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(Safe Medicine Disposal for ME)

For:

"Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse,
Misuse, Diversion and Fraud

Committee on the Judiciary

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There is a perspective on the Prescription Drug Abuse epidemic that has not been widely noted. The final estimated number of deaths for the United States Revolution was 25,000; less than now dies annually from prescription drug overdose. A former US Attorney in Maine noted that the problem is such that we can neither arrest our way nor prosecute our way out of the situation. From a broader perspective, it is more adequately described as a situation where neither arresting, prosecuting, imprisoning, educational efforts, nor treatment resources will in and alone any one of them address the faintest edge of a problem that is now diffused throughout society. All are necessary as well as regulatory reform that is underway most notably at the US DEA in implementing S 3397.

Traditional efforts at each of the approaches listed above have not kept the problem from spreading in part as there is a tendency for each of the approaches to be isolated from each of the others. Efforts to address diversion in the distribution chain for instance can be extended through the entire lifecycle of pharmaceuticals through to destruction. Track and tracing is increasingly important through to the end user not just for diversion avoidance but for product recall. Identifying what is wasted can help with methods to reduce the waste in the first place and subsequently reduce the potential for diversion, misuse, or abuse.

From the outset of individual researchers working on attempting to address disposal of consumer unused

medication, there was little initial awareness between various Federal agencies on what other agencies were doing. As that has improved, the lack of funding for research, pilot projects, education, prevention measures, has not improved. Many programs addressing the unused drug return problem have no resources for education and vice versa. The conflict between 50 separate state regulations and Federal regulations has not improved as various jurisdictions either wait for someone else to move first or take action that may well conflict with other jurisdictional regulations that may even clash.

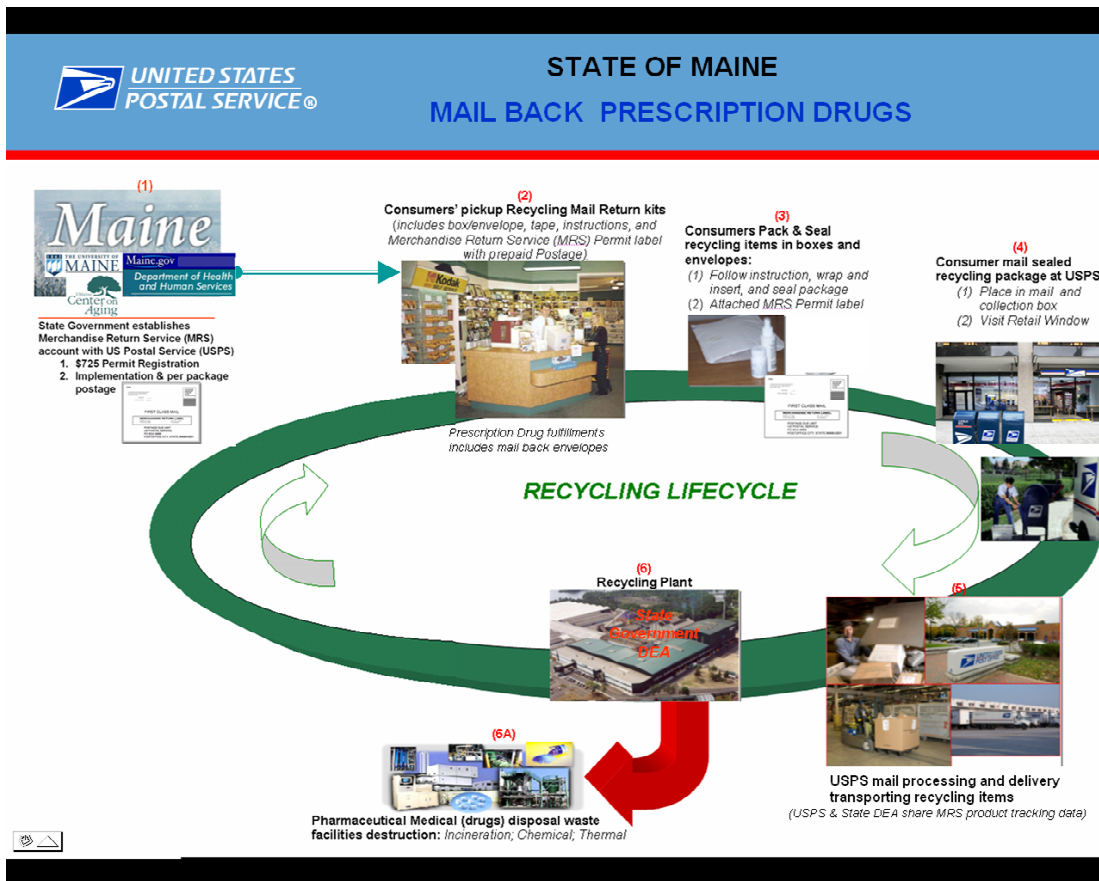
Most of the following will address the area we are most familiar with but the overall message must be that to address the current problem funds must be refocused and coordination must be the primary approach along with cooperation.

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 harm’s 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.

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 = $83\% \times 2,373 \text{ lbs of drugs} = 1,970 \text{ lbs of drugs}$ 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.

Policy Implications

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 jurisdictions, 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 funding legislation for the United States Drug Enforcement Administration to promulgate regulations and provide grants to ensure that diversion is minimized and that best practices are followed. The Executive Office of the White House Office of National Drug Control Policy has likewise the need for adequate

funding to be able to seed and foster innovative and proven helpful that do not fall in to the current general mainline. Likewise the budget must reflect the need for education, public as well as professional, and public awareness.

2. The other is to review 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. This has been proposed in several settings for the last two years.

5. Initiate the review of what pharmaceuticals are wasted and are being returned so that policy can be reviewed for better practices as occurred in Maine and as CMS is now considering. Adherence and compliance are issues that impact significantly the health of the entire country and efforts to improve will likewise reduce waste and potential for diversion.

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11. AMA Resolution # 515, 2010 (quoted on page 7 above)

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