing an industry with a high-level of safety, security, and accountability. In addition an environmentally responsible method of destruction is used for unused product. Several federal agencies have regulatory oversight of the reverse distribution industry and/or the unused, expired, or recalled medications. These agencies include the DEA, EPA, FDA, DOT, and OSHA. Specific state pharmacy and environmental regulatory agencies also impact the industry.

In order to adhere to the regulations the pharmaceutical products returned to reverse distributors are subject to a several step process. The procedures include, but are not limited to, capturing the name and address of the returning entity as well as the DEA registrant number if it is a controlled substance return. In addition, the product is counted with the lot number and expiration date also captured. Reverse distributors are required to report the transfer of specific controlled substances to the DEA through the use of the Automation of Reports and Consolidated Orders System, or ARCOS report. An example of some of the controlled substance information regularly reported to the DEA includes the receipt, inventory and destruction of controlled substances, along with a requirement to report any product loss.

If the product is determined to be waste, the waste is segregated based on characteristics of the product and the requirements of the Resource Conservation & Recovery Act (RCRA). The outcome of the segregation process is an accumulation of non-hazardous waste and an accumulation of separated categories of hazardous waste such as toxic, corrosive, ignitable, and reactive as some examples of the categories. The waste separation procedures in place within reverse distribution provides for the safe storage and transportation of hazardous pharmaceuticals. The hazardous waste that is generated at GPS is shipped to an approved treatment, storage, and disposal facility for incineration. The non-hazardous pharmaceuticals are incinerated at a waste to energy facility.

The progression of the unused product being turned from waste to energy is initiated when the product is shipped from GPS to the incineration site. The pharmaceuticals are fed into a hopper for incineration. The product is combusted at a high temperature creating the steam which spins the turbines that generate electricity. The waste to energy facility utilized by GPS meets the federal environmental standards and utilizes a multi-step process to ensure appropriate environmental performance. The result of using a waste to energy facility decreases the use of oil or coal for energy as well as elicits a net greenhouse gas reduction. Currently, over 90% of the unused product that is determined to be waste at our facility is non-hazardous under RCRA and is sent to the waste to energy incineration site.

It is noteworthy to mention that there is some existing confusion with the term reverse distributor. The DEA does not have a separate registration category for incineration facilities that dispose of controlled substances and utilizes the reverse distribution registrant category for these incineration sites. Typically, the incineration sites are only destroying the product and do not have the same rigorous set of standard operating procedures as I have described in this testimony. When I am using the term reverse distributor it is not referring to a disposal-only facility registered by the DEA as a reverse distributor.

Unused Medications from Consumers

As I have attested to unused products generated by pharmacies and other business entities are processed at reverse distributors following multiple procedures and regulations. It is important to reiterate that these procedures and regulations promote the safety, security, accountability and the most environmentally safe method of disposal. Simply put, reverse distributors core business function is drug take back. As a result, we are often asked if we can take back unused medications from consumers. With only a few exceptions, reverse distributors customarily do not take back unused pharmaceutical product from consumers

Our primary barrier to entry into consumer take back is the Controlled Substances Act. This Act only allows for transfer of controlled substances among DEA registrants thereby creating the closed loop of distribution. The closed loop of distribution for finished pharmaceuticals starts with the manufacturer who ships to drug wholesalers. The wholesalers sell to pharmacies. The unused, expired or recalled product is shipped back to the reverse distributor. Each of these businesses is a DEA registrant. When a pharmacy dispenses the medication to a patient, the patient is not considered to be within the closed loop of distribution and is not a DEA registrant. As a result, reverse distributors as well as the other DEA registrants cannot take controlled substance product back from patients as they are not part of the closed loop of distribution.

The expenditures associated with the processing and disposal of unused pharmaceutical product from consumers has also been considered a potential barrier to a successful take back program; however, we believe that a resolution to this exists based on our customer requests for a program. GPS has received requests from our customers, including both large pharmacy chains and pharmaceutical manufacturers to provide a consumer take back solution. Regrettably we have not been able to develop this business opportunity due to the Controlled Substances Act.

A consumer take back program is not a new concept to GPS and other reverse pharmaceutical distributors. In 2006 GPS created and presented a model for the use of a mail-back consumer returns program at the 3rd Annual Unused Drug Return International Conference. This presentation not only included the proposed procedures for a mail-back program for consumers, but it also included the recommended changes to the Controlled Substances Act. The proposed changes allowed for controlled substance to be shipped to reverse distributors from non-DEA registrants or the patients.

In 2008, GPS conducted a small feasibility pilot to determine if consumers in two counties in Wisconsin would utilize a ship-back program for their unused or expired medications. GPS worked with the county waste departments, the Wisconsin Department of Natural Resources as well as other interested individuals. The program was funded by grants from the EPA Great Lakes Sea Grant Program as well as the Wisconsin Department of Agriculture Trade & Consumer Protection.

The procedures that accompanied the feasibility pilot included several key elements, including advertising, education, data collection, and proper safety, storage and disposal of the returned product. We advertised to consumers through the use of local media including newspapers, flyers, radio and television. GPS designated a specific 1-800 phone number for consumers to request an informational packet and the appropriate shipping materials for their product. We deliberately chose to engage the individuals in the return process through a phone conversation as this provided us with the opportunity to explain to the consumer that we could not accept certain materials including bio-contaminated product and controlled substances. Written directions were shipped to the address provided by the caller to reiterate the detailed message that was initially provided through the phone conversation. We also proactively informed the DEA that we were conducting the pilot program in the event that we did receive controlled substances from individuals.

The pilot program ended after approximately six months. In this time we received 1730 calls with 1259 households returning product. The 1259 households returned 15164 medications. The medications returned to GPS included a variety of therapeutic categories including cardiovascular medications, hormones, antibiotics, and diabetic medications as only a few examples. A small percentage of the returned product also included controlled substances despite the written and verbal education provided to consumers. Subsequently, the controlled substance returns were reported to the DEA. In the brief period we operated the pilot we concluded that there was consumer acceptance for this type of prescription take back program.

Since our pilot program we have received numerous requests to continue a consumer take back program covering a larger geographic area than our initial feasibility study; however, we have not been able to continue a program due to the potential to inadvertently receive unsolicited returns of controlled substances from non-DEA registrants. While we did our best to educate individuals on the definition of a controlled substance, including why we could not accept these products, we found that consumers did not fully understand and incorrectly sent us controlled substances.

It is noteworthy to mention that due to the multiple systems in place within reverse distribution we did manage the controlled substances to the same level of accountability as if received by a DEA registrant. This included counting the product, providing witnessed incineration and reporting the receipt and destruction of these products to the DEA. Again, we have not progressed with any other consumer take back program as we did not want to purposefully continue this practice when it was evident that individuals will return controlled substances even when educated not to return these products.

Our discontinuation of this program puts us at a disadvantage to those operating other prescription take-back programs that allow consumers to send back their unused or expired medications. Any take back program that accepts controlled substances is required to have law enforcement present; however, based on the questions that we receive about consumer take back it is evident that not everyone is familiar with the regulatory requirements and may not be reporting receipt of controlled substances to the DEA.

Clarifications and Exemptions to the Controlled Substances Act

Despite the challenges with the Controlled Substances Act for consumer returns, the DEA has been very helpful in providing some clarifications or variances for reverse distributors. These variances and/or clarifications have included the ability to receive a specific controlled substance product directly from patients and the ability to receive any controlled substance from a patient in the event of a patient level recall. In addition, a variance provided by the DEA was for the acceptance of controlled substances from long term care facilities in Kentucky.

First, a clarification provided by the DEA to GPS was provided when the take-back of one particular controlled substance was questioned. This product is fentanyl citrate transmucosal lozenge or the trade name Actiq. The product has the active ingredient at the end of a stick making it somewhat shaped like a candy sucker or lollipop thereby potentially making it extremely dangerous to children. In the clarification letter provided by the Drug Enforcement Administration the DEA determined that no special exception is needed as this situation is covered under the Special Exceptions for Manufacturer and Distribution of Controlled Substances in Title 21 of the Code of Federal Regulations (CFR), Section 1307.12. This states that the manufacturer or its designated registered agent may accept returns from a non-registrant who is lawfully in possession of a controlled substance regardless of the schedule of controlled substance. GPS is contracted with Cephalon, the manufacturer of the product Actiq and therefore may accept returns from non-DEA registrants for this product

The second clarification to the Controlled Substance Act mentioned and currently used is for reverse distributors and manufacturers to receive controlled substances from non-DEA registrants in the event of a patient level recall. All product that is returned from patients under these circumstances is brought into the highly regulated environment which results in the product being counted and sent for witnessed incineration with full reporting to the DEA. GPS has managed many recalls on behalf of pharmaceutical manufacturers.

Finally, a variance to the Controlled Substance Act, although not widely used at the time it was issued, is an exemption for reverse distributors to accept controlled substances from long-term care facilities located in the state of Kentucky. The Drug Enforcement Administration allowed for a variance for reverse distributors indicating that they were aware of a critical problem within the State of Kentucky regarding the disposal of controlled substances at long term care facilities. The DEA indicated that they were providing the variance as a result of controlled substances stockpiling within the long term care facilities and presenting a public health problem. In order to avoid the potential diversion of these controlled substances the DEA agreed to allow long term care facilities to ship controlled substances for disposal to DEA registered reverse distributors. Unfortunately, the program was not widely utilized as many facilities either did not know about it or did not want to pay for the disposal process.

As a result of these clarifications, reverse distributors are allowed to take back controlled substances from non-DEA registrants in certain circumstances. GPS would welcome the ability to expand its part in the take-back of unused consumer product including controlled substances and is providing recommendations as part of this testimony.

Recommendations and Conclusion

As the problem with unused medication continues to be an issue among consumers it is evident that the Controlled Substances Act needs to be amended to allow take-back of controlled substances from non-DEA registrants. Since reverse distributors' core business function is the safe and secure processing of unused medications, GPS is a proponent of unused products being processed through reverse distribution. Reverse distributors have systems in place to adhere to the highly regulated environment and utilize the most environmentally safe method to dispose of medications.

If the number of reverse distributors continues to be lower than other types of DEA registrants we believe that it may be easier for the DEA to monitor the take back of controlled substances by reverse distributors. In conducting a review of the DEA diversion website for total DEA registrants, the website listed only 55 reverse distributors as opposed to 66,257 retail pharmacies alone for May, 2010. As the DEA works to prevent the diversion of controlled substances, we believe that the fewer number of registrants or individuals that handle the product the less likelihood of diversion, although we fully recognize that diversion can occur in any setting and only takes one individual.

GPS previously submitted recommended changes, including proposed language for the Controlled Substances Act to the DEA. This was most recently submitted in 2009 when the DEA solicited information on the disposal of controlled substances through their advanced notice of proposed rulemaking. The general recommendation from GPS included the ability for reverse distributors to take back controlled substances from non-DEA registrants.

An additional recommendation to the DEA is to distinguish the reverse distribution registration from disposal-only facilities. The current terminology used by the DEA does not match other regulatory agencies use of the term reverse distributor and creates confusion for the industry and agencies involved. The use of disposal or incineration as a registrant type would help provide the necessary clarification.

It is also important to note that unused medication from consumers is considered household waste and therefore is currently federally exempt from the environmental regulations. GPS proposes that when these products are collected from households they undergo the same rigorous environmental procedures and destruction standards as utilized by the reverse distribution industry. The process of incinerating unused product, particularly at a waste to energy facility is the most environmentally responsible method currently available today and the procedure utilized by GPS for all non-hazardous pharmaceuticals.

In summary, GPS recognizes the significant problem of unused consumer medications in the United States. We believe with changes to the Controlled Substances Act, GPS, along with our customers and other reverse distributors can have a significant impact on reducing the amount of unused medications in homes across the U.S. As a result we anticipate the occurrence and prevalence rates of misuse, abuse, and accidental poisonings from prescription product would decrease. Finally, we also believe that a solution will minimize the contribution of pharmaceutical contamination in our environment.

Thank you Chairman Kohl, Ranking Member Corker, and the members of the Committee for your commitment to appropriate prescription drug disposal for consumers and your interest in resolving the problems associated with this issue.

The CHAIRMAN. Thank you, Dr. Hendrickson.
Mr. Strain.

**STATEMENT OF BERNARD STRAIN, FATHER OF TIMOTHY
MICHAEL STRAIN, PHILADELPHIA, PA**

Mr. STRAIN. Yes. Good afternoon, Chairman Kohl, Senator Corker, my friend and Senator Casey from Pennsylvania, Senator Collins, and members of the committee.

My name is Bernie Strain. I am 52 years old, a lifelong Philadelphian. For 28 years, I have been married to Beverly, who is here today.

We had three wonderful sons together. Brian, 27, is serving our country as a sergeant in the United States Air Force. He has served several tours overseas, one in the sands of Iraq. Andrew, 23, a recent Penn State grad who put himself through that great school.

Our third son, Timothy Michael Strain, was 18 years of age at his untimely and tragic death. Tim was soon to attend college. Early in 2009, while working to put money away for college, he severely burned his hand on a lawn mower, after touching the muffler.

He was treated by a doctor and then seen at St. Christopher's Hospital in the Philadelphia burn unit. He was prescribed pain medication and scheduled for skin grafts.

Time went by, and while at his girlfriend's mother's home, he complained of continuing severe pain in his hand. The mother, who was arrested for this act, gave him medication—methadone—from her own medicine cabinet.

The mixture of drugs that were in his system killed our son that night. Timothy Michael Strain—charming, good-looking, great athlete—was dead.

Months passed, and a news article was published in the Philadelphia Daily News. The article was about the tragic way our son Timmy died. After reading that newspaper article, Beverly and I wondered how medications are routinely disposed of, as well as the incidence of misuse of prescription drugs.

Our questioning led us to realize that there are drugs in many of our homes that are unused and outdated. If we can dispose of cans, bottles, batteries, paint, oil properly, why can't we responsibly dispose of unused and outdated medication that could be possibly lethal?

The same newspaper article caught the attention of an environmental educator in Illinois. Paul Ritter, in my opinion, should be teacher of the century. Paul and his students developed the P2D2 program. This is a prescription drug give-back program.

Paul called my wife and I on one of our darkest days following the funeral of our youngest son. We never thought that this could happen to us. It was always somebody else's child pictured on that T-shirt with the words "rest in peace." Paul had the answers to all of our questions. He has since become a dear friend following the night he called us and offered his sympathy.

One phone call initiated a new direction in our lives, to try to turn lemons into lemonade. With his experience and knowledge, he introduced us to Gail and David Katz. They, too, lost a son to pre-

scription drug medication. Gail and David started Save a Star Foundation in honor of their son Daniel. Soon we were on our way to see how we were going to try to save a child, a senior citizen, or one other potential victim.

Mr. Chairman, you are aware that on May 24th, our Tim's birthday, a resolution was passed in the U.S. Senate, calling on all 50 States to start thinking about the issue regarding how properly to dispose of unused medications. Last week, in the city of Philadelphia, through a resolution that was passed in the City Council, called on our city of the first class.

Councilwoman Blondell Reynolds Brown introduced the resolution and cosponsored by council members Tasco, Green, and Jones. Through the District Attorney Seth Williams and Mayor Michael Nutter, we will soon have a program in place. We will develop a give-back program where our citizens can properly dispose of our medication and not dump them into the water, which is common practice, or simply throw them in the trash.

According to our water department, there are 50 plus pharmaceuticals in our drinking water. More people die in the United States from legal prescription drugs than from illegal drug use. It is our intent to save another life. It may be a member of your family.

If this legislation is passed, I respectfully ask you to consider naming this "Timmy's Law" in honor of our wonderful son.

In closing, I would ask all of the members of this committee to tell your children and family members that you love them before you leave each day to serve our great Nation. As I left that fateful day to serve the citizens of Pennsylvania, I received that devastating phone call on my way to work that Timmy was dead. You just never know.

My wife and I are most sincere and dedicated to this cause, as you can see by us driving here today. Our two other sons, Brian and Andrew, are helping us with this effort as well and hoping to make a positive difference in our neighborhoods, city, and the Nation while preserving the memory of our beloved son, Timothy Michael Strain, as well as trying to save just one other life.

Thank you.

[The prepared statement of Mr. Strain follows:]

**Bernie A Strain's Testimony before the US Senate's Special Committee on
Aging at Upcoming Hearing on Prescription Drug Disposal June 30, 2010**

Good afternoon Chairman Kohl, Senator Corker, my friend and Senator Casey from Pennsylvania and members of the Committee.

My name is Bernie Strain. I am a 52 year old life long Philadelphian. For 28 years I have been married to Beverly, who is here today. We had three wonderful sons together. Brian, 27, is serving our country as a Sergeant in the United States Air Force. He has served several tours overseas, one in the sands of Iraq. Andrew, 23, is a recent Penn State Grad who put himself through that great school.

Our third son, Timothy Michael Strain was 18 years of age at the time of his untimely and tragic death. Tim was soon to attend College. Early in August 2009, while working to put money away for college he severely burned his hand on a lawn mower, after touching the muffler. He was treated by a doctor and then was seen at Saint Christopher's Hospital at the Philadelphia burn unit. He was prescribed pain medication and was scheduled for skin grafts. Time went by and while at his girlfriend's mother's home, he complained of continuing severe pain in his hand. The mother, who was arrested for this act, gave him medication (methadone) from her own medicine cabinet. The mixture of drugs that were in his system killed our son that night. Timothy Michael Strain, the charming, good looking, great athlete was dead!

Months passed and a news article was published in the Philadelphia Daily News. The article was about the tragic way that our son Timmy died. After reading that newspaper article, Beverly and I wondered how medications are routinely disposed of as well as the incidence of misuse of prescription drugs. Our questioning led us to realize that there are drugs in many of our homes that are unused and outdated. If we can

dispose of cans, bottles, computers, batteries, paint, oil, etc. properly, why can't we responsibly dispose of unused and outdated medication - that could be potentially lethal?

This same newspaper article caught the attention of an environmental educator in Illinois, Paul Ritter. In my opinion, Paul is the teacher of the century! Paul and his students developed the **P2D2 Program**. This is a prescription drug give back program. Paul called my wife and me on one of our darkest days following the funeral for our youngest son. We never thought this could happen to us! It was always someone else's child pictured on that T-shirt with the words *Rest in Peace!* Paul had the answers to all of our questions. He has since become a dear friend following the night he called us and offered his sympathy. One phone call initiated a new direction in our lives – to try to turn Lemons into Lemonade. With his expertise and knowledge, he introduced us to Gail and David Katz. They too lost a son to prescription drug medication. Gail and David started the **Save a Star Foundation** in honor of their son, Daniel. Soon we were on our way to see how we were going to try to save a child, senior citizen or any other potential victim!

Mr. Chairman, you are aware that on May 24th, our Tim's birthday, a Resolution was passed in this United States Senate, calling on all 50 States to start thinking about this issue regarding how to properly dispose of unused medications. Last week, the city of Philadelphia, through a resolution that was passed in the City Council, called on our City of the first class to start a program. Councilwoman Blondell Reynolds Brown introduced the resolution and it was cosponsored by Philadelphia City Council members Tasco, Green and Jones. Through the District Attorney Seth Williams and Mayor Michael Nutter, we will soon have a program in place. We will develop a give back program where our citizens can properly dispose of medication and NOT dump them into our water system (which is a common practice) or simply throw them into the trash.

According to our water department there are 50 plus pharmaceuticals in our drinking water.

More people die in our United States from legal prescription drugs than from illegal drug use. It is our intent to save another life. It may be a member of your family. If this legislation is passed, I respectfully ask you to consider naming this ***“Timmy’s Law”*** in honor of our wonderful son.

In closing, I would ask all of the members of this committee to tell your children and family members that you love them before you leave each day to serve our great nation. As I left that fateful day to serve the citizens of Pennsylvania, I received that devastating phone call on my way to work, that Timmy was dead! You just never know. My wife and I are most sincere and dedicated to this cause as you can see by our driving here today. Our two other sons, Brian and Andrew are helping with this effort as well – and hoping to make a positive difference to our neighborhoods, city and the nation while preserving the memory of our beloved son Timothy Michael Strain as well as trying to save maybe one other life.

With Utmost Respect and Thanks,

The Strain Family

Four important websites to note:

<http://www.p2d2program.org> – see Timmy's Story

<http://www.saveastar.org>

<http://www.friendsdontletfriendsdie.com>

Timmy's Law on <http://www.facebook.com>

The CHAIRMAN. Thank you very much, Mr. Strain.

Mr. STRAIN. Thank you.

The CHAIRMAN. Dr. Gressitt?

STATEMENT OF STEVAN GRESSITT, M.D., FOUNDING DIRECTOR, MAINE INSTITUTE FOR SAFE MEDICINE, FACULTY ASSOCIATE, UNIVERSITY OF MAINE, CENTER ON AGING, UNITY, ME AND ASSOCIATE PROFESSOR OF CLINICAL PSYCHIATRY, UNIVERSITY OF NEW ENGLAND COLLEGE OF OSTEOPATHIC MEDICINE

Dr. GRESSITT. Good afternoon, Senator Kohl, Senator Corker, Senator Collins, and members of the Special Committee on Aging.

I am Dr. Stevan Gressitt, Founding Director of the Maine Institute for Safe Medicine. I am the co-principal investigator on a U.S. EPA grant that tested the concept of using the U.S. mail to remove unused and unwanted medication from the community. Our final report is attached to my written testimony.

Thank you for the opportunity to outline what we accomplished and sketch some of our findings and proposals.

Today, virtually every home in America has unused medicine like OxyContin, Valium, and antibiotics in the medicine cabinet, and they are a hazard. After reviewing a number of drug abuse prevention programs, we realized none of them were actually removing a single tablet from harm's way.

We researched Federal agency rules and regulations and found that if our Maine Drug Enforcement Agency was explicitly responsible in State law that we might be able to use the mail to have consumers dispose of their medication directly. We wanted the easiest, simplest, 24-7 process, and mailboxes are always open for deposit.

State legislation passed in 2005 included facilitation of consumer unused medication into the scope of our Maine Drug Enforcement Agency. Special agreements were made between the Maine DEA, the U.S. DEA, and the United States Postal Service. We are unaware of any other State that has taken this one crucial step. We received the U.S. EPA grant in 2007.

The mail-back program is simple for the consumer, who can request an approved, prepaid mailer from any of over 100 pharmacy sites across the State. The mailer includes instructions and an utterly elective survey form. Unused medication is put into the envelope and dropped in the mail.

The mailer is delivered to a post office box owned by the Maine Drug Enforcement Agency. I have brought a few mailers for your inspection. We have achieved a 43 percent return rate on these mailers. Demand for mailers is escalating as more is written about the problem of unused drug disposal.

The three most commonly returned types are central nervous system drugs, which include the opiates; cardiovascular drugs, hypertension medications; and then psychotherapeutics, which include benzodiazepines, antidepressants, antipsychotics. Seventeen percent of the returns are controlled drugs.

We have received drugs over 50 years old, old tonics containing chloroform, completely unused 1,000-milligram morphine pump cartridges. Approximately 50 percent of what was returned had lit-

tle environmental impact data available for us to use. A review of waste in Maine resulted in a limit to 15-day first prescriptions for three groups of drugs for Medicaid recipients.

Adherence and compliance are up as a direct result of this policy, which not only reduces waste, but brings more attention to adherence or unacceptable side effects. We have removed over a ton of drugs from harm's way, whether that is defined as harm from abuse, diversion, resale, or environmental impact.

There are several additional immediate needed contributions that Congress can make beside funding that would enhance a drug disposal process or processes. One, enabling legislation for the United States Drug Enforcement Administration to promulgate regulations or rules to facilitate more drug return programs safely and of various different formats, as ONDCP has recommended.

No. 2, enabling legislation for the United States Postal Service to more readily expand availability of their services to the consumers of the country.

Three, support for a national resource and research center on drug disposal. One is needed for the dissemination of best practices, evaluation of evidence, policy, and to help advise on further pilots based on what has become a significant and substantial amount of work done to date all across the country and frequently without much support.

Thank you for this opportunity, to describe our efforts and I will try and answer any questions that you may have.

[The prepared statement of Dr. Gressitt follows:]

Statement of

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(Safe Medicine Disposal for ME)

Before the

Special Committee on Aging

United States Senate

Room 106 Dirksen Senate Office Building
Washington, D.C. 20510

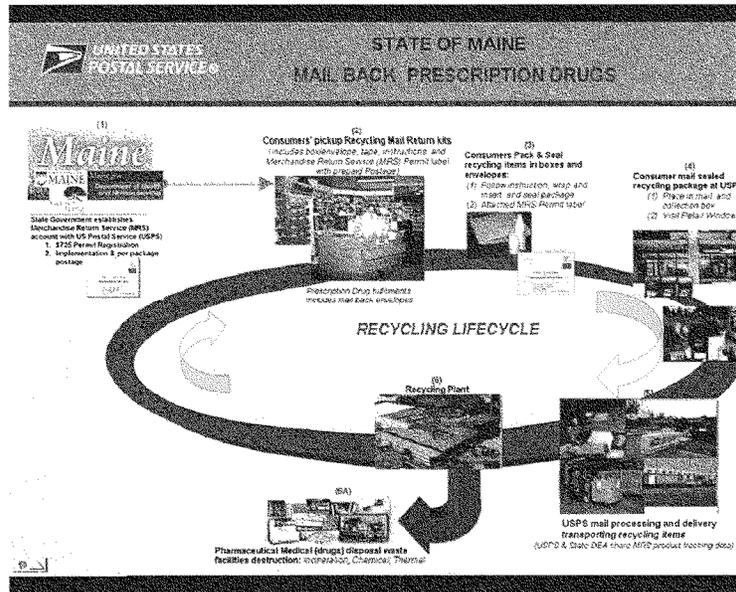
Hearing on Prescription Drug Disposal

June 30, 2010

Introduction

Today, in nearly every home across America, there is a medicine cabinet containing unused prescription and over the counter medications. These can include controlled medications such as morphine, oxycodone, valium, and Tylenol with codeine as well as non-controlled antibiotics and cardiovascular medications. While all were originally prescribed for legitimate purposes they are now sitting in the unlocked medicine cabinet unused. They represent a serious hazard to children. They have become an attraction to initiate burglaries. They are now one of the most significant sources of teen drug use. They are also an emerging source of identified pollution in our waterways.

Our United States Environmental Protection Agency funded pilot has shown definitively that residents across the State of Maine are eager to rid their homes of these unused medicines and thus these potential hazards in a safe and environmentally friendly way. What was required to achieve this goal was the development of an effective and easy way to enable citizens to dispose of unused medications. I will provide an overview of the process we developed, tested and now can report on its overwhelming success. The diagram below succinctly outlines the process we developed.



Before developing our current program, we reviewed a number of antidrug programs and noted that some were quite expensive to join, or to purchase quite professionally produced materials. Many programs focused on public awareness campaigns, exhortations to just say “no,” or were extensive displays with impressive visual effects, or handouts, or “take aways,” or even trinkets. However none of these programs actually addressed the critical safety goal of removing drugs from harms way. We knew that this element needed to be included or even an explicit goal and put together an approach that has now been tested and successful.

Why did the State of Maine need this program? Diverted, abused, and misused prescription drugs are a major cause of accidental poisonings and arrests in the State. The State is ranked by the 2009 National Drug Intelligence Center Drug Threat Assessment as first in the country in terms of the perceived relationship of pharmaceuticals to violent crime and property crime, and second in terms of the availability of pharmaceuticals for abuse. Forty percent of Maine law enforcement agencies perceive prescription drug misuse as the State’s most serious drug threat.

Between 1999 and 2006, the number of accidental overdose deaths in Maine tripled. In 2005, the number of deaths from overdoses for the first time exceeded deaths from automobile accidents. Preliminary statistics from 2009 noted 179 overdose deaths, 92% of which were tied to prescription drugs. In addition, over 400 infants born in the state last year showed signs of withdrawal from narcotics or other illicit drugs.

Between 2007 and 2008, the number of drivers found impaired by hydrocodone - the generic form of Vicoden, rose by 750%. The number of impairment cases involving oxycodone rose by 450% and cases involving methodone, 150%.

The Safe Medicine Disposal for ME (SMDME <http://www.safemeddisposal.com/>) program is a statewide model for the disposal of unused household medications using a mail-back return envelope system. Established through State legislation in 2005¹ (Public Law 2003 Chapter 679) and implemented in 2007 with a grant from the U.S. Environmental Protection Program’s Aging Initiative, the program is authorized to handle both controlled and non-controlled medications. The significance of the law is that it defined assistance with consumer unused medication as an explicit part of the Maine Drug Enforcement Agency responsibilities. This significance cannot be underestimated as this was the single fundamental legal approach we developed to open doors to the federal DEA and to the USPS. We are unaware of any other states taking this step explicitly while attempting on the other hand to bypass that step. All drugs collected undergo high-heat incineration, according to the procedure already established for Maine’s law enforcement drug seizures.

In 2007 the State of Maine legislature further funded this initiative by enacting LD 411, “An Act to Establish a Pilot Program for the Return of Unused Prescription Drugs by Mail.” Additional resources were then provided to extend the original United States Environmental Protection

Agency (U.S. E.P.A.) funded pilot more broadly across the state and which allowed the program to continue for an additional two years beyond the initial U.S. E.P.A. grant. The U.S. E.P.A. grant has expired and the funds allocated through LD 411 are ending. There are only 2,500 mailers left and efforts are being made now for redistribution of some from lower to higher demand sites within the state.

The highly rural nature of Maine and its distinction as being the “oldest state in the nation” (based on median age of residents) presented distribution, collection, and financial challenges for mounting a state-wide expired and unwanted prescription drug return program.

Six reasons for citizens to tackle unused drug disposal have been identified^{2,3,4,5}:

- (1) to curtail childhood overdoses
- (2) to restrict household drug theft
- (3) to limit accumulation of drugs by the elderly
- (4) to protect our physical environment
- (5) to restrain improper international drug donations, and
- (6) to eliminate waste in the international health care systems of all countries.

The U.S. Postal Service system was chosen as the method for addressing these challenges due to the fact virtually all of Maine’s citizens have regular access to the mail, and the US Mail has a special protection under law.

Program Development and Operation

The goals for the prescription drug return program in Maine included:

- 1) to devise, implement and evaluate a mail-back plan to remove unused and unwanted medications, both prescription and over-the-counter, from residences;
- 2) to dispose of them in compliance with applicable State and federal laws and sound environmental practices, and
- 3) to test the effectiveness of an educational campaign about the hazards to life, health, and the environment posed by improper storage and disposal of unwanted medications.

A cost-effective model for the disposal of unwanted medication would be created and implemented, and an educational campaign would be instituted in each of Maine’s 16 counties. Further, the project was scheduled to address potential barriers to participation due to age, infirmity, rural locale, and other challenges.

Program objectives included:

- 1) calculating the weight, type and hazardous characteristics of returned medications by actual pill count and drug classification;
- 2) calculating the cost of the mail-back program as a model for future use nationally, by other organizations and states; and
- 3) offering a statewide education campaign targeted toward the proper use and disposal of prescription drugs with an initial focus on citizens 65 and older. With State support this was expanded to the entire population of the State of Maine.

Many project partners throughout the state and nation contributed significantly to program success including: the Maine Drug Enforcement Agency, the Maine Department of Health and Human Services, its Office of Adult Mental Health Services, and Office of Substance Abuse, the Maine Benzodiazepine Study Group, the Maine Department of Environmental Protection, the U.S. Postal Service, the Maine Department of Health, the Maine Office of the Attorney General, the U.S. District Attorney for Maine, and the University of Maine Center on Aging. A technical expert advisory task force was formed that included members from each of these and a cadre of partnering organizations. A Community advisory group provided a critical consumer perspective, including the perspectives of individuals involved “on the front line:” the older adult project volunteers handling community education and marketing.

A number of national specialists and associations also committed to the project including the Community Medical Foundation for Patient Safety and the National Council on Patient Information and Education. Rite Aid Corporation, the nation’s third largest drugstore chain and the largest on the east coast, formally committed to participation in the pilot project with their pharmacies serving as distribution site locations. Researchers from the University of Maine Margaret Chase Smith Policy Center contributed to project evaluation and a manual for replication development.

An “operational test agreement” was formed between the U.S. Postal Service and the Maine Drug Enforcement Agency – the first of its kind. Operational test agreements are traditionally crafted so the postal service can test out novel options. A letter of authorization under 21 CFR 1307.21 was issued to the Maine Drug Enforcement Agency by the U.S.D.E.A.⁶

The pilot program began with 11 participating pharmacies in four counties serving as envelope distribution sites, and over a period of two years expanded to include approximately 150 pharmacies and health and human services agencies in all 16 counties of Maine. The program currently maintains a waiting list of interested community-based envelope distribution sites.

Using a double verification process, MDEA law enforcement personnel counted and collected returned mailers from the Post Office on a regularly scheduled basis and took them directly to a

secure consolidation facility. The audit process involved a repeat count of the number of packages received and verification of accounting logs conducted by the U. Maine Center on Aging. Throughout the process the MDEA maintained continuous, unbroken custody of the returned medicine.

Cataloging of returned drugs was done under law enforcement supervision by volunteer project pharmacists and pharmacy students from Husson University and the University of New England Colleges of Pharmacy over a total of eight counting events. As participation has increased over time, the program moved from cataloging 100% of returns to a 25% random sample to a 20% random sampling procedure and then to 10% due to volume. Using a sampling method was found to be both cost effective and yielded a data sample that was statistically representative of the full inventory data set. For the envelopes that did not receive a full inventory, all non-controlled drugs were sorted for disposal, and all controlled drugs were fully inventoried.

During the cataloging, drugs were sorted according to whether they were controlled drugs or not and further into controlled hazardous or controlled non-hazardous categories. This sorting method facilitated appropriate disposal and therefore helped control disposal costs.

Public education and outreach was limited as indicators of success from early on left the problem of how to avoid building unrealistic expectations given the time limited nature of the pilot. The fear was that if there was a buildup of expectation that could not be met there would be dissatisfaction at least till the program could be sustainable and a period of confusion and discontinuity of service.

Program Results and Findings

The mail-back program, during its first two phases of EPA-funded operation, has disposed of more than 2,300 lbs of drugs, representing 3,926 envelopes. A total of 9,400 envelopes were distributed during this period representing a 42% envelope utilization and return rate. Additionally, over 380,000 pills were cataloged via the drug inventory process, 2,777 telephone calls were answered via the program helpline, 250 pounds of controlled drugs have been destroyed, the average weight of a returned envelope was 7 ounces, and the estimated Average Wholesale Price (AWP) of medicine collected was \$572,772.35.

Approximately 17% of the drugs were schedules II, III, and IV –“controlled drugs.” These include narcotic pain relievers, tranquilizers and sedatives, as well as stimulants.

Most returns were in tablet/capsule form. Fourteen percent of returns represented liquids, gels, ointments and patches. A negligible amount of medical supplies and devices were returned including unused morphine pumps.

Full, unused bottles were sometimes returned, including prescriptions from mail-order pharmacies or VA pharmacy services, as well as anti-retroviral drugs for HIV/AIDS treatment.

It was not uncommon to find a mix of local and mail order pharmacies represented in mailers where a patient was receiving the same drug from both sources.

Based on surveys and analysis of returned drugs, it is estimated that the percentage of individuals indicating using trash or toilet to dispose of drugs prior to the program = 83% x 2,373 lbs of drugs = 1,970 lbs of drugs prevented from entering the water supply and landfills.

Findings from program participant surveys confirm multiple reasons for drug accumulation in their homes, including:

- Medicine belonged to a deceased family member (19.6%)
- A physician told the patient to stop taking the medication or gave the patient a new prescription (27.3%)
- The person had a negative reaction or allergy to the medicine (11.9%)
- The person felt better or no longer needed the medicine (18%)

Participants had multiple reasons for removing the drugs from their homes, including concerns for the environment, drug compliance, drug safety, as well as for preventing drug diversion. Some noted they did not want anyone else to use the medicine. Some were concerned about the potential poisoning dangers to children, or the risks of drug abuse diversion. Often the medicine was expired or outdated and no longer useful. Nearly half (46%) of those surveyed reported that, in the absence of a take back program, they would have flushed drugs down the toilet. Another one third (37%) would have dumped left over prescriptions into their trash. Overwhelmingly, 77% of program survey respondents cited participation because, "it's best for the environment."

The per-envelope cost in the initial years of the program is greatest given the staff time and effort needed to design and implement the program. Donated time and effort by pharmacists and pharmacy tech staff and Community Educator volunteers reduced operational costs. Phases I and II actual and in-kind contributions calculate to \$18.79 per unit mailer. Subsequent mailer costs (Phase III) are calculated at \$7.50 per unit mailer^{7,8}. These costs were based on full commercial prices with no bulk discounts and should be clearly viewed as subject to further reduction with expansion of volume.

An unexpected benefit of this program is that the information gathered is proving to be a unique and rich source of useful drug utilization and patient compliance/adherence data. In addition there has been some initial work begun by the University of New England College of Pharmacy in identifying whether or not our sampling could provide the basis for post-market surveillance of counterfeit product.

The mail back method returned a large quantity of drugs that would have otherwise been disposed of directly into the water system through flushing or into landfills through the trash. A short survey inserted in the envelope allowed us to track the reasons for participation, the sources

of the drugs, and the demographic profile of the participants. This is information that is useful not only for project planning and education, but also policy development. Data gathered during this project has already begun to shape policy both statewide and nationally. For example, a recent MaineCare (Maine's Medicaid program) policy change has led to the enactment of limits for some drugs on how much of a supply can be filled in an initial prescription. Further data collection on compliance data can refine policy further and with more measured impacts and outcomes based on the evidence.

Program Accomplishments and Conclusions

The Safe Medicine Disposal for ME program has allowed drugs to be returned directly to one agency within the State, which reduced coordination costs and provides for secure collection and consolidation of returns. In Maine, the Maine Drug Enforcement Agency (MDEA) has statewide jurisdiction and was involved from the outset in concept development. This program partnership with Maine Drug Enforcement Agency has facilitated a review and subsequent approval of the program by the federal Drug Enforcement Agency. The statewide mail-back model offers a centralized coordination component, adds an element of confidentiality and anonymity not found with in-person take back programs and is the least burdensome of all models in terms of consumer participation.

Maine's citizen mail back program has demonstrated that this approach is not only feasible, but effective, and highly popular. The program utilized a phased implementation plan, beginning by targeting elders and focusing on pharmacies as distribution sites for the mail back envelopes. A broader target population was then phased in, adults of all ages, as well as a broader range of distribution sites (other providers of health services).

The mail back program provides a rich opportunity to educate a broad public citizenry about prescription drugs and the environment via community outreach and information distributed with the mailer. It involves citizens in an easy, "DIY" (do it yourself) problem-solving program that prevents environmental harm, prevents drug diversion, and prevents poisoning. Community education by older adults was found to be both effective and engaging while encouraging new users of the program to spread the word in their local communities. It is for this reason the consumer involvement should be a key component in any drug return program model.

We think that one possible extension of the program would be to offer an amnesty or anonymity for returns of illegal drugs as long as proper controls are exercised with proper authorization given the US DEA for the issuance of such regulations to control the very real specter of diversion. This potential for diversion also cannot be underestimated both of controlled drugs and the potential of non-controlled drugs returning through the gray market for repeat sales. Prosecution for just this has occurred already.

Though predominantly distribution was through pharmacies, there have been meetings where attendees received mailers. There have been individual requests called in. A number of potential

distribution systems have been identified. Starting with elementary school and setting an example in school health classes where distributing mailers along with messages regarding medication safety can impact the child's household storage of medicine. Long term care facilities could use a process to facilitate their disposal in larger envelopes or boxes. In a preliminary conversation with a hospital organization great interest was shown in distributing mailers to discharged patients with the message to put what they may no longer be taking in a mailer and get rid of it and put their new medicine in their medicine cabinet. As the majority of drug-drug interactions or adverse events occur shortly after hospital discharge this is the ideal time to offer this sort of readmission prevention program. In addition, drug-drug interactions or adverse events are one of the more significant causes of readmission. Neither payers nor hospitals can afford to continue to have the readmission rates that now exist and have sought for ways to reduce it. This is one promising option. Even one saved readmission is worth a great many mailers. Law enforcement has expressed desire that they have a larger share of the mailers for their community based drug abuse prevention efforts. Hospice pharmacies have expressed interest in adding mailers to their shipments so that family members can deal with departed family members left over medications. There are a wide variety of possible uses and methods of distribution that serve a number of different purposes, all for the benefit of the public health. Continuation and expansion of the Maine program could continue to provide useful information for more evidence-based policy and regulatory decision making. Indeed in addition to the hearing at which we are presenting today in Washington, in the next legislative session across the country there are a patchwork of potentially further complicating bills that address unused drug disposal. The prospect of these various jurisdiction, including municipalities, coming up with similar or compatible legislation is not likely given the varied and broad range of perspectives and interests in the problem of what to do with unused medications.

A major challenge for this and other disposal programs across the United States continues to be sustainable funding for such efforts. All disposal programming, whether mail back or event-based take back programs, require a considerable amount of time and effort to plan, execute, and educate the public. The first two phases have shown us that the interest and the community need exist and in fact, clearly outweigh the resources available to address the issue of drug disposal. However, it is imperative to continue as many programming and outreach efforts as possible to provide drug disposal options directly to the consumer at the same time that information is disseminated so as to avoid the confusion and misinformation the surrounds the issue of drug disposal.

Our experience has identified national need for such a program to be brought to the public as soon as possible. In 2005⁹, the United States Pharmacopeia passed a resolution to address unused medicine and reiterated this position at the 2010 Convention¹⁰. Within the past month the American Medical Association House of Delegates passed Substitute Resolution 515 which states:

RESOLVED, That our AMA support initiatives designed to promote and facilitate the safe and appropriate disposal of unused medications. (New House Of Delegates Policy)¹¹

Conclusion

The removal of the unused medication from risk for misuse has an inestimable value if only one life is saved from overdose or accidental poisoning.

We believe that this project could serve as a model for replication both at a state level and nationally. There are implications for health care policy, as exemplified by the State of Maine adopting pharmacy regulations to reduce waste, and CMS issuing a request for comment for a similar Medicare Part D approach. There are implications for environmental policy in looking at relative risks, and for law enforcement in looking at how to reduce both supply of, and demand for, illicit drugs. We believe that other benefits exist, but a proposal resulting from this project is the recommendation and invitation we make that the program be continued and expanded, and plans developed for replication in the immediate future. We hope we have made a significant contribution to the environmental as well as public health of the country.

There are several additional contributions that Congress can make besides funding that would facilitate this process.

1. The first is enabling legislation for the United States Drug Enforcement Administration to promulgate regulations or rules that will facilitate more drug return programs as the Executive Office of the White House Office of National Drug Control Policy has recommended.
2. The other is enabling legislation for the United States Postal Service to more readily expand availability of their services to the consumers of the country.
3. There is also the need for a better coordination between the various Federal agencies and the various and individual state agencies. DEA has a need for new avenues of communication outside the law enforcement community to hazardous waste and disposal and reverse distributors, while EPA could use new forums for communication with law enforcement across the country and within the multiplicity of jurisdictions that have an interest in solving this problem. This brings increasing time urgency for Federal action and facilitation of best practices nationwide.
4. There currently is no national resource or research center on drug disposal. Instituting one is sorely needed for dissemination of best practices and evaluation of evidence and policy.

Thank you for the opportunity to discuss our unused medicine disposal pilot and process. We look forward to assisting national solutions move forward.

I look forward to your questions.

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10. **USP 2010 Resolution #9 also at:** <http://www.usp.org/pdf/EN/members/2010-2015-Resolutions.pdf>
11. **AMA Resolution # 515, 2010 (quoted on page 7 above)**
12. **Additional material from the Maine Medical Association**

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The CHAIRMAN. Thank you very much, Dr. Gressitt.
Mr. Behringer.

STATEMENT OF BRUCE BEHRINGER, ASSOCIATE VICE PRESIDENT AND EXECUTIVE DIRECTOR, OFFICE OF RURAL AND COMMUNITY HEALTH AND COMMUNITY PARTNERSHIPS, EAST TENNESSEE STATE UNIVERSITY, JOHNSON CITY, TN

Mr. BEHRINGER. Thank you, Senators, and thank you, Senator Corker, for the kind comments about our E.T.S.U. College of Pharmacy.

I don't want to read the testimony, but I would like to make a few comments that would reinforce, Senator Kohl, the themes that you identified. I do not want to say anything that would denigrate the area in which I live. I think, though, that the State of Tennessee has the unfortunate ranking of being first or second among all States over the course of the last four years in the number of prescriptions per person dispensed. I think that part of the issue that we are dealing with is a volume issue, so many prescription medications, including controlled substances, being in the hands and on the streets and in the medicine cabinets all across the State.

Substance abuse has been explained to me as having an amoeba-like characteristics and is very complicated. It keeps moving and changing form. Unfortunately, it has moved in the direction of controlled substances and medications in our area. One of the true indicators of the movement was from a group of communities that we pulled together from rural Appalachia, and we asked them to talk to us about what their issues were. We thought it was methamphetamine, and this is back in 2006 when you will remember there was a huge campaign against methamphetamine.

They started by saying, yes, that is a problem. But we need to think about substance abuse as the broader problem. Then, by the end of this conference sponsored by the Appalachian Regional Commission, they said, no, that is not it. The real issue is the culture of substance use that we have in our country. It is not just in the mountains. It is not just in Tennessee. It is all across the country.

Patients expect prescriptions in order to have a successful encounter with a health professional. There is a pill for every ill nowadays, and the pharmaceutical companies have gotten so much better and effective in giving relief in a better, a stronger, and a faster way. So there are many legally prescribed medications that are sitting, unfortunately, unused because, as you have said, people have a tendency to hoard things. They are very expensive, and they would rather save them for another day if, in fact, they are needed.

We also need to recognize that the State of Tennessee is bordered by eight other States. We have a number of people who may be seeking medications across State borders. Right now, we have very limited ways of knowing about that. We also have people who, unfortunately, find pill mills in other States and get on airplanes, go there, bring the pills back.

We have had a series of very unfortunate circumstances in our region that are on the front page of the paper on a regular basis about people who have had pills confiscated or they have been ar-

rested, or actually have been involved in murders. It has been a very, very dangerous situation.

What I did want to say is I had the honor of teaching a Health Disparities in Appalachia course in our College of Pharmacy. These pharmacy students, are the next generation of people who are going to be on the front line. They came up with a set of three recommendations after they looked at the prescription medication problem.

The first one is that we need a balanced educational program, one which helps to teach physicians not just what the right drug is to prescribe, but also the signs of addiction. Pharmacists need to be taught about medication management and counseling. Patients need to be taught about not misusing pills and never, ever giving pills to somebody else.

General public needs to understand how dangerous this situation really is, that it affects everybody. The elderly are petrified in many communities if they have prescription drugs, and they are thinking that somebody may come to get them.

Secondly, the pharmacy students found out that not all prescribers and not all dispensers are actually using the prescription medication monitoring programs in the different States. I think that you, from this committee, could make a very strong moral case that this is a horrible issue in this country. You have put money forth to help States to create those registries, and you should encourage all physicians, encourage all organizations and all pharmacists to use those registries because they will help to save lives.

Finally, our pharmacy students went out into the community as part of take-back programs, and they learned how communities really do want to be helpful. What they really need is something to pull them together to make them aware of the situation, and the take-back programs that have been sponsored in northeast Tennessee have done that. They have found pill bottles going back 35 years ago that people will turn back if given the opportunity.

So I do encourage the committee as strongly as possible to take the high road in encouraging all of us to consider that this is a problem for the Nation, and it is a problem in our communities, and it is a problem in our families. To encourage us to think about it as something that we should all contribute to the solution of.

[The prepared statement of Mr. Behringer follows:]

**Statement of
Bruce Behringer, MPH
Associate Vice President, Office of Rural and Community Health
East Tennessee State University
Johnson City, Tennessee**

Before

**The Special Committee on Aging
United States Senate**

**Hearing on
Prescription Drug Disposal**

June 30, 2010

Thank you Chairman Kohl and Senator Corker and Members of the Committee for allowing me to contribute some perspectives regarding prescription drug disposal. I can only assume that the inclusion of "Drug Waste" in the title of the hearing has a double meaning – that of unused medications and that of the scourge that misused medications now inflicts upon many families and communities across our country.

Allow me to state that I am not an expert in pharmaceuticals, substance use and abuse, or the legal frameworks which we have created to protect ourselves from the problems. Instead, I have learned about this issue through many interactions over time with rural Appalachian communities, with concerned health professionals and students, and with regional and state leaders aware of our "numbers" that only partially describe the breadth and depth of our problems. Over the years, in almost every communities with which I have had the honor to work, the two health issues that dominate most lists of community health concerns and worries are cancer and substance abuse.

Drug abuse is a nationally recognized health problem. Diversion is a small and unintended outcome of a legal and medically necessary process at the end of a long chain of events that feeds some unknown amount of drug abuse and leads to negative economic, social, educational and health impacts. From one perspective, we would not need to discuss diversion of medications if they were not prescribed or dispensed. The pharmaceutical industry has been very effective in meeting and cultivating Americans' demands for immediate relief – better, stronger, and faster pain relievers. We live in a culture of expectation that there is "a pill for every ill." Marketing of medications leads to patient demand. Patient demand influences providers' prescribing patterns, which in turn dictate the business of pharmacies. Pharmacists dispense powerful pills into households and communities. Once those substances get into the hands of patients, another whole set of very uncontrollable behaviors that affect diversion take over.

I have learned that the vast majority of patients do not seek pills for diversionary purposes. Patients from areas of the country like East Tennessee have many legitimate needs for pain medications. Our people work in dangerous occupations like farming, forestry, and mining. We have one of the nation's highest cancer death rates leading to dispensing strong pain medications for palliative care. We are the homeplace of many Veterans who require long term use of medications because of military injuries and service-related osteoarthritis.

Once controlled substances are dispensed, human nature takes over. Patients may not use the full number of pills, hoarding unused pills for future use, sharing with other ill family members, or, in some cases, for selling to others.

Tennessee continues to rank either first or second among all states for prescriptions per capita. DEA 2006 state data reports indicate extraordinarily high amounts of control substances in the state - Oxycodone (189% higher than US rates), hydrocodone (277% higher), Morphine (285% higher) and Mepeirdine (417% higher) as measured in milligrams per 100,000 population. The rate of unintentional poisoning deaths increased 53% 2002-2006 in Tennessee (TN Controlled Substance Monitoring Data Base). In fact, Tennessee's increase is less than for many other states. In some regions of the country, more people die of unintentional poisonings from prescription medications than from traffic accidents. Increasingly, front page stories report the all too frequent drug sales busts, confiscations, overdose deaths. Now even our smaller towns and rural areas are confronted with drug-related violence and murders from the street trade in pills. These are frightening visions for our elderly citizens who use these pills and are fearful for their own safety.

Misuse of prescription medications is an amoeba-like problem. This includes the changing use of substances being abused, a broadening circle of people involved in the street trade of dangerous pills, and a complex involvement of even well-meaning people wanting to help others. What we are learning from law enforcement reports is the great diversity in the source of diversion and abuse. Some pills are from filled prescriptions that patients resell rather than use. Some pills are stolen. Many pills confiscated in our area are from out of state physician practices known to prescribe pain medication, some in neighboring states and some from the now all-too-well-known round trips to the Florida pill mills.

No one is certain about the size and description of the diversion problem. There is no central national data base that reliably exposes the depth and breadth of the prescription medication abuse problem in the Tennessee or in the United States. The most reliable place-based and population data may be its unfortunate end points - mortality and arrest records. This data is not deemed totally reliable or available for analysis.

I had the honor to teach a course in the new Gatton College of Pharmacy at East Tennessee State University (ETSU) this year entitled "The Relationship of Pharmacy and Health Disparities in the Appalachian Region." Pharmacy students collected data and viewpoints from community organizations and regional leaders to describe factors involved with controlled substance use and diversion. Their general conclusions reflect a unique perspective of the next generation of health professionals who must help address our collective problems:

1. Education

Diversion of controlled substances is truly an issue that affects all people in all communities. We need a balanced approach to increasing awareness of the multiple manifestations of the problems. We need to underscore the intertwined responsibility of patients as consumers, of medical care providers as prescribers, of pharmacists as dispensers, of law enforcement and judicial system as regulators and protectors. We should not allow the growing time pressures in the health care system to be an excuse for not ensuring that every patient receives warnings from their prescriber and counseling from their dispenser about the dangers of misuse of controlled substances.

Among the student recommended actions:

- *Physicians* and other prescribers need to be educated not just on what to prescribe, but also the science of the addiction.
- *Pharmacies* should guarantee that pharmaceutical practice requires patient counseling and medication management for all prescriptions being used by patients and potential danger of mixing medications.
- *Patients* should be educated about risks of misuse of the drugs they are prescribed, the dangers of not properly storing them in their homes, how to dispose of unused pills, and never to share pills with others.
- The *general public* needs to be told the truth about the growing scope of accidental poisonings. Community attitudes should engage health providers to be accountable in part for the volume of controlled substances being used while challenging health insurers to pay for patient education and medication management. At the same time, we should ensure that the public pendulum should not swing so far as to deny access to prescription medication that is truly needed.
- All *students* who become prescribers and dispensers should have required interprofessional opportunities to learn their legal responsibilities and to experience how to have that difficult communication with other health professionals to confront questionable situations of prescriptions for controlled substances.

2. Prescription Drug Monitoring Systems:

Clinicians need full information about a patient's current use of controlled substances when they assess the patient and form a treatment plan. Having unencumbered healthcare provider access to controlled substance prescription information is critical for better clinical decision-making and for enhanced patient safety. More informed healthcare providers are in a better position to prevent narcotic overutilization and drug diversion and can protect the patient and the community from narcotic intoxication and dependence. States have developed prescription monitoring programs that are underused as a resource. Not all prescribers or dispensers use in-state or tap out-of-state registries. Action should be taken to:

- Reduce complications in using state monitoring systems. All states' systems should assure timely access to data. NASPER should be funded so that states are able to implement these programs.

- National standards for interoperable state systems should enable timely inquiries that would allow detection of doctor shopping cross state lines. This is important for states like Tennessee which is bordered by eight other states.
- Formally inquire why major prescriber and dispensing groups do not currently use data bases. Cost to practice, legal privacy interpretations and concern for patient dissatisfaction have been cited. The national importance of the issue and a nationwide intent should be made clear that all public and private sector healthcare providers should use databases prior to prescribing or dispensing controlled substances. Perhaps additional national incentives should be considered.

3. Take-Back Programs:

Many communities across the country have successfully sponsored and promoted programs to dispose of no longer needed prescription drugs. ETSU pharmacy students participated in three such programs and reported that the public enthusiastically appreciated relieving themselves of old stockpiles of personal and family pills. Hundreds of pounds medications were received, including a prescription bottles dating from over 30 years ago. Take-back activities promote a visible and united community front for personal action and public education. Events demonstrate a common cause among law enforcement, pharmacies (chains and independents), medical providers, solid waste, senior centers, schools, children's services, and prevention agencies. Students however pointed out that a lack of clear understanding of policies regulating these events dissuades some professionals from participating. Clarification is needed from all agencies (FDA, EPA, DEA, and ONCDP) regarding the laws and regulations regarding disposal of unused medications.

Diversions turn the wonders of modern medicine into poison. The poison has led to addictions that gnaw at the fabric of our families, our communities, our economy and our nation. It is hard to describe all characteristics of the amoeba-like condition of misuse of controlled substances. It is harder to contain that which appears to not be able to control its own form. The Committee should adopt and create a balanced vision and encourage Congress:

- Not to be timid in regulating what is needed to protect the public;
- Encourage a national effort that involves multiple stakeholders, levels of government, and public and private sectors; and
- Challenge those involved in both demand and supply of controlled substances to see their responsibility and role for preventing the daily tragedies that are pronounced in the media.

Thank you for this opportunity to share the views of many concerned citizens and health professionals from East Tennessee and Central Appalachian region.

The CHAIRMAN. Thank you very much, Mr. Behringer.

Mr. Rannazzisi, we understand that there is going to be a nationwide day of disposal later this year for Americans who want to do away with their leftover drugs. Can you tell us something about that plan that you are putting together and what you hope to achieve and how it is going to be publicized?

Mr. RANNAZZISI. Yes, sir. Well, we are planning a nationwide take-back day. We are working out the details. Right now, it would be premature for me to announce it, but we will have a nationwide take-back day.

It will be done in cooperation and in coordination with our law enforcement partners, community groups, coalitions. It will be—we should have media play throughout the country and locally for this day, and we would like a very strong turnout. But at this point in time, I can't give you any more detail than that.

The CHAIRMAN. Mr. Rannazzisi, I would like to digress for just a minute to take up a single question, no more than that. In an appearance that you made before our committee in March on dispensing of prescription drugs in nursing homes, at that time, you heard testimony about the problem of identifying and treating nursing home residents who are in extreme pain and treating them with their needed drugs in a timely manner.

According to other witnesses, your agency's stepped-up enforcement policies were causing serious documented problems in the delivery of these pain-relieving drugs to elderly patients who were badly in need of them. By the end of that hearing, it seemed that we were well on our way to a compromise between DEA and the nursing home industry.

However, it wasn't until just yesterday that DEA issued a solicitation in the Federal Register asking for information from interested parties concerning this pain medication issue. This is the first that we have heard from DEA since your testimony back in March.

So I was hopeful that our hearing back then and the urgency of the issue as it played out in that hearing was going to result in some rather immediate kind of dialog and compromise between you and the nursing home industry. Can you tell us where we are and how we are going to get where I believe we all want to get and as soon as possible?

Mr. RANNAZZISI. Yes, sir. I believe when we left that hearing, the National Association of Boards of Pharmacy had recommended that the nursing homes obtain State registration, State controlled substance registration and authority. At that point in time, DEA would look to providing them or authorizing them with a controlled substance registration so they could change the way they are doing their business right now.

We have been in contact with the Ohio Board of Pharmacy on numerous occasions, providing technical assistance. Ohio Board of Pharmacy is taking the lead in creating regulations. They are working with other States in the National Association of Boards of Pharmacy to create pattern regulations for the other States to move forward with State authorization for controlled substances.

That advance notice that was sent out yesterday is to provide more information to us so when the time comes and when we do

start receiving the State authorizations for long-term care facilities, we will be prepared to issue their registrations. It is just background information on what the long-term care facilities are doing and how changes within their structure of how they are doing business we can incorporate into what we are trying to do.

The CHAIRMAN. How long will this process be playing itself out?

Mr. RANNAZZISI. Well, again, I could only move as quickly as the States do. The authority that I could provide is based on the State controlled substance authority. Now I know that the State of Ohio is moving forward very quickly but cautiously because they want to make sure if their regulations are being used as a pattern regulation for other States, they want to make sure it is correct.

But I could assure you that we are providing all the technical information necessary to help them create those regs. As soon as we have that first reg in place, we will move forward quickly.

The CHAIRMAN. Of course, there is always the danger in a situation like this that 6 months from now and a year from now we will still be talking about it. As you could imagine, we are trying to move as quickly as we can to alleviate a serious problem. Can you say anything by way of aid and comfort today?

Mr. RANNAZZISI. I would like to tell you that the Ohio Board of Pharmacy is moving as fast as they can, and I believe that the individuals who are working on that reg in the Ohio Board of Pharmacy are reaching out to the other States, and they want to get a reg in place as quickly as possible because, let us face it, Ohio especially, there are many problems in Ohio. I believe Ohio is what kind of triggered a lot of the problems throughout the United States.

So they are trying to move forward. The Ohio board president, William Winsley, has taken a personal active role in creating these regs. So knowing Mr. Winsley the way I know him, I am sure that they will move forward as quickly as possible. I could assure you that once we get the regs, we will move forward as quickly as possible.

The CHAIRMAN. All right. If it is all right with you, we will be in contact with you on a regular basis to see how we are doing?

Mr. RANNAZZISI. Yes, sir.

The CHAIRMAN. Thank you so much.

Dr. Hendrickson, you mentioned in your testimony that people wishing to dispose of prescription drugs find the process of separating controlled or noncontrolled products to be confusing. Except for a change in the law, how can we better educate people about the existing rules and how to properly separate their medications?

Dr. HENDRICKSON. I think that could be through multiple different efforts. When we conducted our program, we educated people through having them call a 1-800 number. So that allowed us to provide feedback to them on the definition of a controlled substance, but then also what types of categories were within the controlled substance. So we said pain medications, sleep medications.

We also had someone available to answer questions, if they had a specific question about alprazolam a controlled substance? In addition to that, we followed up with written information when we sent out the mailer or the shipping materials for the product to be sent back to us.

So I think in general, through multiple different media methods—verbal, as well as written—would be helpful.

The CHAIRMAN. All right. Senator Corker?

Senator CORKER. Thank you, Mr. Chairman.

First, I want to tell Mr. Strain that his testimony was very moving. I thank him and his wife for having the courage to be here today and taking the time and effort to be here. I thank you very much.

Dr. Hendrickson, just to follow up on the last question, I mean, wouldn't it be simple just to label these things when they were prescribed so people don't have to go to the effort of making calls and doing all of that?

Dr. HENDRICKSON. They are actually labeled. There is a label that says Federal law prohibits transferring this to someone else other than who it is written for. That actually is labeled on prescription medications.

In my experience as a pharmacist, people struggle even with the directions on how to take their medication in the right times or the right dosage. They especially don't seem to read some of the warnings that are also on the prescription container.

Senator CORKER. So them calling is even more difficult, right?

Dr. HENDRICKSON. I think it provides added education to them. It is an additional reinforcement method that we utilized.

Senator CORKER. Yes.

Dr. HENDRICKSON. I think it certainly prevented medications from coming back based on the questions that we had. So when we educated people, we found that they were asking questions and understood that they couldn't take things back. So it did certainly prevent instances of controlled substances coming back, that additional education.

Senator CORKER. Thank you.

Mr. Behringer, you mentioned registries. Would you mind explaining to me how that works exactly?

Mr. BEHRINGER. The prescription monitoring programs that have been established across the country in each State would enable a prescriber—a physician, nurse practitioner, a dentist—as well as the dispenser, the pharmacist, to check through a database whether or not that same type of medication had been prescribed sometime in the past.

Those registries are there to enable two things. No. 1, they would enable a physician to figure out whether or not some other physician had prescribed something that would be either the same or something that might counteract with the pharmaceutical which he or she would want to prescribe. So it is a safety measure to enable a physician to know everything that that patient is taking.

The second thing it would do, obviously, is if a physician or a prescriber were to check the database and find out somebody had just been to another physician last week or the week before and got the same medication, it might give an indication that they probably would not want to write that prescription.

Senator CORKER. What is the status of registries right now?

Mr. BEHRINGER. I believe there are registries in all 50 States now and that not everybody is using them, which is the problem.

Senator CORKER. Right.

Mr. RANNAZZISI. If I may jump in, sir?

Senator CORKER. Sure.

Mr. RANNAZZISI. I think what Mr. Behringer is referring to is the prescription drug monitoring programs. I believe there are about 38 States currently either in process or have programs up and operational. They are exactly what he said. The doctor could go to the monitoring program database and look and see if a patient has visited any doctor, any other doctor for the same ailment, requesting the same drugs.

Kentucky, Tennessee, Indiana, many States have up and operational programs—Ohio—that are very, very good when utilized. If they are not utilized, though, it is a waste of time.

Senator CORKER. So, based on your own experience, Mr. Behringer, the registry use in Tennessee and surrounding States, is it high? Is it not high? So, basically, today it doesn't work. So how do you make the registry be robust and used by people on a daily basis so it is effective?

Mr. BEHRINGER. No. 1, physicians and—prescribers and dispensers need to be assured that it is legal to do so, and I believe that it is legal. Perhaps the associations can help them, the professional associations help them to understand that this is something that is legal to do within the framework of the law.

No. 2, the registries have to be made timely so that if a prescriber were to want to check on it, that they would be able to get the most up to date information necessary for that prescription—for them to write the prescription.

No. 3, there have to be either company, corporate or organizational policies that not only encourage, but require prescribers and dispensers to use them. There are some companies that are just saying it is too timely. It is not efficient. We can't afford to do this at this point in time.

I think that if this is a national issue, your attention to ensuring that all States are participating in this and that funding for these prescription monitoring programs that you have provided in the past may be able to be expanded to ensure that all those who would use them feel comfortable that they are getting the right information at the right time, that they are helping from a safety standpoint with some patients, and they are helping to deter other patients from receiving the medications they shouldn't get.

Senator CORKER. How much effort is there for companies to actually use these, and how does that bump up against all the HIPAA regulations regarding privacy and that kind of thing?

Mr. BEHRINGER. I believe the HIPAA regulations have been taken care of. It is basically an additional step that someone would take, just as if you were to have an electronic medical record, and you would go into that person's record. This is a much broader record, and it takes some time to access it through the computer. It takes some time for the response in the computer. Things need to be made in a more timely fashion in order to be efficient.

But I think the intention should be that we as patients and we as the public need some degree of protection. As long as—we can check anything on the Internet nowadays. As long as it is made efficient and as long as there is an intention that that should be used and the expectation is that it should be used, then all those compa-

nies that are involved or those prescribers should pick this up as part of their policy.

Senator CORKER. Mr. Chairman, thank you.

If you don't mind, I might let the gentleman go ahead.

Mr. RANNAZZISI. There are two funding mechanisms for prescription drug monitoring programs. One is the Harold Rogers grant program out of the Appropriations Committee. The other one is the NASPA program. Both fund, continue to fund prescription drug monitoring programs throughout the country. As Mr. Behringer said, it is getting the doctors to use it.

Now every State has a program tailored to their specific needs. There is not a uniform method of creating these programs. Every State does something different, and I believe the States try and tailor their programs to what is happening within their State. Some States don't have all controlled substances, but most of the States, the requirement is for the pharmacies, once the prescription has been dispensed, to send that prescription information into the State whatever regulatory agency or law enforcement agency is controlling it. So they could submit it into the overall database.

It works very well when utilized. But as Mr. Behringer said, it must be utilized in order for us to reap the benefits of it. Thus far, I don't believe it is widely utilized.

Senator CORKER. I guess if you are in a State like Tennessee with eight bordering States and each State having its own protocol, that is semi-problematic, right?

Mr. RANNAZZISI. Yes, sir. But Tennessee, Ohio, Kentucky, and Indiana have very aggressive programs, and the regulatory boards and law enforcement agencies work very closely in those States to ensure that information obtained by the doctors—from the doctors and from the pharmacies, when necessary, is acted upon.

Senator CORKER. I thank all of you for your testimony and for being here and, Mr. Chairman, for having this hearing. Thank you.

The CHAIRMAN. Thank you, Senator Corker.

Senator CASEY.

Senator CASEY. Mr. Chairman, thank you.

I want to thank you, first of all, for your leadership on this issue and for convening this hearing because every day of the week, both Chairman Kohl and Senator Corker and I know that we can have hearings on lots of subjects, and they are all important in one way or another, but often they tend to be broader and more general. They give us information, but they don't necessarily lead to a strategy to create and develop legislation.

Today is an exception to that. Chairman Kohl has called a hearing where we have a very specific and urgent problem, and we are getting very specific and detailed advice not based upon theory, but based upon trial and error and practice and, unfortunately, springing in many cases from tragedy.

That leads me to, first of all, apologize for being late. I was going to give a more formal introduction of Bernie Strain, who is an old friend of mine. But it probably worked out better because he speaks very well for himself, as he always has. I am grateful, Bernie, you are here, grateful for your witness.

We know that in Washington, we often have, as we do today, all of our witnesses bring experience and learning and passion to these

issues. It is especially significant when someone brings their own personal story, as Bernie Strain did today. So we are grateful that he is here. We are grateful that he shared this story, Timothy's story.

But he is worthy of special commendation that he is willing to put his own story on the record and from his own tragedy to give us information and I think inspiration to solve this problem.

I wanted to start with Bernie, and I want to get to everyone, each of our five witnesses. But I wanted to ask Bernie Strain about, as you have learned about this problem in the aftermath of Timmy's death—and you and I have spoken about this somewhat, but not at length—about the strategies or the programs that you have seen in practice or that you have read about or learned about that you think work particularly well. I know we have examples here, and I want to hear from other witnesses.

But what is your sense of how this would work best, especially on a national scale?

Mr. STRAIN. Senator, thank you for the kind words. Once again, I would like to thank my wife, Beverly, for joining me as well.

Senator, this problem, as well as a lot of the problems in the United States, will not be solved with one program. This problem will be solved with a mix of Senator Collins's program in Maine, Senator Corker's program in Maine, and many of the other programs that were spoken about here today. But in this case and in my case, engaging the youth in a program, and that is why I often say the P2D2 program.

It is rare we bring our youth into the decisionmaking process. Until the youth take ownership of this problem and/or problems, being on the environmental side, as well as the drug problem side, the law enforcement side, until our youth take ownership in this program and when our youth take ownership in this program, they will help mold that program that will work.

When I mention the P2D2 program, and you can check it on their Web site, but it is a program where the youth is involved in the creation of this program, as well as the implementation of this program. So when they take ownership in their studies and their environmental impact—and it is a twofold problem, where it is environmental as well as drugs. But until they take ownership and when they take ownership, Senator, I think the world and our country will be a better place.

So with the program that I often mention, like I said, there are other programs that are out there. It is a program that is a drug give-back program. But it is also in September, we, as in the school that Timmy attended, will bring the P2D2 program on an educational side of things into the school.

Timmy attended a Philadelphia school that was environmental friendly. The school is the Walter B. Saul school, and they call it the "farm school." Yes, Senator, there is a farm school in the city of Philadelphia, and they often win prizes in the State farm show, as you know.

But it is with bringing that program into those schools, where Saul can Skype the school in Illinois, and it is the continuing education process that will make this program and other programs

take effect and give them a responsibility to get involved in this program or a program.

Senator CASEY. I think that education part of this is vitally important because this is not a problem that you see on the front page every day, as you all know. So that part of it is going to be a challenge.

I guess one of the challenges that I am trying to wrestle with here is how best to do this if we can do something at the national level. Sometimes the Federal Government does too much. We try to have one program, one-size-fits-all, too prescriptive where States and even jurisdictions smaller than a State already have a strategy figured out, and they basically say don't get in our way. Just give us some help, and we have it pretty well taken care of.

I guess I wanted to get some guidance. I noticed in the testimony, Dr. Gressitt, that you gave on page 4, when you highlighted the goals for the Maine program, you said—and I will read them quickly—“devise, implement, and evaluate a mail-back plan.” That is obviously central to it. “Dispose of the medications in compliance with the law.” Then, third, “to test the educational campaign.” What I am wondering about from you, and I will start with you—and I know I am a little over time; I will be quick—as well as others, how do you see this playing out on the national level? Do you think it is best to have State programs in place as they see fit or with Federal help? Or do you think there needs to be a more national standard or, at a minimum, national goals?

Dr. GRESSITT. Thank you, Mr. Casey.

I believe that if the DEA can set some national standards and regulations and rules which help stop the diversion, stop the resale, and maintain a safe system, both States and commercial entities or DEA or ONDCP can lead forward. I don't believe there—as Mr. Strain has said, I don't believe there is going to be one size that fits all. But at this point, we need at least some authorization and ability across the country in order to move forward, at all.

If the mail-back program—the mail-back program that we did was originally designed to be replicable, and we have held that. So that replication, done with due regard to DEA concerns, I think can stand on its own. But that is not the only way.

Community take-backs and some drop boxes are certainly available. I know Mary Hendrickson may have some thoughts on that as well.

Senator CASEY. I won't ask another question. Maybe one more, and then I want to make sure Chairman Kohl has his time for questions. Anybody else on this issue before we move on?

Dr. HENDRICKSON. I would also like to add obviously or add upon what Dr. Gressitt said. So federally, obviously, the changes with the Controlled Substances Act, but also the one other item would be at a State level, as federally funded RCRA, Resource Conservation Recovery Act, household waste would be exempt. However, there are State agencies that regulate this potentially a little bit more strict.

So I think it would need to be a combination. Our biggest—or the biggest issue for us is obviously the Controlled Substances Act also federally.

Dr. GRESSITT. If I could add a footnote to mine?

Senator CASEY. Sure.

Dr. GRESSITT. What Mary just said brought strikingly back, the cost of disposal can be very different in different states because of state variability in control. If the Federal Government could help with ensuring that those costs don't skyrocket, that would be another element that would be helpful.

Senator CASEY. Thank you very much.

The CHAIRMAN. Thank you.

Dr. Gressitt, Maine's medication program, as you know so well, has instituted a policy limiting initial prescriptions of certain drugs to 15 days as a way to combat waste. How is this program working?

Dr. GRESSITT. Three classes of drugs were selected by MaineCare—opiates, second-generation antipsychotics, and second-generation antidepressants. The information was announced to the providers in the State, and although there was some trepidation, the feedback I got—at that time I was the medical director for the State for the office of Adult Mental Health. The feedback I got from the other physicians in the State was, you know what, this is just good common sense.

Then one of the members of the Maine Psych Association came up to me and said, "you know, it is such a good idea. This isn't just going to be for MaineCare. It is every insurer." So regardless of who the insurer was, she made a personal decision that she would adhere to a shorter first prescription as a general good clinical practice.

I would say that is where the success is. I would say that having a check at 15 days to look at adherence and side effects is important, unless—aware I am a doctor, I am not an accountant—what the actual dollars are as far as savings.

The CHAIRMAN. All right. Dr. Hendrickson, what is the environmental impact of drug incineration?

Dr. HENDRICKSON. It would depend on whether it is hazardous or nonhazardous product. Ultimately, both products end up to be incinerated. There is out of all methods of destruction, incineration would be the most environmentally friendly.

I could not speak to the specifics of the outcome of the steam-generated. Ultimately, the environmental impact, though, of our product that is nonhazardous that is incinerated is actually generation of electricity and a reduction in the need for the use of coal or other energy sources in that instance.

The CHAIRMAN. Mm-hmm. Mr. Strain, is there some advice or counsel you would offer parents around the country with respect to attempting to prevent the tragedy that occurred in your family?

Mr. STRAIN. Senator, if you have about 4 hours today and this committee has 4 hours, I would love to go over steps from raising a child. Like I said, I have a son in the United States Air Force. I have had a son who put himself through Penn State University. There is no book on raising a child. I don't claim to have ever read that book or I might not ever claim to write that book.

But accidents happen. If we could just—there is no—if I could put it into 5 minutes, it is an event that happened. He was misadvised on what he was given. He was of age. He was 18 years

of age when it did happen. But he was just misadvised, as well as a lot of these young people are.

They all think he was a weightlifter. He had a football scholarship. He was the kid next door. These things happen. Like I said in my testimony that I am trying to make lemons from lemonade, and it is just a terrible tragic thing that happened. We will never forget it.

But I will scream to the highest mountain or I will scream across the deepest sea that every teenager and/or person or senior citizen, if you put something the size of a dime in your mouth, it could possibly kill you.

The CHAIRMAN. All right.

Bob, do you have anything more?

Senator CASEY. Maybe just one. I wanted to get a sense from those who have a more complete understanding than I do about what are the barriers to making this an effective national policy? I mean, obviously, we have got rules on disposal, and we know how difficult some of those are to navigate and to surmount or overcome.

But give me a sense of what the biggest and most difficult barriers are right now.

Mr. RANNAZZISI. Yes, sir. If I may start?

Senator CASEY. Sure.

Mr. RANNAZZISI. The Drug Enforcement Administration's hands are tied right now because we cannot promulgate a regulation because the statute is prohibiting us from doing so. 1359 and the companion bill, 1292 and 3397 in the Senate, will give us the regulatory flexibility to create a baseline infrastructure so the States could then fill in, and the municipalities and the counties, how they want to set up their program.

But we need that statutory authority in order to do that. That will give us the authority to write regs based on ultimate users transferring drugs and long-term care facilities transferring drugs. It will give us the opportunity to create that baseline infrastructure. But without that, our hands are tied.

Senator CASEY. Anybody else on that specific question?

Dr. GRESSITT. Very much so. I would like to simply say I agree with everything he said. We have bumped into every word he said several times.

Senator CASEY. When you were——

Dr. GRESSITT. Many times. It would certainly be helpful across the country if what he has asked for is, indeed, implemented sooner than later because regs take time. That time is a delay, and in that delay will be more deaths.

Senator CASEY. Yes, Bernie?

Mr. STRAIN. Senator, if I might ask, through that resolution that was passed in the Philadelphia City Council last week if when they have the hearings, if you could come to testify at that hearing, we would love to have your expertise and your testimony with that hearing. But we also would like to put together a program model after various programs—Senator Collins's program, mail-back programs.

If we could use that program that we are putting together in the city of the first class and the city of Philadelphia, you are aware

that the District Attorney in Montgomery County in Pennsylvania, Risa Ferman, put together a drug give-back program. So if we can use putting together that model in the city of Philadelphia, maybe we can carry it across the State of Pennsylvania.

Senator CASEY. Well, thank you. I hope I can be there. I will check with the schedulers. We always love being in your great hometown.

Mr. STRAIN. If you can have your people call our people, we would appreciate it.

Senator CASEY. Thank you. Thanks, Bernie.

Mr. STRAIN. Thank you.

Senator CASEY. Thank you very much, Chairman Kohl.

The CHAIRMAN. Thanks, Senator Casey.

We thank you all for being here today. It has been a very good hearing, informative and important with respect to this issue that we are dealing with.

Thank you.

[Whereupon, at 3:30 p.m., the hearing was adjourned.]

APPENDIX



STATEMENT
of the

AMERICAN HEALTH CARE ASSOCIATION
&
NATIONAL CENTER FOR ASSISTED LIVING

*Before The U.S. Senate Special Committee on Aging
Hearing On
"Drug Waste and Disposal:
When Prescriptions Become Poison"*

June 30, 2010

The American Health Care Association and the National Center for Assisted Living (AHCA/NCAL) appreciates Chairman Kohl, Ranking Member Corker, and the Members of the U.S. Senate Special Committee on Aging for today's hearing on the disposal of unused prescription medications. While AHCA/NCAL and our nearly 11,000 member facilities focus primarily on the delivery of high quality care, we recognize that safe handling of prescription medications and appropriate disposal of unused medications is a significant responsibility - one that may impact our communities.

Even though nursing homes and other long term care facilities generate much less volume in terms of drug waste than hospitals or individuals living at home, we remain concerned about drug waste and disposal issues. Ensuring that prescription drugs are appropriately disposed of affects not only our patients' and residents' immediate environment, but the environment we all share. The long term care community remains concerned about drug waste and disposal methods and is eager to work with the Environmental Protection Agency (EPA), the Office of National Drug Control Policy (ONCDP) and the Drug Enforcement Administration (DEA) to address this important issue.

American Health Care Association ♦ National Center for Assisted Living
1201 L Street NW, Washington DC, 20005

Long Term Care Providers Commitment to Safe Handling & Disposal of Prescription Drugs

Safe handling of prescription drugs is critical to ensuring that patients' medications are not tampered with or diverted for other uses. Ensuring that these drugs are disposed of in an environmentally-safe manner is also a concern for long term care providers.

Within the specific context of the long term care (LTC) profession, AHCA/NCAL's overreaching goal is to help identify, evaluate, and disseminate ways to dispose of unused medications in order to protect the environment and human health, while being cost effective and appropriate to the way LTC facilities operate within the confines of both state and federal regulations and statutes. Providers are looking for more guidance on best practices for the disposal and/or reuse of unused medications.

Providers are concerned about polluting waste water and ground water resulting from seepage of pharmaceutical wastes from dumping sites. However, this issue also needs to be understood within the context of our nation's overall health care system – of which long term care is just one small part – especially since the majority of pharmaceuticals are taken by people in their own homes or workplaces within local communities, and not institutional settings. In looking at the amount of drugs in ground water and waste water systems, it is also necessary that EPA and other responsible entities consider that while most drugs are metabolized first prior to being excreted, some drugs are excreted by the kidneys without being metabolized first.

The lack of unified national and state direction in implementing drug take-back and reuse programs, national and state inconsistencies in interpreting recommended practices, as well as failure to eliminate/resolve barriers to short-term methods allowing safe disposal are all concerns of long term care providers.

Long Term Care Providers Support a National, Consistent Approach to Pharmaceutical Waste Disposal

The inconsistent web of federal and state rules and restrictions governing the disposal of unused pharmaceuticals, including controlled substances, is both complex and confusing. Currently, controlled substances are destroyed in the facility by a licensed professional and according to state pharmacy regulations. Many LTC facilities are able to return non-controlled drugs to the pharmacy for disposal, some states allow for incineration of unused and unwanted medications, other states require medications to be destroyed in the facility and flushed into the sewer; however, certain states do not allow for sewer disposal – leaving LTC facilities with no disposal options for controlled substances. Currently, common practice for most facilities is to flush controlled substances according to state guidelines when the pharmacist visits the facility and when the Director of Nurses or a nursing designee is present.

AHCA/NCAL supports a national approach for dealing with drug waste and disposal that works with state regulators and other relevant agencies, and that would allow providers to send unused

drugs to an “authorized collecting entity” that would safely dispose of the drugs. Also, long term care providers recommend that all unwanted or outdated pharmaceuticals (controlled substances and other medications) be addressed and handled in a single system to minimize program costs, confusion resulting from having to contend with multiple and sometimes conflicting regulations, and the burden associated with managing duplicative efforts.

A national strategy to address waste and disposal of controlled substances and other pharmaceuticals should be developed and implemented to eliminate any ambiguity concerning the destruction process for these drugs by all end users. Such national recommendations should supersede state and other related regulations holding health care providers harmless as long as nationally-approved guidance is followed.

More specifically, AHCA/NCAL recommends that the Drug Enforcement Administration (DEA) work cooperatively with the Environmental Protection Agency (EPA), other federal agencies and stakeholders on a three-pronged initiative. This initiative would define a national vision for the management of unused and outdated pharmaceuticals by all consumers or end users; evaluate existing state “take back” and drug destruction pilots and reverse-distribution programs to determine where such programs align with the national vision; and develop strategies, steps, and a time line for expanding existing efforts into a fully functional national program.

We also strongly encourage Congress to direct the DEA to work closely with providers on the unique issues around controlled drugs. We believe that, by convening an advisory panel comprised of long term, post-acute and other health care professionals, DEA could identify regulatory, operational and other barriers to compliance with national recommendations and adoption and use of current drug take back, reverse distribution and disposal programs.

We also ask that the concerns we raised with respect to DEA activities in our testimony before this Committee on March 24, at the listening session entitled *The War on Drugs vs. The War on Pain: Nursing Home Patients Caught in the Crossfire*, be reviewed as part of this process and that Congress look to update the *Controlled Substances Act*.

Long Term Care Providers Recognize and Appreciate Recent Congressional Efforts to Improve Disposal Methods

AHCA/NCAL recognizes and appreciates recent Congressional efforts and the several bills have been introduced in the 111th Congress that would amend the *Controlled Substances Act* and change current law and make it easier for patients to dispose of unused controlled substances by participating in drug take-back programs or delivering them to entities authorized by law to dispose of them. AHCA/NCAL particularly notes Congressional findings in Senator Amy Klobuchar’s recently introduced *Secure and Responsible Drug Disposal Act of 2010* (S. 3397) observing that “[l]ongterm care facilities face a distinct set of obstacles to the safe disposal of controlled substances due to the increased volume of controlled substances they handle.”

Americans are living longer and our nation's aging population is growing – many of whom have significant medical or cognitive conditions which require care in and outside a nursing facility. Currently more than three million Americans rely on the care and services delivered in one of the nation's nearly 16,000 nursing facilities each year, one million are cared for in more than 38,000 assisted living residences, and the demand for such services is going to increase dramatically every year. Accordingly the demand for controlled substances will increase with this aging population. Therefore, it is imperative that solutions to the issues of disposal of pharmaceuticals, diversion of controlled substances and timely access to of long term care residents to much-need pain medications be addressed expediently.

Thank you for the opportunity to offer this statement on behalf of millions of professional, compassionate long term caregivers and the millions of frail, elderly, and disabled Americans they serve each day.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT OF
THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SENATE SPECIAL COMMITTEE ON AGING

HEARING ON

"DRUG WASTE AND DISPOSAL: WHEN PRESCRIPTIONS BECOME POISON"

JUNE 30, 2010

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Chairman Kohl, Ranking Member Corker, and Members of the Committee, thank you for accepting this statement for the record from the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA recognizes that disposing of medications properly is important to minimize both the risk of harm from accidental exposure and the environmental impact of these products.

Today, tens of millions of people in the United States depend on prescription and over-the-counter (OTC) medications to sustain their health—as many as 3 billion prescriptions are written annually. But these medications, which play such an important role in treating disease, can also cause injuries. Harm from unintentional exposure to medications is not a rare problem and harm from unused portions of medications is part of this larger problem. In 2007, there were 23,783 cases of accidental exposure to another person’s medication reported to Poison Control Centers, though the percentage that caused harm is unknown.¹ In principle, harm from accidental exposure is entirely preventable. Unintentional exposures most commonly result from failure to keep medications out of the reach of children. Each year, many thousands of children are accidentally exposed to prescription or OTC drugs, and some die as a result.² Toddler-age children are often able to open and drink liquid medications. Approximately 4,600 emergency department visits yearly result from unsupervised pediatric ingestion of OTC cough and cold

¹ Bronstein Bronstein, AC et al. *2007 Annual Report of the American Association of Poison Control Centers’ National Poison Data System (NPDS): 25th Annual Report*, Alexandria, VA., p.938.

² Centers for Disease Control and Prevention, 2007 Unintentional Poisoning Deaths, United States, 1999-2004. February 9, 2007. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5605a1.htm>

remedies; other risks involve mix-ups among various medications used by family members.³

Based on related studies, an estimated 71,224 emergency department visits for medication overdoses are made annually by children aged 18 and under; approximately 68 percent of overall emergency department visits are for unintentional pediatric poisonings.⁴

FDA SAFE USE INITIATIVE

To prevent individuals from unnecessarily coming into contact with medications that could cause an injury, FDA launched the Safe Use Initiative in November 2009. The Safe Use Initiative aims to reduce many types of preventable injuries (e.g. mix-up at the pharmacy) in addition to unintentional exposure.

FDA believes that too many people suffer unnecessary injuries, even death, as a result of preventable medication errors or misuse. Through the Safe Use Initiative, FDA seeks to join in partnership and collaboration with other stakeholders to reduce preventable harm from medications and improve patient health.

Although FDA and many other stakeholders have been working to improve how the health care system manages medication risks in the United States, we recognize that more needs to be done to protect the public from preventable harm from medication use. All participants in the health care community at large—patients, consumers, caretakers, health care practitioners, pharmacists,

³ Schaefer, MK, Shehab, N, Cohen, AL, and Budnitz, DS, Adverse Events From Cough and Cold Medications in Children, *Pediatrics*, Official Journal of the American Academy of Pediatrics, April 2008, p. 785.

health care systems, health insurers, drug manufacturers, FDA, and other federal agencies—have a role to play in managing medication risks and reducing preventable harm from medication. We believe that much preventable harm from medications results from problems that can be addressed best in a more coordinated, systematic manner, with interventions across all sectors of the medication distribution and use system.

PROPER DISPOSAL OF UNUSED MEDICATIONS BY PATIENTS

One way to reduce the risk of harm is to properly dispose of unused portions of medications. FDA, along with other federal agencies, collaborated with the Office of National Drug Control Policy to develop federal guidelines for proper disposal of prescription drugs by patients which ONDCP updated in October 2009. These guidelines call for almost all medications to be thrown away in the household trash after mixing them with some unpalatable substance (e.g., coffee grounds) and sealing them in a container.

However, certain medications may be especially harmful and, in some cases, fatal in a single dose if they are used by someone other than the person for whom the medicine was prescribed. For this reason, a few medications have special disposal directions that indicate they should be flushed down the sink or toilet after the medicine is no longer needed. Disposing of these medications down the sink or toilet ensures immediate removal from the home so that they cannot be accidentally used by children, pets, or anyone else.

⁴ Schillie, SF, Shehab, N, Thomas, KE, and Budnitz, DS, Medication Overdoses Leading to Emergency Department Visits Among Children, *American Journal of Preventive Medicine*, 2009;37(3), Elsevier Inc., p. 181.

FDA's website provides information for consumers on proper disposal of unused medications:

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm#Overview>. FDA lists the unused and expired medications that should be flushed to avoid harm. It is important to note that FDA does not recommend flushing for the vast majority of medications. Most of these products can be disposed of in the daily trash after mixing with an unpalatable substance like coffee grounds.

FDA supports other disposal options, so long as they are compliant with state and federal law and regulations, such as medicine take-back programs for disposal, if they are available. We recognize that some programs have successfully collected unused medications for proper disposal; however, many of these programs vary in how they operate and what types of medications they can collect.⁵ Many do not provide patients with an easy, immediate option for disposal because they are not commonly available in communities in the United States on a consistent basis. Other programs may have limitations due to current laws and regulations. Until effective disposal alternatives are developed (i.e., widely available take-back programs or devices that render a drug product immediately unavailable), our recommendations for disposal of most medications is in the household trash, and for a few select medications, we recommend flushing instructions to ensure the immediate disposal.

⁵ Community Medical Foundation for Patient Safety, *National Directory of Drug Take-Back and Disposal Programs* (2008)

PHARMACEUTICALS IN THE WATER SUPPLY

FDA is aware of recent reports that have noted trace amounts of pharmaceuticals in the water system. We recognize that there is a need to better understand whether these trace amounts of pharmaceuticals in the environment have a harmful effect on human health. For this reason, we have been involved in an inter-federal government workgroup to look at research areas and needs for improving how we analyze possible risks from pharmaceuticals in the environment. Research on this topic has been initiated by other agencies such as the U.S. Environmental Protection Agency (EPA)⁶ and the U.S. Geological Survey (USGS).⁷

At the present time, FDA believes that flushing the small number of medications on the select list is necessary to mitigate the real possibility of life-threatening risks of ingestion of these medications. Studies have shown that the vast majority of drug residues in waters is not due to the disposal of unused products but is instead a consequence of patient drug use; these drugs enter the environment through normal excretion and elimination.⁸ However, we would be supportive of an easy, immediate option for disposal in place of flushing if one were developed.

CONCLUSION

Again, FDA and many other stakeholders have been working to improve how the healthcare system manages medication risks in the United States. It is particularly important that we encourage disposal methods for medications that reduce the risk of unintentional exposure and

⁶ EPA Pharmaceuticals and Personal Care Product Research Areas: <http://www.epa.gov/ppcp/work2.html>

⁷ USGS Toxic Substances Hydrology Program – Research Projects – Emerging Contaminants in the Environment: <http://toxics.usgs.gov/regional/emc/>

minimize the environmental impact. Thank you very much for the opportunity to provide written testimony.

⁸ New Hampshire Department of Environmental Services, *How to Address Unused Medicine Disposal in New Hampshire*, (April 2008)



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association of Chain Drug
Stores
For
U.S. Senate Special Committee on Aging
Hearing on
Drug Waste and Disposal
June 30, 2010
2:00 p.m.
Dirksen Senate Office Building
Room 106

National Association of Chain Drug Stores (NACDS)
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www.nacds.org

NACDS thanks the Committee for the opportunity to submit a statement for today's hearing on Drug Waste and Disposal. The National Association of Chain Drug Stores (NACDS) represents 154 traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chain pharmacy companies operate 37,000 pharmacies, and employ more than 2.5 million employees, including 118,000 full-time pharmacists. They fill more than 2.5 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States.

NACDS has been pleased to work with members of Congress and federal agencies such as the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and the Drug Enforcement Agency (DEA) to address issues related to patients' medication therapy and disposal of patients' unused medications. We have appreciated the opportunity to discuss the valuable role of the pharmacist in medication therapy management, medication adherence, and drug safety. In addition, many of our member companies have voluntarily participated in drug take-back programs offered by various state and local government entities that are provided in accord with applicable federal and state environmental quality departments and that operate under DEA approval.

PATIENT ADHERENCE AND COMMUNITY PHARMACY'S ROLE IN IMPROVING PATIENT CARE AND REDUCING HEALTHCARE COSTS

An estimated one-third to one-half of all patients in the United States do not take their medication as prescribed. There are many reasons. Many simply fail to pick up their medications from their pharmacy. Others fail to take their medication correctly, stop taking it altogether or never take it to begin with. These circumstances seriously undermine quality of life and quality of care, patient outcomes and the value of healthcare dollars spent. Poor medication adherence costs the U.S. approximately \$290

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billion annually¹ – 13% of total healthcare expenditures. Clearly, steps need to be taken to address the issue of lack of adherence with medication therapy.

Community pharmacists are uniquely qualified through their comprehensive education and training to significantly reduce the problem of poor medication adherence. As medication use experts, pharmacists assist patients in achieving positive outcomes from their medication therapy. Pharmacists help patients every day by counseling on proper use of medications, checking for possible side effects, drug interactions or allergies, and helping to coordinate insurance benefits. All these activities help ensure patients receive maximum therapeutic benefit from their medication therapy. When patients adhere to their medication therapy, it will reduce costs from higher-cost medical care, such as emergency room visits and catastrophic care.

MEDICATION THERAPY MANAGEMENT

Reducing pharmaceutical waste will require a multi-pronged effort. While it is critical to develop an effective method to return unused pharmaceuticals, it is also vital to ensure that patients are on the correct medication therapy, and adhere to their prescription drug regimen.

The best way to make sure Americans take medications appropriately is through the professional counseling services of a licensed pharmacist – otherwise known as “medication therapy management” (MTM). MTM includes a range of activities that help prevent medication errors, ensure medication compliance and get patients more actively involved in their medication therapy. Evidence shows that MTM improves outcomes while reducing unnecessary medical services. In one study, for every \$1 invested in MTM programs, overall healthcare costs were reduced by \$12. (Journal of the American Pharmacists Assoc, March-April 2008.)

¹ New England Healthcare Institute, Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease, August 2009, available at http://www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_chronic_disease (last accessed March 5, 2010)

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The just-enacted health reform law recognizes the importance of MTM. The law creates new grant programs to promote MTM in the treatment of chronic diseases and within the medical home concept. It also made modest but important improvements to the MTM benefit available to seniors in Medicare Part D. However, while these enhancements are welcome, more needs to be done to control the huge costs associated with medication non-adherence and to improve seniors' access to MTM services.

Legislation to improve the Medicare Part D MTM benefit has been introduced by Senator Kay Hagan. NACDS and a number of other pharmacy and healthcare groups support the legislation, and we urge members of this committee to cosponsor and work for the bill's eventual passage. Specifically, the legislation does the following:

- Ensures that more seniors in Medicare Part D have access to MTM services. Under current restrictions, fewer than 13% have access to the MTM benefit. But of those eligible, 85% have enrolled in MTM, providing a clear indication that the benefit is highly valued. The legislation revises the eligibility criteria for MTM to include any senior that suffers from any chronic disease that accounts for high spending in the Medicare program (as determined by CMS), as well as first time dual-eligible beneficiaries and individuals in transition of care. These individuals typically take multiple medications and could clearly benefit from MTM services.
- Improves seniors' choices of where to receive MTM by ensuring they can visit any pharmacy in their health plan's network that agrees to participate. This will expand access to MTM services, providing seniors with the convenience of their local pharmacy.
- Establishes reimbursement standards for providers furnishing MTM, ensuring they are paid based on their time and resources. A reasonable cost based reimbursement system is needed to ensure an adequate number of pharmacies will participate.

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This legislation is one important way to address the growing problem of medication non-adherence. Through the use of MTM, local pharmacists play a critical role in helping patients take their medications as prescribed – which will go a long way toward helping reduce pharmaceutical waste.

INITIAL PRESCRIPTIONS FOR PRESCRIPTION MEDICATIONS

Some have suggested placing limits on a prescriber's initial prescription for some medications, certain patients or under certain circumstances as a potential option to decrease the amount of unused medications that require disposal.

While we understand the interest in exploring such an option, we believe that on balance providing patients with a limited supply of their medication runs the risk of worsening the problem of patient non-adherence to their prescribed medication therapy, which as mentioned above creates a \$290 billion drain on our economy annually and is one of the leading drivers of growing healthcare costs. For example, patients may stop taking their medications when they run out of the limited initial fill. In this circumstance, the patient may not return to the pharmacy for any number of reasons, including being busy or confused about whether they need to continue the medication.

Patients often take a number of medications and are accustomed to receiving a 30-day supply or up to a 90-day supply of their chronic medications. Usually only short-term medications such as courses of antibiotics are provided in smaller quantities. Accordingly, patients may easily become confused and not understand the need to refill a medication that was provided in a limited quantity. Also, limiting initial prescribing is likely not appropriate for certain classes of drugs where dose titration is required to adjust the patient to the optimal dose. In addition, studies have recognized that many individuals in the United States have health literacy problems. A significant percentage of patients function at the 6th grade level or lower relative understanding their healthcare and treatment. This further exemplifies the misunderstanding that patients may easily develop if they are given a limited quantity of a medication that is meant for their

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ongoing use. On balance, the potential for confusion and misunderstanding outweigh any perceived potential benefit of providing patients with limited amounts of their medications as a potential option to address disposal of unused drugs.

In addition to our concerns about the potential impact on patient adherence, NACDS has significant concerns about the how this policy would impact pharmacy reimbursement. There are multiple components to pharmacy reimbursement – payment for product, the cost to dispense as well as payment for professional services such as medication therapy management (MTM). Together, these account for total pharmacy reimbursement. It is important to note that pharmacies face the same cost of dispensing whether the patient obtains a 15 day supply or a 30 day supply. Partial fill would require the pharmacy to dispense the same prescription twice, with the same effort and workload each time. Therefore, it is imperative that pharmacies be paid the negotiated dispensing fees for the trial fill and any subsequent fills. Adequate consideration for each of the reimbursement components is critical to ensure that the total reimbursement remains fair and sufficient for the pharmacy.

Therefore, NACDS does not support the use of limited fills as a means to reduce pharmaceutical waste.

CHAIN PHARMACY'S PRINCIPLES FOR RETURN AND DISPOSAL OF CONSUMERS' UNUSED PHARMACEUTICALS

The chain pharmacy industry supports the goal of finding a safe and effective means for disposal of consumers' unused pharmaceuticals. We appreciate that there is increased attention to addressing this issue and that varying options have been proposed including recommendations for consumers to mix their unused drugs with undesirable substances such as coffee grounds in containers for disposal into household trash, prepaid mail-back envelopes for consumers to use, and other programs for collection and disposal through hazardous waste management programs.

At its heart, a safe and effective means for disposal of consumers' unused drugs must protect public health and safety and preserve the security and integrity of the drug

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distribution system. To achieve these goals, chain pharmacy believes it is essential to adhere to the following key principles.

- ❖ Protect patient health and safety and the integrity of the drug distribution system by maintaining a physical separation between pharmacies where drugs are dispensed and the location for return of consumers' unused drugs. Consumers should not return unused pharmaceuticals to pharmacies.
- ❖ Use a safe and effective system that provides consumers with a safe, feasible, and readily understandable means to return their unused drugs such as prepaid mail back envelopes.
- ❖ Ensure necessary funding through a sustainable resource.

Protect Patient Health and Safety and Integrity of the Drug Distribution System

To protect patient health and safety and preserve the integrity of the drug distribution system, consumers' unused drugs must be returned to locations that are *separate and apart from pharmacies where drugs are dispensed and consumers purchase other healthcare products and consumer items* such as food products. Having consumers return medications that have left the secure drug distribution system back to pharmacies is ill-advised due to the importance of maintaining the security and integrity of the drug distribution system. A pharmacy taking back dispensed prescription drugs creates potentially hazardous public health circumstances since the drugs have left the secure drug distribution system and could be contaminated or adulterated. Pharmacists would have no knowledge about where the drugs had been stored or under what conditions. The drugs could be contaminated with infectious diseases or other hazardous substances posing potential risks to the public through inadvertent exposure to such contaminants or potentially contaminating other products in the retail establishment.

Although pharmacies have taken back consumer medications in limited pilot programs or one-time collection events, these programs still require the separation of locations that take back consumers' medications and pharmacies where drugs are dispensed. Placing containers in pharmacies for consumers to return unused drugs is not a solution for

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providing consumers with a safe and effective means for disposal of their unused drugs. Pharmacies are not designed to accept returned drugs. They lack the space to take back consumers' returned drugs and the potential for inadvertent comingling exists. In addition, many states have laws and regulations that prevent pharmacies from taking back drugs recognizing the importance of maintaining the integrity of the drug distribution system through separation of products ready for dispensing or sale and drugs that have left the pharmacy.

In addition, the federal controlled substances laws and regulations prohibit pharmacies from taking back controlled substances from consumers and consumers are only permitted to return their controlled substance medications to law enforcement officials, and only if permitted by the state. Controlled substances account for as much as 15% or more of all prescriptions, so these barriers are significant reason that pharmacy take-back programs will not work.

Provide a safe and effective means for consumers' disposal of their unused drugs.

A program for consumers' return of their unused pharmaceuticals must be easy to use, readily understandable, and maintain the integrity, safety, and security of the drug distribution system.

For example, prepaid mail-back envelopes provide such an option. The concept of mailing is universally understood by consumers. It would be readily understandable through public service announcements, consumer education, and foster public acceptance and involvement. It would also maintain the separation between pharmacies that dispense drugs and the facilities that accept unused drugs for disposal. Another possible option is return to state waste management programs in conjunction with law enforcement. However, as noted above, because federal controlled substances laws and regulations permit consumers to return their controlled substance medications only in limited circumstances, the Drug Enforcement Administration would either need to approve a waiver or changes to federal controlled substances laws must be made.

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Ensure Necessary and Sustainable Funding

We believe that any drug return and disposal program needs to be funded through a sustainable funding source such as grants or other revenue sources. Providing sustainable funding provides public health and safety benefits by allowing consumers a safe and consistent means to return unused pharmaceuticals. When considering funding sources, lawmakers should bear in mind that retail pharmacy is a low profit margin business, retaining a net profit of less than 2% per prescription. As such, pharmacy is not in a position to fund take back programs, which are neither within its area of expertise nor core to its healthcare delivery business model.

CONCLUSION

NACDS thanks the Committee for conducting this important hearing. Retail community pharmacies have an important role to play in helping society address the issues surrounding drug waste and disposal. By providing medication therapy management and other professional services, pharmacies and pharmacists help educate their patients and the public about the proper utilization of medications and the appropriate handling and disposal of those powerful products. We welcome the opportunity to work with the Committee and Congress in the future on this important issue.

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