Unused and Expired Medicines among U.S. Senior Patients and Consumers: Data Abstraction and Summary from the National Unused and Expired Medicines Registry

A Special Report to the Centers of Medicare and Medicaid Services (CMS)

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Executive Summary

Background and Rationale

Unused and expired medicines (UEMs) are a national and international problem of the complex healthcare system. Experts are referring to the stockpiling of UEMs at home and workplace as an epidemic that promotes medication error, accidental poisoning, drug misuse and abuse, and drug diversion. Improper disposal of UEMs can lead to contamination of the water supply.

A new organizational concept called Community of Competence™ (CC™) developed and trademarked by Elizabeth A. Smith, PhD offers a framework and method to study UEM issues and the inherent dangers of excess medicines. CC™ has been used by researchers to gather data about UEMs and to search for solutions. Specifically, the Community of Competence™ for Unused and Expired Medicines was developed by various stakeholders and interested parties to study the problem on the national level.

Federal response to the UEM problem has been limited or absent. Guidelines to properly dispose of household UEMs are often contradictory, ambiguous and confusing. Definition and classification of UEMs vary according to an annual survey.

Status and Progress of Drug Take-Back Programs in the U.S.

One community-based initiative to deal with UEMs is the drug take-back program, which may range from a one-time event or pilot study to an ongoing program to collect and dispose of UEMs. Information about drug take-back programs comes from an annual survey conducted by the nonprofit research group Community Medical Foundation for Patient Safety (CMFPS), based in the Houston, Texas area. Results of the survey are published in the National Directory of Drug Take-Back and Disposal Programs and on a number of approved websites.

Awareness and knowledge of UEMs are shaped by the media. These news stories often are related to environmental pollution caused by pharmaceuticals in the water. Care must be taken in consideration with appropriate ways to disseminate information about the dangers of UEMs. Risk communication and public education methods may be employed to give accurate information without causing misinformation.

Various models of drug take-back programs have emerged across the country with measured success. These models include drop-off at retail pharmacies or police stations and a direct mail-back system. Variations among the programs exist when comparing purpose of the program, definition of UEMs, collection and disposal methods, and involvement with law enforcement. The State of Maine is leading the nation in passing legislations and implementing a well-studied drug return system that allows citizens to mail back their UEMs, including controlled substances.

The direct mail-back system in Maine is supported by the partnership among the State, University of Maine Center on Aging, U.S. Postal Service, and the Environmental Protection Agency’s Aging Initiative. The pilot study to test and evaluate the mail-back system called the Safe Medicine Disposal for ME first targeted seniors. The program was later expanded to provide services for the entire state.
The National Unused and Expired Medicines Registry

CMFPS first identified the important need for UEM data and set up the first national registry in 2005 to collect UEM data through a uniform method. The Registry, consisting of five data components or modules, serves as the primary data repository for drug take-back programs. Basic variables of each UEM required for systematic coding and entry into the Registry are: drug name, drug strength, quantity returned, reason for return, and zip code. From these five variables, characterization each UEM includes therapeutic classification based on the Drug Abuse Warning Network (DAWN), environmental risk and hazard classification based on the Swedish JANUSInfo, estimated cost based on average wholesale price (AWP), and demographic analysis based on zip code data of the U.S. Census.

The Registry contains data on approximately 35,000 items (UEMs representing returned prescription and OTC medicines that would otherwise be thrown in the trash or flushed down the sink or toilet). It also has data on more than an estimated 2.5 million pills, capsules, and tablets. Information from the Registry can be readily used by a number of agencies and organizations to study the impact of wasted medicines and healthcare dollars. Moreover, policies and strategies based directly on evidence can be developed to reform health care, in particular the pharmaceutical care portion of the overall healthcare system.

Seniors as a Vulnerable Population

Today, seniors are faced with many challenges in maintaining their health and wellness. This Special Report focuses on the growing population of American seniors and the impact of this population on the national healthcare cost, specifically in the area of prescription medicines. While seniors comprise about 12% of the U.S. population, they represent 34% of total expenditures for prescription medicines. The phenomenon of stockpiling UEMs at home is most apparent among senior patients and consumers. At the same time, they are the population that most likely would participate in drug take-back programs, given the convenience, support and encouragement.

As a vulnerable population to the risk of medication error, drug overdose, accidental poisoning, and other medication-related problems, seniors tend to keep UEMs at home for a variety of reasons. In addition to the problem of stockpiling medicines, non-adherence to medical treatment among seniors should be closely investigated to ensure that therapeutic benefits from medicines are not being compromised.

Unused and Expired Medicines among Senior Patients

Data for this study among seniors were abstracted from the Registry. The original source of the data is Dataset 17 of Phase I of the pilot study Safe Medicine Disposal for ME. The most frequent medicine that was returned is Lisinopril, an angiotensin converting enzyme (ACE) inhibitors. Four controlled substances, including one benzodiazepine and three narcotic pain relievers are listed in the top 10 most common UEMs among some 800 participating seniors.

By therapeutic category, the central nervous system (CNS) agents, such as analgesics and muscle relaxants, lead the proportion of returned items at 24%, followed by cardiovascular agents at 19%. Most of the UEMs were prescription medicines. A detailed analysis of CNS
agents shows two additional therapeutic subclasses to illustrate the amount of controlled substances in the sample.

The proportion of wasted medicines, by pill form and pill count only, is calculated by dividing the *quantity returned* by the *estimated standard packsize*. An estimated proportion of wasted medicines, prescription and over-the-counter (OTC), was 52%. Adjusted for only prescription medicines, the proportion was calculated at 43%. The estimated cost of waste was $83,180.14, based on AWP. With market price mark up, this cost may range between $108,134.18 and $133,088.22.

**Conclusions**

UEMs are a systemic symptom of a weakness in the complex healthcare system. Drug take-back programs only address the problem at the back end. A more effective solution is to examine the front-end practice of prescribing, dispensing and consuming medicines to patients, particularly seniors.

By the year 2050, 21% or 86.7 Americans will be 65 or older. Therefore, senior patients are important consumers of the healthcare system as their medical needs grow. Special attention and efforts must be considered in maintaining and ensuring proper health care for seniors. They often have co-morbidities or pre-existing health conditions that result in polypharmacy. Additionally, seniors have cumulative lifetime exposure to environmental toxicants which may exacerbate the aging process and decrease the quality of life.

Non-adherence remains a patient safety concern for elderly patients as long as they are required to manage the numerous prescription medicines by themselves or with some assistance. Reportedly, some seniors take as many as 15 or more medicines.

This Report describes the ideal drug take-back system that is based on evidence from the Registry and the annual survey. Some espoused attributes are: convenience for participants, user-friendly format and instructions, compliance to all state and federal regulations, involvement of law enforcement, standardized data collection system, and proper documentation and monitoring for safety and security. The mail-back system in Maine, the Safe Medicine Disposal for ME, is an exemplary model compared to others.

**Recommendations**

The authors offer six innovative ideas and recommendations to address UEMs and provide improved continuity of care for patients. They include the implementation of an integrated pharmaceutical system, the introduction of patient-centered medical home, the expanded concept of patient-centered health community based on CC™, the creation of a national drug take-back system, the establishment of a national center for safe drug disposal, and immediate changes in legislations governing the collection and disposal of UEMs.

UEMs are a modern problem that requires combined efforts and commitment from all communities working together and sharing responsibilities. From public safety and patient safety to environmental stewardship, everyone must be involved and must work toward the same solution.
Acknowledgements

The Community Medical Foundation for Patient Safety gratefully acknowledges the individual and collective contributions of the authors to address the issues and policy concerning unused and expired medicines (UEMs) in the U.S.

The Special Report would not be possible without the participation and contribution of the Center on Aging, University of Maine (UMaine). We appreciate the valuable insight and experience of Len Kaye, DSW, PhD, Director, UMaine Center on Aging and Professor, UMaine School of Social Work, and Jennifer Crittenden, MSW, Research Associate, UMaine Center on Aging, and program manager of the Safe Medicine Disposal for Maine (ME) program—the U.S. EPA Grant# CH-83336001-0 which resulted in the most successful and well documented statewide drug mail-back program in the country. Data for this Special Report were abstracted from the State of Maine’s elderly population. Interpretation and sense-making of the volume of data in this Report was provided through the health law and policy expertise of Don Griffin, MS, MBA, MS, JD, FACHE, Assistant Professor, School of Health Administration, Texas State University.

The authors extend our appreciation to the reviewers of this Special Report and for their advice and recommendations for editing and revision. We also acknowledge the technical assistance of Mr. Link Filion to abstract and analyze data from the National Unused and Expired Medicines necessary for this report and the final proofreading of the report by members of the Community Medical Foundation for Patient Safety, Ms. Peggy Hightower-Lee, MPH and Mr. Donald J. Lefeber, BA.

About The Health Sciences Institute
The Health Sciences Institute of the Community Medical Foundation for Patient Safety serves as the educational body to support the mission of the Foundation. The Institute aims to foster and promote interdisciplinary exchanges and knowledge building across all health science disciplines involved with health care and patient safety. The educational vision and principles of the Institute follow the framework and ideals of the Community of Competence™, the Community and Foundation for Life.

About Community Medical Foundation for Patient Safety
Community Medical Foundation for Patient Safety, established in December 2003 as a nonprofit 501 (c)(3) tax-exempt, active learning organization based in the Houston area, is a leader in patient safety research and education. Our mission is to promote and support patient safety through research, education and the demonstrated practice of patient-centered health care. On behalf of the Secretary of the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality has recognized and listed Community Medical Foundation for Patient Safety as Patient Safety Organization #29.

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BACKGROUND AND RATIONALE

1.1. A National Epidemic

Previous studies of non-adherence to medicines are largely limited to hospital settings where the patients can be closely observed and monitored. After discharge from the hospital or clinic, the patient is considered outside of the “system”. Follow up of patients, such as elder patients who may be alone or without support networks after leaving the hospital is very poor, particularly with monitoring adherence to medical treatment.

The U.S. healthcare system encompasses various modalities of healthcare delivery, including home health care and hospice care at home. In the future, more healthcare services will be provided at home to accommodate the patient’s safety, privacy, and convenience, to alleviate the overcrowding in some hospitals and clinics, and to expand the growing market of home health care specifically targeting the aging population.

The amount of prescribed medicines and consumption of medicines at home will significantly increase as the “baby boomers” retire and as life expectancy continues to expand. Direct marketing to consumers and immediate access to information on the Internet play major roles and drive the interest in and demand for medicines. Older patients will depend on greater amount of medicines to maintain their quality of life, which has surpassed that of the previous generations.

At the same the time, the demand for more new medicines and use of a steadily increasing number of existing medicines (greater number and amount of medicines to treat multiple co-morbidities, also referred to as polypharmacy) will present a new challenge for the aging population in general, as well as patient population and healthcare providers. This challenge is now being recognized and must be addressed by healthcare providers and health policy experts as part of a comprehensive strategy to conserve valuable healthcare resources while providing quality health care.

An associated phenomenon to the trends mentioned above is the accumulation or stockpile of prescribed or over-the-counter (OTC) medicines that have surpassed expiry date or are no longer used by patients or consumers. The problem has reached a national epidemic level, considering the amount of unwanted medicines in practically all American homes. These unused and expired medicines (UEMs) accumulate at home, at the workplace and at other locations, such as school clinics and first aid stations where medicines are usually taken and are stored. Some reasons why and how individuals accumulate medicines at home and workplace are:

- Patients may not follow instructions for prescription medicines as directed by their doctors
- Patients tend to be non-compliant with medical treatment and prescription medicine regimens
- Patients in general do not discuss concerns or problems about their medicines with their doctor or pharmacist
- Individuals tend to overuse medicines because they believe medicines can cure all ailments
- Individuals misuse medicines by self-medicating and sharing prescription medicines with others
• Prescription medicine addicts and abusers often keep excess medicines at home or know where to obtain prescription medicines easily
• Physicians give abundant free samples of new medicines
• Physicians overprescribe or inappropriately prescribe medicines
• Third-party payers encourage bulk purchase of medicines
• Individuals do not adhere to expiry date and believe that medicines do not expire
• Individuals want to save money and keep medicines for the next time they get sick
• Individuals want to have enough essential medicines for themselves and their families in preparation for an emergency or disaster
• Individuals become overly dependent on medicines and often are not informed or aware of other appropriate, effective therapies that may not include prescription of medicines
• Direct consumer marketing by drug manufacturers is highly effective
• Most guidelines for disposing unwanted medicines are confusing
• Most communities do not have a safe and legal drug take-back program for patients and consumers

UEMs, according to researchers and experts, are a measurable and valid indicator of non-adherence or non-compliance by patients. By addressing non-adherence of medical treatment, the healthcare community may improve patient care as well as lower healthcare costs by managing the prescription and utilization of chronic or maintenance medicines more effectively and judiciously. In addition to increased risk of mortality, poor or non-adherence to prescription medicines is costly. It is believed to cost as much as $290 billion annually in increased medical costs and responsible for 33 to 69 percent of all medicine-related hospital admissions in the U.S., at a cost of about $100 billion per year (Healthcare Intelligence Network, 2010)

1.2. The Community of Competence™ as a Framework and Solution Model

The research team of the Community Medical Foundation for Patient Safety (CMFPS) comprised of epidemiologists and other experts immediately explored the connection between potential harm of UEMs and the impact on patient safety and public health. Others involved in the early phases of discussion focused on pertinent issues, such as drug diversion, prescribing patterns, safe and legal collection and disposal of unwanted medicines, regulations and policies specific to collection and handling of UEMs, and the environmental risk to humans and other life forms resulting from improper disposal of UEMs.

Much of the leadership and direction of these discussions came from the Maine Benzodiazepine Study Group (MBSG). Formed in the late 2002, MBSG was established as an initiative of Northeast Occupational Exchange (NOE) in Bangor, Maine. Original members of MBSG were physicians, epidemiologists, nurse practitioners, drug abuse specialists, healthcare providers, payers, advocates, and other interested parties of Maine, including the University of Maine (UMaine) Center on Aging. Later, members from other U.S. States and the Canadian provinces of Newfoundland and Labrador, Prince Edward Island, New Brunswick and Quebec joined MBSG in order to discuss shared cross-border concerns related to UEMs. The original mission of MBSG was to gather data on benzodiazepine use and to consider evidence-based strategies that promote appropriate prescribing and usage of medicines. Monthly meetings were held in person or by the use of various information technology services, such as a listserv, conference calls and web-based meetings. Visit http://www.benzos.une.edu/ for general information about MBSG.
CMFPS joined the MBSG in late 2004 by invitation of Stevan Gressitt, M.D., former medical director of the Office of Adult Mental Health Services, Department of Health and Human Services of the State of Maine. Early on, it was understood that the collective work of a multi-disciplinary and diverse team would have a major impact on innovative methods of drug collection and disposal, and possibly on the behavior and attitude about medical treatment and healthcare costs in the U.S. and around the world.

CMFPS was and still remains the only outside group that advocates the inclusion of patient safety as part of the ongoing discussion and one of the high-priority aims in addressing the concerns and dangers of UEMs. Specifically, CMFPS's primary concerns from the perspective of patient safety and healthcare quality were:

- Medication errors among seniors
- Accidental poisoning among children
- The growing trend of drug abuse among teen-agers (referred to as pharming)
- Drug abuse and misuse in all ages
- Non-adherence to medical treatment,
- The long-term exposure to trace amount of active pharmaceutical ingredients (API) in drinking water as detected across the country in our lakes, rivers, and streams

Unlike the European counterparts, the U.S. Environmental Protection Agency (EPA) has yet to set safe limits for pharmaceutical compounds in the water supply due to lack of scientific evidence relevant to the direct adverse health effects on humans from acute or chronic exposure to pharmaceuticals in the water.

Prior to 2005, data about UEMs from homes were nonexistent. Researchers at CMFPS believe that it is most prudent to adopt and apply the precautionary principles and try to understand as many of the potential hazards associated with UEMs as possible through rigorous research design. Very few federal, state and local agencies have collected useful data on UEMs. The best data at the time were provided by several community-based organizations and partnerships that implemented drug take-back programs, collected UEMs and reported only bulk weight or volume of the collection. While many other countries have set up systematic drug return programs to deal with UEMs, few have demonstrated a remarkable data collection system that can be used for research and policy.

Beginning in 2005, the research team at CMFPS performed a comprehensive study of the UEM problem, including the challenges. Over time, this team devised a strategy that would satisfy most, if not all, stakeholders and parties. The strategy closely followed the framework and methodology described by Elizabeth A. Smith, PhD in her concept of Communities of Competence™ (CC™) (Smith, 2005, 2006). The research team formed CC™UEM by engaging experts in the areas of concerns most relevant to the issues of UEM (Smith & Mireles1, 2, 2010). The original disciplines and interest groups of the CC™ are shown in Figure 1.
Figure 1. Community of Competence™ for Unused and Expired Medicines (CC™UEM): Government, Non-Government, Organizations, and Research Groups Engaged in the Discussion of UEMs.

The CC™UEM provided an ideal case study to apply this new organizational concept to solve a modern, complex problem from the individual to the organizational level. The basic research question was “are unused and expired medicines a significant problem in the U.S.?” The aim of the research was to devise a statistical sampling design to collect sufficient data, compare the data across the nation, and report the findings. The superordinate goal of the CC™UEM was immediately determined by consensus to be “find and present scientific evidence to demonstrate that UEMs are a significant health care and public health problem”.

Community Medical Foundation for Patient Safety
Communities of Competence®

“Not just any group, committee, or coalition...but a true community of individuals based on knowledge, skills, expertise, experience, motivation, and competency”

Elizabeth A. Smith, Ph.D.

The basic structure of the CC™UEM was based on the ongoing work of MBSG, and the gathering of members by telephone conference or face-to-face annual symposia encouraging members to recognize, respect and depend on the expertise and experience of others. The diversity of the issues and the membership created an immediate challenge. The EPA was
interested specifically on the protection of water quality. The Drug Enforcement Administration (DEA) was mostly concerned about drug possession and drug diversion. The Center on Aging, UMaine advocated protection of senior citizens. CMFPS joined the CC™UEM to represent the interest of patients and consumers with issues specific to patient safety and healthcare quality, including the rising healthcare expenditures, particularly in the cost of prescription medicines. Members, despite different missions and goals, supported one important common consensus—to keep the patient/consumer as the focus of our research pursuit and conduct.

The recommendations of the research team that were presented and approved by the Board of CMFPS and later by the CC™UEM included:

- Create a standardized way to collect data from drug take-back programs
- Promote this data collection as a basis for the ongoing study of UEMs
- Design a coding protocol for UEM data based on existing and available classification systems,
- Compile the data into a national database or registry for the purpose of continued research on UEMs

The overwhelming agreement of the CC™UEM based on extensive literature search and several monthly telephone conference calls required that data collection be totally anonymous to protect the individuals returning their unwanted medicines. One possible expectation was the collection of illicit drugs from households. For a new data collection system, members agreed to collect and report only the following variables to ensure consistency and uniformity:

- Name of drug (brand or generic name)
- Strength of the drug
- Estimated quantity of drug returned (e.g. approximate number of pills)
- Reason for the return
- Zip code (standard 5 digit U.S. code)

1.3. Expanding the Community of Competence™ for Unused and Expired Medicines

CMFPS is a leader in patient safety research and education. The research team of CMFPS explored the outreach strategies to increase awareness of the dangers of UEMs at home and within the communities. CMFPS had already been pursuing research in patient safety in response to the Institute of Medicine (IOM) 2000 Report that estimated 44,000 to 98,000 U.S. patients are fatally harmed by medical errors annually. The UEM project became a research opportunity to address the concerns about over-prescription of medicines, non-adherence to medical treatment, and the reported changes in the pattern and behavior of drug abuse in the U.S. At the time, the team believed the UEM issues and challenges will remain a national and global patient safety concern for years to come, and these issues would exact a heavy toll on healthcare expenditures for the nation and the quality of life for many.

The team believed that the gathered information, particularly findings from our research, is highly sensitive and must be presented with the greatest care regarding risk communication and public safety. The public must be informed, and patients and consumers should be directed to the most accurate source of information about UEMs, in particular the implications of contaminated drinking water, unsafe home and neighborhood environments, increased rate of prescription medicine abuse particularly by teens, and the cost of wasted medicines. This
Special Report examines the patterns of significant non-adherence to medical treatment among senior patients and the estimated costs and amount of wasted prescriptive medicines.

Under the CMFPS’s community education and outreach concept of C.A.R.E., which represents targeted areas for intervention and primary prevention based on four basic educational goals and strategies, an expansion to the CC™UEM began. CMFPS developed and launched a community outreach campaign titled C.A.R.E. for Safe Medicines. The team worked with national experts, such as the National Center for Patient Information and Education (NCPIE), Center on Aging at UMaine, and the State of Maine’s Office of Adult Mental Health Services, Department of Health and Human Services.

One immediate product that emerged from C.A.R.E. for Safe Medicines was the Get Rid of Unused Pharmaceuticals (GROUP) Program. Based on an extensive literature review and interviews with federal agencies, it was apparent that guidelines to properly, safely, and legally collect and dispose of UEMs from home and workplace were lacking in every state. Most of the drug take-back programs organized by various communities were operating without knowledge of the DEA, National Association of Drug Diversion Investigators (NADDI) and EPA, as well as local and state drug and law enforcement authorities.

The GROUP Program was launched in Houston on Earth Day, April 16, 2005. The acronym purposely conveyed a strong sense of “community” and shared common concerns. The steadily increasing number of UEMs at home and in the environment is a complex national and global problem that poses a threat to everyone. The structure and organization of the GROUP Program was based again on our CC™ concept and framework to enable groups and communities to initiate a proper drug take-back event or program. Therefore, as members of this (everyone belongs to this) community, everyone must work together to find solutions to a common problem or threat. Hence, the focus of the program is on joining this GROUP campaign and program.

Community Medical Foundation for Patient Safety

C.A.R.E. for Safe Medicines®

C – Community: build the community or identify the targeted group, such as an at-risk population of senior citizens or other age group

A – Awareness: create and increase the knowledge or understanding of a specific problem or concern for this community

R – Responsibility: delineate the important individual and collective duties and responsibilities

E – Empowerment: provide and reinforce members with accurate information and other resources to change behavior and engage in a defined goal-driven, action-directed endeavor determined by the community
Without proper guidelines for consumers’ drug collection and disposal, CMFPS quickly developed and published the GROUP Manual of Procedures (Mireles, 2006). The Manual is one of the most comprehensive “how-to” instructions and guidelines to planning and organizing a community-based drug take-back program. It describes in great detail the background of UEM issues, ideas for a take-back event, community plan, strategies for recruitment and training of volunteers, itemized budget, materials for promotion and publicity, checklists and time schedule, data collection, and evaluation tools. The promotional materials included on CD ROM accompanying the GROUP Manual are ready to be adapted and used by any community group. This Manual and all mentioned published materials, including a series of Patient Safety Checklists® (PSC) are available in printed hardcopy or electronic format (PDF). Most importantly, the GROUP Manual describes the steps to begin a systematic and standardized data collection that would be the foundation of the National Unused and Expired Medicines Registry (Registry). Detailed instructions with standardized forms guide the users of the Manual in conducting a standardized data collection. Prior to the publication and introduction of the Manual, no one was uniformly collecting or analyzing UEM data.

Drug take-back programs often reported only the total weight or the volume of the collection. Organizers and evaluators of these programs were unable to characterize what UEMs were collected or maintain any chain of custody in the case of federally controlled substances (FCS). The rationale for reporting weight and volume clearly indicated the lack of research experience in data collection and the immediate convenience of reporting a crude measure (e.g. 500 pounds of UEMs; 200 30-gallon containers: 150 Hefty bags, etc.) that was required to price the cost of transporting and destroying the collected UEMs by commercial incinerator or landfill operators.

The GROUP Manual of Procedures was presented to a number of federal agencies for review and comments, including the U.S. Food and Drug Administration (FDA), DEA, and EPA. All comments were highly positive, and only slight revisions were made in the final publication of the Manual. Today, the Manual serves as an example or template for other similar publications and continues to be popular with community groups seeking instructions and guidelines to organize a safe and legal drug take-back program. Moreover, the Group Manual of Procedures explains the rationale and importance of the standardized UEM data collection.

1.4. A Response from Federal Leaders

Given the growing attention on UEMs and the community-based activities occurring across the nation, fundamental questions regarding recommendations and guidelines for proper collection and disposal were begin discussed by members of the CC™UEM. CMFPS conducted a survey of various state and national agencies and concluded that recommendations and guidelines for disposal of consumers’ UEMs were completely absent or inconsistent with established federal and state regulations as well as with the current discussion of precautionary principles and prudence. In many instances, they were contradictory, ambiguous, and confusing. To illustrate, most poison centers and retail pharmacies highly recommended flushing UEMs down the sink or toilet to emphasize the immediate safety concern within households, particularly to prevent accidental poisoning. Environmental agencies and water treatment facilities, including pretreatment plants, objected to flushing UEMs into the water supplies. Law enforcement groups advocated controlled, witnessed incineration similar to procedures for destruction of illegal drugs and strongly cautioned against illegal possession of controlled substances. Most healthcare organizations and pharmaceutical companies dismissed entirely the idea that UEMs
are a major public or health concern. Other experts in patient safety could not fully understand or appreciate the connection and impact of UEMs and possible adverse health effects (e.g. surge in the emergency department due to increase of drug overdose cases; medication errors among seniors; accidental poisoning among children and seniors, etc.).

From the Annual Drug Take-Back Survey independently conducted by CMFPS in 2008 and 2009 among recognized drug take-back programs, the research team learned that, outside healthcare institutional facilities (hospitals, clinics and nursing homes), the classification or the definition of UEM varied greatly. In Figure 2, the responders (n = 90) clearly showed inconsistency with classifying or defining UEM.

Regarding the purpose of the drug take-back programs (n = 326; responders were allowed to check more than one responses; responses were not mutually exclusive), many reported environmental protection as the primary purpose of their program. Figure 3 shows the responses to this question. Many programs indicated multi-purpose aims for drug collection and destruction.

Figure 2. Classification of UEM. Survey response (n = 90), Community Medical Foundation for Patient Safety, 2009. Presentation at the 2009 International Symposium on Pharmaceuticals in the Home and Environment, Sixth Annual Unused Drug Return Conference, Northport, ME, October 19, 2009.
The method of destroying collected UEMs in the communities was an important variable. Our annual survey (Figure 4) illustrated that without guidance from federal authority, most community-based programs adopted the preferred destruction method of controlled, witnessed incineration. There was a correlation between this method and the partnership between drug take-back programs and local law enforcement. Law enforcement officers were present during a drug take-back event or the collected UEMs were given directly to the officers after the event. Presently, law enforcement incinerates all confiscated legal or illegal drugs.

Figure 5. Involvement of Law Enforcement, Survey response (n = 79), Community Medical Foundation for Patient Safety, 2009. Presentation at the 2009 International Symposium on Pharmaceuticals in the Home and Environment, Sixth Annual Unused Drug Return Conference, Northport, ME, October 19, 2009.

However, despite the strict federal regulations related to possession and custody of FCS (e.g. narcotics), 59% of the programs operated without oversight or involvement of law enforcement as indicated in Figure 5.

In several communiqués with the EPA and the White House Office of National Drug Control and Policy (ONDCP), we discussed findings from our independent annual survey and key conclusions drawn by the CC™UEM, namely to request funding support and federal guidelines to assist patients and consumers with the most appropriate ways to dispose their UEMs. CMFPS previously developed and disseminated two important Patient Safety Checklists©: Prevention of UEMs (page 19) and Safe Disposal of UEMs (page 20). The research team hoped to address the UEM issue from the strategy of prevention and prudence by reducing or eliminating excess medicines at home and the workplace, which would eventually expire and, in most cases, be forgotten.

Despite our effort and against the advice of many credible experts, in February 2009, ONDCP, in collaboration with the FDA, issued the first consumer guidelines for drug disposal. In addition, the original guidelines presented in this section (page 21) failed to acknowledge the growing interest in and the availability of community-organized drug take-back programs throughout the nation as a viable option to flushing UEMs. The guidelines created much confusion and presented a counterproductive strategy to the diligent effort and progress of the MBSG and CC™UEM to utilize existing drug take-back programs so that individuals would be encouraged to make the right choice regarding disposal of UEMs.

In October 2009, ONDCP revised its guidelines to mention, for the first time, drug take-back programs as an option, but it retained the original recommended steps to render UEMs unusable or unrecoverable. Anecdotally, the federal guidelines did not appear to have a significant impact on how the public views and understands the issues of UEMs or provide a reasonable method of destruction that would encourage greater participation in proper disposal.
Patient Safety Checklist®

Prevention of Unused and Expired Medicines (UEMs)

(CMFFORM0086)

What: A Checklist to help you prevent or reduce the amount of UEMs in your home, workplace and other places you have unwanted medicines.

Why: Preventing and reducing UEMs make your home, community and environment safe.

When: Use this Checklist several times a year as a reminder of the proper use medicines and the dangers related to having excess or unwanted medicines.

How: Check the boxes and follow the recommendations below.

- Talk to your doctor or pharmacist about your new prescription medicine and make sure this medicine is necessary at the right strength, dosage, amount and length of time.

- Ask your doctor for the smallest possible but most reasonably effective amount of the necessary medicine for your ailment or condition.

- Make sure that the new medicine is not a duplicate of your current medicines or will not interfere with your other medicines or normal diet.

- Ask your doctor if you can return any excessive amount of the medicine that he or she prescribes or a medicine that may cause you any problem.

- Write down the all instructions prescribed by your doctor. If you do not understand the prescription instructions for your medicine, ask your doctor, nurse, or pharmacist to repeat the instructions slowly and clearly until you can understand them.

- Take your medicine strictly as prescribed until you finish the prescription.

- Report to your doctor any problem you might have with your new medicine. If your doctor discontinues the medicine or orders a new one, immediately return any remaining medicine to your doctor’s office.

- At least twice a year, do an inventory of your medicine cabinets and drawers at home, workplace, or wherever you keep medicines. Use Patient Safety Checklists©: Safe Medicine Cabinet and Storing Medicines at Home.

- Remove any medicine that has expired or is no longer used. No unused medicine should be kept more than a year.

- Always keep an updated list of all your current medicines and when and why you have to take them. Use Patient Safety Checklists©: Safe Medicines Log or My Medical Journal© to accurately record your medicines, when you start taking them, when you refill or finish the prescription, and when you stop taking them. Show this information to your doctor and pharmacist.

- Return any unused and expired medicine only to a drug take-back program. Never flush them down the sink or toilet or throw them out with your household trash.

- For more information about unused and expired medicines and locations of the nearest drug take-back programs, visit Community Medical Foundation for Patient Safety at www.communityofcompetence.com or call 1-832-778-7777.

Source: Community Medical Foundation for Patient Safety, www.comofcom.com
Patient Safety Checklist®
Safe Disposal of Unused and Expired Medicines (UEMs)
(CMFFORM0087)

What: A Checklist to guide you with the safe and legal disposal of your unwanted medicines.
Why: You must get rid of unused and expired medicines carefully and properly to keep your home, community and environment safe.
When: Use this Checklist when you need to get rid of unused and expired medicines.
How: Check the boxes and follow the recommendations below.

- Find the nearest drug take-back program in or closest to your community. Check The National Directory of Drug Take-Back and Disposal Programs at www.communityofcompetence.com.
- Contact the drug take-back program to get location and schedule for the next drug take-back event or to obtain a free mailing kit.
- Do an inventory of your medicine cabinets and drawers at home, workplace, or wherever you keep medicines.
- Remove all unused or expired medicines and follow instructions for drug take-back program.
- Write down the name, strength, amount of the unused or expired medicines, and the reason why you are returning these medicines. Some drug take-back programs provide an inventory form for this information.
- Update your list of current medicines, and note the unused and expired medicines.
- Remove your name, address, doctor’s name, telephone number, and any other personal information from the medicine label by blackening this information with a permanent black marker or scraping the information off the label.
- Store the unwanted medicines safely until you can drop them off at the nearest drug take-back program or mail them to an approved drug collection site.
- When mailing back unwanted medicines, get a proper mailing kit and complete the enclosed inventory form, leave the medicines in their original containers, place them in the provided return package, and drop the sealed package in your mailbox or at your nearest post office.
- If you have a large amount of unwanted medicines to return, use more than one mailing kit and complete the enclosed inventory form for each mailing kit.
- For more information about unused and expired medicines and locations of the nearest drug take-back programs, visit Community Medical Foundation for Patient Safety at www.communityofcompetence.com or call 1-832-778-7777.

Source: Community Medical Foundation for Patient Safety, www.comofcom.com
Federal Guidelines:

- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the FDA’s website.

- To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government’s household trash and recycling service and ask if a drug take-back program is available in your community.

- If a drug take-back or collection program is not available:
  1. Take your prescription drugs out of their original containers.
  2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
  3. Put the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
  4. Conceal or remove any personal information, including Rx number, on the empty containers by covering it with black permanent marker or duct tape, or by scratching it off.
  5. Place the sealed container with the mixture, and the empty drug containers, in the trash.

2. STATUS AND PROGRESS OF DRUG TAKE-BACK PROGRAMS IN THE U.S.

2.1. Annual Drug Take-Back Survey

Data from the Annual Drug Take-Back Survey conducted by CMFPS in 2007-2008 offered for the first time a glimpse of the myriad of UEM activities and programs in the U.S. No state or federal agencies had captured this information. Some rely on the information gathered by our research team. In 2007, the official count of drug take-back programs was 66, with many clustering on the Maine’s east coast and California-Washington west coast. Today, due to the increased awareness of UEMs and more effective outreach of the CC™ UEM, the updated count of active drug take-back programs is approximately 250 collection sites and programs. Results of the annual survey are published by CMFPS in the first and only National Directory of Drug Take-Back and Disposal Programs (Mireles, Miller, and Smith, 2008). New drug take-back programs will be included in the next official list of the second edition of the National Directory to be published late 2010.

In addition to identifying active drug take-back programs in the U.S., the annual survey ascertained important information about the classification of UEMs, funding sources for the program, destruction methods, collection schedule, primary purpose of the program and involvement of law enforcement in the collection of controlled substances. Results from this annual survey provide a direct comparison of active drug take-back programs and help evaluate the progress of community-based drug return and destruction system in the U.S. Results are often reported to federal agencies. Take-back programs not officially listed in our National Directory may draw suspicion and special interest from the DEA if the programs are collecting and processing controlled substances.

Today, our one-of-a-kind National Directory contains the most accurate count on drug take-back programs and commercial reverse distributors. CMFPS publishes this unique reference as a convenient information resource for the community. Patients and consumers may use this reference to learn about the issues of UEMs and locate the nearest drug take-back site to dispose of their UEMs safely and legally.

2.2. Influence of the Media

Knowledge about pharmaceutical compounds in U.S. water supplies has existed since the mid-1970s among environmental scientists, including U.S. Geological Survey (USGS). Improved testing equipment and methods capable of detecting and characterizing these compounds in the range of parts-per-trillion are only available recently. Today, there are still no official safe limits on the amount or concentration of pharmaceuticals in drinking water. Very few municipal water authorities even test for their presence at extremely low levels. The media seldom cover stories about water quality or contamination of water by improper disposal of UEMs.

In March 2008, the Associate Press (AP) reported its own investigation that discovered minute amounts of pharmaceuticals in the water supply of 24 major U.S. metropolitan areas. AP also estimated at least 46 million Americans drink municipal water with trace levels of pharmaceuticals, such as antibiotics, anti-convulsants, mood stabilizers and sex hormones. While no studies to date suggest any association between drugs in the water and deleterious health effects on humans, the EPA has identified more than 100 individual pharmaceuticals and personal care products (PPCP) in our drinking water (Daughton, 2003, 2005). Researchers are
expressing growing concern that environmental pollution caused by UEMs is already adversely affecting wildlife, and may threaten human health.

Public outrage from the AP story prompted Senator Barbara Boxer (D-California), Chair of Senate Committee on Environment and Public Works, to reprimand Benjamin H. Grumbles, EPA assistant administrator for water, for the agency’s failure to require testing for pharmaceuticals and for public disclosure of test results. The following timeline from AP (http://hosted.ap.org/specials/interactives/pharmawater_site/) illustrates the impact of the news story and responses across the nation in 2008:

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 9</td>
<td>AP story released</td>
</tr>
<tr>
<td>March 12</td>
<td>Illinois orders immediate water testing</td>
</tr>
<tr>
<td>March 16</td>
<td>Scientists, environmentalists, utilities agree: more testing needed on drugs in drinking water</td>
</tr>
<tr>
<td>April 3</td>
<td>New York City leaders say city must test drinking water.</td>
</tr>
<tr>
<td>April 12</td>
<td>Philadelphia water officials to address worries over drugs in water and corrected data</td>
</tr>
<tr>
<td>April 13</td>
<td>On eve of hearings, White House documents show federal agencies failing to take action on drugs in water</td>
</tr>
<tr>
<td>April 14</td>
<td>Philadelphia City Council wants local and federal action to curb drugs in drinking water</td>
</tr>
<tr>
<td>April 15</td>
<td>Senate hearing on drugs in water; Senators criticized EPA over lack of knowledge on drugs in water</td>
</tr>
<tr>
<td>April 15</td>
<td>EPA urges Great Lakes residents not to flush old medicines</td>
</tr>
<tr>
<td>May 6</td>
<td>Water tests reveal Phoenix water is drug free</td>
</tr>
<tr>
<td>May 12</td>
<td>New Jersey lawmakers told effects of drugs in water unknown</td>
</tr>
<tr>
<td>May 13</td>
<td>Massachusetts detail steps to keep pharmaceuticals from water supply</td>
</tr>
<tr>
<td>June 9</td>
<td>Texas town releases name of drug found in water; mayor cited terrorism as reason for secrecy and nondisclosure</td>
</tr>
<tr>
<td>July 25</td>
<td>Medicine collection drive on tap</td>
</tr>
<tr>
<td>Sept. 11</td>
<td>Recent tests detect pharmaceuticals in drinking water of 46 million Americans</td>
</tr>
<tr>
<td>Sept. 14</td>
<td>Healthcare industry sends tons of drugs into nation’s wastewater system</td>
</tr>
</tbody>
</table>
### Models of Drug Take-Back Programs

As communities attempt to design and implement a working drug take-back program for a number of purposes previously discussed above, variations occur in the model and operation of these take-back programs to accommodate limited resources and to comply with local and state laws. From the same Annual Drug Take-Back Survey independently conducted by CMFPS in 2008 and 2009 among recognized drug take-back programs, we identify four basic categories for the programs. Figure 6 illustrates the models and methods of drug take-back programs. The majority (41%) of the programs, particularly on the west coast, demonstrates a strong partnership with retail pharmacies to allow patients and consumers to return UEMs. It is intuitive for most individuals to return unwanted medicines to the same source or location where the medicines were dispensed or purchased.

Some communities organize one-time or periodic take-back events by which participants may drop off their UEMs during specific hours. These drop-off events (31%) may be staged at a local high school, community center, senior hall, etc. In Indiana, the TRIAD program, through a partnership with local law enforcement, senior citizens, and the American Association of Retired
Persons (AARP), promotes monthly or quarterly drop off events at AARP meetings. Other drop-off events involve a drive by in a motor vehicle through a designated parking lot, and the driver gives the UEMs to a volunteer or deposits them into a collection bin. One special take-back event was held in the main rotunda of the State House in Maine. Drop-off events appear to be experimental in nature. Organizers use these events commonly as a pilot study to look at the logistics and feasibility of planning a more long-term program.

Drop-off models for drug return utilize collection bins on site or temporary set up at an event. Design of collection bins also varies with construction and security. In a retail pharmacy, these bins are positioned as close to the pharmacist’s counter as possible. In some neighborhoods, the bins are free standing on the street curb, and participants may drop off UEMs at any time. Subsequently, there is a growing concern for the safety and illegality of some of collection bins, especially when controlled substances are included in the collection.

A police station or police storefront in the community (15%) is becoming an attractive location in certain residential areas. Any UEMs, including controlled substances, may be dropped off at the designated police location. Federal laws exempt law enforcement officers as first registrants and allow them to collect, confiscate, and destroy controlled substances. Partnership with law enforcement is one of the most recommended models to consider for a drug take-back program.

Recently, the DEA sponsored a national drug take-back campaign which occurred throughout numerous communities on September 25, 2010. Unwanted prescription and OTC medicines were collected and disposed by DEA officers. While UEM data were not specifically collected to sample what was returned, the campaign appeared to galvanize a coalition between community-based organizations and law enforcement.

![Figure 6. Models and Methods of Drug Take-Back](chart.png)

The direct mail-back model (3%) is, by far, the most organized and complex take-back system. Involvement of the US Postal Service enhances the program by adding a level of federal protection from tampering with U.S. mail. Participants obtain a mailing kit from convenient locations, do a simple inventory, pack the UEMs, completed a survey, and mail the UEMs, all in the comfort and safety of home. All UEMs are mailed directly to the DEA office. At the time of our annual survey, only a few other models of direct mail-back systems existed. Now, private companies are offering others options with direct mail back of UEMs, usually at a cost applied directly to participants or the sponsoring agency, such as a retail pharmacy chain or supermarket that wants to promote the program.

Finally, “Others” (10%) include drug take-back programs organized by a company exclusively for employees and families or variations of the above models. New models are quickly being developed and put into operation to give patients and consumers a way to dispose of UEMs.

2.4. Leadership in Maine

Without much media attention and publicity, colleagues in Maine have been the true leaders in shaping public policies that have far-reaching implications within the U.S. and abroad. The State of Maine is now recognized as the pre-eminent and the ideal testing ground and laboratory for innovative and sustainable solutions to the UEM problem. In 2003, Maine State legislators passed the first House Bill LD 1828 to create the Unused Pharmaceutical Disposal Program, administered by the Maine Drug Enforcement Administration, to provide for the safe, effective and proper disposal of UEM. The program involves the use of prepaid mailers to be made available and used by the public to mail UEM to a single collection location. The drugs received may be handled only by Maine Drug Enforcement Administration (MDEA) officers and must be disposed of in a manner that ensures the safety of the public and the environment. The director of the MDEA is authorized to accept funding from public and private sources to carry out the purposes of the program.

Activities related to safe drug disposal increased in number and significance within Maine and other U.S. states with other state legislations under consideration. On September 5, 2008, Governor of the State of Maine John E. Baldacci proclaimed October 31, 2009 as Proper Drug Disposal Day (Appendix 3).

On the international front, many countries already were addressing the issues of UEMs with a call for stronger multinational collaboration and programs to raise awareness of the issues and work cooperatively toward reducing UEMs. On August 3, 2007 at the Second International Conference on Environment in the City of Athens Cultural Center, delegations from many nations convened to initiate a global referendum on UEMs. This gathering, represented by the U.S. delegation headed by Stevan Gressitt, M.D., of the MBSG, produced the first international statement on UEMs, called the Athens Declaration (Appendix 4).
The Athens Declaration defined the six reasons to support and engage in safe drug disposal:

- To curtail childhood overdoses
- To restrict household drug theft
- To limit accumulation of drugs by the elderly
- To protect our physical environment
- To restrain improper international drug donations
- To eliminate waste in the international healthcare systems of all countries

Other national and international declarations on UEMs were issued after the meeting in Athens. These included the Istanbul Declaration, 2009, and the Northport Declaration (US), 2009.

2.5. **EPA’s Aging Initiative**

The mission of the EPA is to protect human health and safeguard the natural environment. Protecting the health of older persons is a priority for because by 2030 the number of older persons aged 65 and older is expected to double to 70 million—one out of every five Americans.
The EPA has a national outreach program that aims to protect the environmental health of older persons. According to the EPA’s Aging Initiative (http://www.epa.gov/aging/index.htm), due to the aging process, older persons may experience increased health risks from exposures to pollutants in the environment. As people age, their bodies become more susceptible to hazards from the environment which may worsen pre-existing chronic or life threatening health conditions, such as asthma and chronic obstructive pulmonary disorder (COPD). The capacity of the body’s organ systems decreases with the aging process, and the ability to detoxify and eliminate toxins from the body is significantly diminished with age. Seniors also have accumulated a lifetime of environmental and occupational contaminants, which are capable of remaining in their bodies.

The Aging Initiative leads the development of a National Agenda for the Environment and the Aging. The National Agenda will prioritize environmental health hazards that affect older persons, examine the environmental impact of an aging population in a smart growth context, and encourage civic involvement among older persons in their communities to reduce hazards. The National Agenda for the Environment and the Aging, developed through a public participatory process, will help guide the Agency’s work to protect the health of older persons now and in the future. The four identified priorities for the National Agenda for the Environment and the Aging are:

1. Identify research gaps in environmental health
2. Translate research findings into public health prevention strategies
3. Create tools to address the impact an aging society has on the environment (Built Environment)
4. Provide opportunities for older persons to be environmental stewards in their communities

Ultimately, the National Agenda will help translate research findings into public health interventions. One area that has caught interest of the EPA in improving the environmental conditions for seniors is community-based drug take-back programs. Seniors often must deal with excess medicines at home and need a convenient way to get rid of unwanted medicines. The Aging Initiative, through the leadership of Kathy Sykes, M.A., Senior Advisor, U.S. EPA Aging Initiative, recognized the work being done in Maine and supported the funding of a direct mail-back program for seniors.

2.6. Safe Medicine Disposal for Maine

There are numerous models and pilot studies of drug take-back programs throughout the country. They vary from drop off collection bins at a retail pharmacy for non-controlled drugs only and drop off events sometimes with a local law enforcement officer to a direct mail back system. Maine was the first state to demonstrate a direct mail-back system that is enacted and supported by state legislations.

The Safe Medicine Disposal of Maine (ME) involves the partnership among the Center on Aging at UMaine, U.S. Postal Service (USPS) and the MDEA. Most of the state appropriated and matching funds from the EPA (Aging Initiative Grant #CH-83336001-0) paid for the USPS envelopes/mailers, shipping and handling, and staff at the Center on Aging to conduct the pilot study. For more details, visit http://www.safemeddisposal.com/.
Program results and findings during the first two phases:

- More than 2,300 lbs of UEMs collected
- A total of 9,400 enveloped distributed
- 3,926 returned envelopes received and processed (return rate = 42%)
- Eight cataloging events organized to inventory UEMs
- More than 380,000 pills cataloged
- 2,777 telephone calls answered via Helpline
- 250 pounds of controlled drugs have been destroyed
- Average weight of returned envelope was 7 ounces
- Estimated cost of UEMs was $572,772
- Approximately 17% of the drugs were FCS (federally controlled drugs)
- Estimated 1,970 lbs of drugs prevented from entering the water supply and landfills

The program also provided insight to the reasons why citizens of Maine accumulated UEMs in their homes. An accompanying survey provided with each mailer revealed some reasons for drug accumulation in consumers' homes.

- Medicine belonged to a deceased family member (19.6%)
- Physician discontinued medication or gave patient 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%)

Safe Medicine Disposal for ME demonstrated that a direct mail-back system is not only feasible, but also effective. The program utilized a phased implementation plan, beginning by targeting elders (Phase I) and focusing on participating retail pharmacies as distribution sites for the mail-back envelopes. A broadened target population (Phase II) then expanded to adults of all ages, as well as to a wider range of distribution sites to include other providers of health and social services in Maine.

According to the program manager, Jennifer Crittenden, the program will continue to operate into 2011 with additional funding from the Fund for Healthy Maine administered by the Maine DEA. Maine is now hosting nearly 150 program sites and distributing 20,000 mail-back envelopes under the current contract with MDEA. The program is statewide and has become a working model and proof-of-concept for other states and organizations considering a similar mail-back system.
3. THE NATIONAL UNUSED AND EXPIRED MEDICINES REGISTRY

In fall 2005, CMFPS formally announced its intent to establish a national repository for UEM data. This repository is known today as the National Unused & Expired Medicines Registry (Registry). The Registry provided a standardized method to collect, code, and archive UEM data for trend analysis and comparative studies between states and communities. As more drug take-back programs emerge from grassroots efforts across the U.S., it became important to gather UEM data in a more uniform or standardized manner and archiving the data in a central location for access and retrieval.

This one-page instrument designed in 2006 was peer-reviewed, tested in various collection locations, and is now accepted as a standard. This instrument has provided the important research foundation to gather unique data never previously attempted and to process and enter the data into the first and only National Unused and Expired Medicines Registry.

Reporting of data by participants of drug take-back programs is anonymous. Participants use the simple data collection instrument (Appendix 6) to quickly list the UEMs at home before taking them or mailing them to a collection site. However, rather than have individuals write down on the collection instrument information about the UEMs they are returning, most programs use volunteers or paid staff to record these UEM data. We recommend the instrument be given to any participant in advance of the drug take-back event. The current instrument can be downloaded at www.communityofcompetence.com. Participants can either complete the data collection instrument on their own or ask someone to help.

3.1. Purpose of the National UEM Registry

Based on the previous recommendation of the CC™UEM, the research team at CMFPS designed an entirely new data collection system for consistency and uniformity to gather UEM data, using only the five essential variables:

- Name of drug (brand or generic name)
- Strength of the drug
- Estimated quantity of drug returned (e.g. approximate number of pills)
- Reason for the return
- Zip code (standard 5 digit U.S. code)

In addition to these five variables, more variables may be collected and reported depending on the needs and evaluation of the drug take-back program, but the essential five variables must be present for the data to be included in the National UEM Registry. Most programs recorded the source of the medicines—where patients bought or obtained their medicines. Some needed to know the age and other demographic information of participants. We often helped with the design or revision of our original instrument to customize data collection while retaining the basic uniformity.

As part of our research team promoted and distributed the standardized data collection instrument, another team concentrated on creating the system and platform to receive, code, and store the UEM data. The rationale for the systematic UEM data collection and preliminary findings was presented at the 2006, 2007, 2008 and 2009 International Symposia on Safe
Medicine (formerly known as the annual International Symposium on Pharmaceuticals in the Home and Environment) held in Maine.

There are two concurrent tracks at these symposia: MBSG Conference and Unused Drug Return Conference. A representative from CMFPS presented findings from the National UEM Registry at the latter track. Only by collecting and studying UEM data can the research team increase understanding of the problems and challenges of UEM in the homes, workplaces and communities. Scientific evidence of any problem is vital for making necessary changes in practice and policies. Equally important is the evidence for a working solution that is cost-effective and sustainable.

The Registry has become an indispensable data system to:

- Characterize UEM by drug name, type and therapeutic category
- Calculate waste and cost of returned medicines
- Identify potential adverse environmental impact
- Serve as a useful drug surveillance tool to study trends and emerging UEM-related problems
- Archive of vital UEM information, such as lessons learned from exemplary take-back programs and best practices and ideas to help curtail drug abuse and pharming among teens

With funding support, information about UEM can be used by researchers and representatives of various law enforcement, environmental protection, public health, consumer advocacy, consumer protection, health care, pharmaceutical manufacturers, health policy, and others to:

- Monitor and compare UEM collections by geographical regions and over time
- Evaluate the efficacy of collection and disposal programs and identify best practices
- Provide data for policies and legislations based on objective analysis and scientific evidence
- Conduct various research projects in patient safety and public safety
- Detect emerging problems with pharmaceutical products and market (e.g., non-adherence to medical treatment due to adverse side effect or drug interaction)

A standardized data collection system and protocol to classify and analyze UEM data are required to conduct a study of the growing epidemic of UEMs in the U.S. and to evaluate the patterns and trends longitudinally. Researchers at CMFPS strongly believe that only valid and reliable data may be considered evidence for effective intervention, program evaluation, and policymaking.

To specifically support and promote the Registry, CMFPS introduced the GROUP campaign and program, designed with a comprehensive and detailed Manual of Procedures to assist community groups planning and organizing an effective and legal drug take-back program. Data gathering is an essential part of this objective. Presently, submitting data to Registry is voluntary. It is an important research aim to gather raw UEM data from numerous take-back programs and through analysis transform these data into new information and knowledge about UEMs. This “first of its kind” data can be directly applied in the form of best practices used to improve our understanding of the impact of UEM on all ages of individuals, on the healthcare system, environment and communities, and help reduce the cost of wasted medicines.
3.2. Components of the National UEM Registry

The National UEM Registry is divided into five primary modules: 1) Administrative Module, 2) Drug Characterization Module, 3) Occupational Exposure Module, 4) Environmental Impact Module and 5) Demographics Module.

3.2.1. Administrative Module

This module is used to keep track of each item in the Registry through a unique assigned identification (ID) number. Each returned medicine with its assigned ID number could be cross-referenced throughout the Registry. The basic unit of analysis (and line item counting) of the Registry is individual returned medicine (register), but the modules allow counting by any variable or data field, such as pill count. Each returned medicine can be coded for approximately 60 data fields in addition to our standard variables and entered into the National UEM Registry. Quality control and reliability checks for data coding and entry are performed by critically examining and recoding approximately a 10% subsample of the batch entries. Any discrepancies are reconciled and documented in a logbook in the research office.

3.2.2. Drug Characterization Module

This model was created after a lengthy search and comparison of existing therapeutic classification systems, including a large number of conventional published formularies, the research team chose to standardize the therapeutic classification on the widely accepted and referenced Drug Abuse Warning Network (DAWN) classification system of the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA). DAWN system was determined to be the most consistent and reliable. With more than 16,000 items, including illicit drugs by common street (slang) names and non-conventional medicines, this classification system proved to be highly superior compared with other classification systems in providing the most usable and convenient therapeutic stratification. The research team created a unique, proprietary therapeutic classification based on DAWN but expanded it to include the German Regulatory Authority’s “Commission E” to classify alternative medicines and dietary supplements. In 2007, researchers added a new therapeutic category “medical device and supply” to the existing DAWN primary therapeutic categories because these items began to appear in UEM collections.

The most important and frequently requested UEM data in this model are the drug characterization data fields containing the codes of the specific brand/trade and generic drug names; therapeutic class, therapeutic subclass 1 and therapeutic subclass 2: marketing status (prescription vs. OTC), form (pill and non-pill), and federal controlled substances (FCS) schedule code (II – V). Other data fields that we code to characterize each item are the National Drug Directory number, estimated standard pack size, average wholesale price, quantity returned, source where medicine was obtained, and reason for return (non-use).

The estimated cost of each returned medicine in the Drug Characterization Module is coded according to the published average wholesale price (AWP) in the Red Book 2005. On August 2008, the reference AWP coding was updated to the Red Book 2008. By a simple algorithm, the estimated standard pack size is selected and matched with the exact drug name and strength to obtain the AWP. The algorithm for estimating pack size has been validated in a
small pilot study conducted in Houston, TX, with a correlation coefficient (r) of 0.97 between estimated and actual original quantities of the returned medicines.

3.2.3. Occupational Exposure Module

This module is currently in the development phase and will be used in the future to provide guidance in proper and safe handling of certain hazardous UEMs according to U.S. Occupational Safety and Health Administration (OSHA) or the National Institute of Occupational Safety and Health (NIOSH). As more individuals become directly involved with the shipment, handling and processing UEMs, exposure to some hazardous materials naturally would increase, putting volunteers and paid workers at occupational risk. Attention to classification of UEM according to occupational exposure will be given to hazardous chemicals (e.g. mercury and radioactive isotopes) and some pharmaceutical products (biological contamination, aerosolized particulates, possible noxious liquids, powers, and gels). Targeted health effects for this module include human carcinogenicity or teratogenicity, epidermal and dermal irritants and respiratory irritants.

3.2.4. Environmental Impact Module

This model provides often-requested information about the potential environmental harm of a particular drug. With precise drug characterization and environmental risk assessment, researchers in Europe provide the most useful classification system for environmental risk and hazard that may be associated with pharmaceutical products. Our coding of environmental impact is standardized to the JANUS Classification System of Sweden (www.janusinfo.se).

Environmental hazard or the inherent potential of a substance to damage the environment is ascertained by three variables: persistence in the aquatic environment (P), bioaccumulation in aquatic life (B) and toxicity (T) in water. Each variable is assigned a numerical value (0–3). The total of these values constitutes the PBT index for the substance. The PBT Index ranges from 0 to 9 (9 being the highest score for potential environmental impact).

Environmental risk, on the other hand, is the acute toxic danger to the aquatic environment, based on the ratio between predicted environmental concentration of the substance (PEC) and the highest concentration of the substance that does not have a harmful effect in the environment (PNEC). Environmental Risk is specified as follow:

<table>
<thead>
<tr>
<th>Risk</th>
<th>Condition</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insignificant</td>
<td>if PEC/PNEC &lt;0.1</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>if PEC/PNEC 0.1–1</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>if PEC/PNEC 1–10</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>if PEC/PNEC &gt;10</td>
<td></td>
</tr>
</tbody>
</table>

More detailed information is available at www.janusinfo.org/imcms/servlet/GetDoc?meta_id=7236

Researchers are currently testing and introducing a new environmental score variable, the Environmental Impact Rating Score (EIRS). This score incorporates the multiplicative instead of the additive cumulative effect of PBT indices, the returned quantity, and strength of the
medicine. The new EIRS will allow researchers to quantitatively compare and improve the accuracy of the score conveying a more accurate relative potential harm from UEMs in the environment.

3.2.5. Demographics Module

This module provides a crude snapshot of participants from an aggregated analysis of demographic information previously gathered by the U.S. Bureau of the Census according to the standard zip code. Zip codes, for example, identify, classify, and define specific populations based on age, income, educational level, socioeconomic status, among many other variables. They are used commonly in other public health research, marketing and demographic analysis of certain population-based trends, such as birth rate and changes in ages of children that would require allocation of public resources to build more schools, etc.

In the Registry, zip codes are used to provide a basic description of the participants and to compare them to other participants of take-back programs across counties, states, and the nation. Using this demographic information with the analysis of returned drugs, researchers created a Registry that is truly one of a kind in the U.S. Eventually with more data, they intend to study and better understand the issues and patterns of non-adherence and healthcare waste as evident in the volume and type of UEMs consumers and patients are discarding.

Based on zip code information already collected and analyzed, participants on the average are highly educated, older, and have above average median household income than the “average” person. Supplemental surveys and interviews conducted by other organizations indicate that participants are most concerned about the impact of UEM on the environment.

3.3. Current Status of the National UEM Registry and Uses of UEM Data

Presently, the Registry contains data on nearly 35,000 items representing returned prescription and OTC medicines that would otherwise be thrown in the trash or flushed down the sink or toilet. Data on more than an estimated 2.5 million pills, capsules, and tablets have been counted and entered into the Registry. Researchers at CMFPS believe the Registry has the largest and most detailed collection of UEM data anywhere. A few federal agencies, such as ONDCP, have confirmed this fact and periodically request access and review of the data.

An effective use of the UEM data is to determine the proportion of wasted medicines collected through organized take-back programs. These medicines typically would have been introduced into the water supply by indiscriminate and improper disposal. Samples of UEM collected on the west and east coasts have consistently shown an estimated 40% waste of prescription medicines (items and proportion of the medicines that were never used by the patients). An example of a practical use of the data is to determine which UEMs are most frequently returned and develop a public education program to reduce wasted medicines and save healthcare dollars. For example, if the UEM data show that certain antibiotics are not used by patients and are thrown away, an effective health promotion program can be developed within the community to:

- Remind physicians to prescribe antibiotics more appropriately and judiciously for the specific infections
• Inform and educate patients about proper adherence to taking antibiotics for specific bacterial infections

• Explain and caution the communities about indiscriminate dumping of antibiotics into the environment which then promotes drug-resistance in bacteria

• Engage local health authorities in reviewing current policies about proper collection and disposal of household medicines or develop new policies consistent with the discussion and recommendations relevant to UEMs

The value of the Registry depends on the quantity and quality of the UEM data gathered across different communities. Organizers of drug take-back programs are strongly encouraged to participate in data sharing based on the established standardized data collection methods and format. Researchers at CMFPS are available to consult with sampling design for data collection and provide technical assistance with using the standardized data collection form and how to submit a dataset to the Registry. The Registry is purposely designed to be in the public domain with aggregated data and summary reports published on the website of CMFPS and other approved websites. With sufficient funding support, UEM data will be made available to the public, researchers and policy makers. Coding protocol and specific classification methodologies remained protected and are considered intellectual properties of CMFPS.

Data analyzed by CMFPS research team are commonly used in program evaluation and as supporting evidence for state legislations dealing with UEM issues. In most instances, the UEM data are the only reliable source of information used in making decisions regarding policies and strategies to reduce UEM and over-prescription of certain medicines. CMFPS has provided, by courtesy, summary reports of UEMs to the State of Maine, ONDCP, various medical associations, individual legislators, and governmental and nongovernmental leaders actively engaged in the discussion of UEMs. CMFPS also provides substantial research support for a number of research programs, including pilot studies of two different drug take-back models, one in California and one in Maine.

3.3.1. Ancillary Studies from Data Mining

The research team at CMFPS analyzes UEM data continually with detailed comparison of UEMs to include primary sources or locations where patients/consumers get their medicines, reasons for the UEMs, and the estimated cost of wasted medicines. Ancillary and related studies that use data from the Registry include:

• A comparison of the UEMs collected by different methods and drug take-back systems; a direct mail-back system results in a higher proportion of controlled substances and illegal drugs compared to drop-off systems at retail pharmacies or police stations; participation rate also appears to be higher for a mail-back system

• A comparison of inventory methods for consumers—paper inventory form vs. an electronic, online inventory form
• A control quality evaluation based on the variety and quantity of UEMs, considering factors, such as take-back system and involvement of law enforcement

• A validation study to compare a complete census (total inventory) of collected UEMs to a simple, randomized or systematic sampling design to increase efficiency of collection

• A descriptive analysis of complementary and alternative medicines that are also returned

• An examination of the direct healthcare waste in term of estimated cost when prescription medicines are not used and thrown away

• A validation study of the method to estimate standard pack size based on only three required variables—drug name, strength, and quantity returned

• A study of the pattern and behavior of non-compliance or non-adherence to medical treatment (medication regimens prescribed by physicians)

• Identification of patterns of the type of medicines and medication practices based on geographic location are now beginning to emerge from the data

• Observing and measuring the impact of specific health education and promotional programs to influence changes in the patterns of UEMs in a defined area and population

Researchers are considering an evaluation study of the efficacy of drug take-back efforts in the communities by comparing DAWN data to our UEM data, before and after a drug take-back program is implemented. A comparative outcome of interest may be the number of drug overdose cases in the emergency department. Law enforcement data with number of drug-related arrests, specifically those dealing with illegal possession, consumption, and diversion of prescription medicines also may be used to measure the impact and efficacy of a take-back program.

Health educators, health promoters, experts and advocates in community outreach may take advantage of the vast volume of information and create programs to increase awareness of the danger of UEMs and teach safer practices regarding the effective and prudent use of medicines.

CMFPS publishes a series of Patient Safety Checklists®. The one-page list of checkboxes reminds patients/consumers of ways to prevent medical error, increase safety, and improve healthcare quality and outcome. As an educational and practical component of our GROUP Campaign to educate the public, the Patient Safety Checklists®: Safe Medication Practice Series is included in various community outreach presentations and workshops to demonstrate simple, practical steps and reminders anyone may use to ensure safety with medicines and reduce UEMs at home.

In support of the Registry, CMFPS administers the Annual Survey each spring to invite all organizers of drug take-back and disposal programs, including commercial reverse distributors, to list and describe their programs and services. CMFPS staff compiles the survey results
which are published in the *National Directory of Drug Take-Back and Disposal Programs* (National Directory). The National Directory is updated periodically online with the current information. The next edition of the printed copy of the National Directory will be published in late 2010.

The National Directory can be used to find the closest and most convenient location of a take-back program to safely and legally get rid of UEMs from home. It lists two innovative take-back programs in Maine. One unique program is the *Caribou Police Rx Prescription Return* ([http://www.cariboumaine.org/police.html](http://www.cariboumaine.org/police.html)) that includes a door-to-door pick-up service by law enforcement officers in Caribou, Maine. Another exemplary program in Maine is the previously discussed free, direct mail-back pilot study *Safe Medicine Disposal for ME*, ([http://www.safemeddisposal.com/](http://www.safemeddisposal.com/)). Other mail-back programs are now beginning to appear in other states with different funding sources and restrictions regarding return of controlled substances. At the time of the publication of this Special Report, only the *Safe Medicine Disposal for ME* permits patients/consumers to return controlled substances by direct mail. Legislations are being discussed to extend special provisions for collection of controlled substances by other authorized parties.

### 3.3.2. UEM Data as Part of a National Patient Safety Database

On December 23, 2008, CMFPS was recognized and designated by the U.S. Department of Health and Human Services as Patient Safety Organization #29. Patient Safety Organizations (PSOs) in the healthcare sector were authorized and created by the *Patient Safety and Quality Improvement Act of 2005* (Public Law 109-41, signed July 29, 2008) ([Department of Health and Human Services, 2008, 2009](http://www.hhs.gov)) to systematically gather, analyze, and compare patient safety information with uniform, federal standards and protection for confidentiality. The purpose of this Act is to help health providers reduce the incidence of patient safety events in order to improve patient safety and healthcare quality.

The Patient Safety Act defines the *Patient Safety Work Product* as any specific patient safety information gathered by a PSO, and this information is qualified for federal protection, according to the Final Rule. Also protected are any data generated by the PSO working with health providers on patient safety activities that can be defined as *Patient Safety Evaluation*. CMFPS is considering the possibility of submitting the entire Registry as a patient safety work product of high significance to patient safety, particularly to reduce medication errors, accidental poisoning, drug overdose, drug misuse and abuse, and the rate of non-adherence with prescription medicines. Technically, the raw UEM data recorded through the standardized collection form and sent to the Registry may be considered a unique patient safety work product. The patient safety evaluation becomes the process and protocol used in coding and entering data into the Registry. If this endeavor is accepted by the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services, UEM data will be the largest, single national database to be received by AHRQ and to gain federal protection.

CMFPS intends to continue to take the lead role in collecting and analyzing UEM data. Sound policy decision should be made based on evidence gathered through scientific methods and design. The Registry is a critical program to support the growing research in UEMs and to develop solutions to eliminate or reduce UEMs through intervention and eventually prevention at the front end of the healthcare delivery and pharmaceutical management system that involves providing proper medicines to patients and consumers.
3.3.3. An Information Repository for Healthcare Policy

Several agencies, including state and federal departments, academic institutions, and pharmaceutical companies, have expressed interest in the information contained in the Registry. Over time as more data are coded and entered into the system, data mining of useful information would demonstrate the true utility of this unique database. The following list illustrates the current use of the UEM data and consideration for other applications:

- The Centers for Medicare and Medicaid Services (CMS), as the primary payer for seniors’ prescription medicine plan, may better understand the actual cost and level of wasted medicines among seniors. The exact cost of buying medicines is often known and can be easily projected. However, the estimated cost of non-adherence and pharmaceutical waste is more difficult to calculate. The Registry provides the best estimation of wasted medicine by collecting data on the quantity of returned drugs and the estimated average wholesale price. Consistently from a number of samples, the rate of wasted medicines that are never used by patients and are thrown away is between 40%-50%.

- ONDCP has reviewed some UEM datasets to compare changes in prescription drug abuse, especially among teens. Data from the Registry showed the precise type and quantity of prescription medicines that are most attractive to teens in certain geographical locations. These medicines are most likely to be pharmed by teens. This office also learned about a more accurate proportion of FCS collected in drug take-back programs. No other database has direct information about FCS obtained directly from sampling communities.

- The Centers for Disease Control and Prevention (CDC) may use UEM data to augment its surveillance program in proper use and misuse of antibiotics. Patients often do not consume all the prescribed antibiotics and discard them improperly by flushing them down the sink or toilet. This practice promotes the emergence of drug-resistant bacteria, which poses a highly dangerous challenge to the healthcare system with nosocomial (hospital acquired) infections and the inability to treat certain infections.

- EPA is closely monitoring and conducting environmental risk assessments in communities where we are sampling UEMs and direct its resources to focus on the most prevalent types and quantity of UEMs that may enter the water system. UEM data may be used to initiate a long-term study of PPCP in the water and possible effects on humans when information, such as incidence of birth defects, miscarriages, cancer clusters, etc., from other independent public health databases are included. Furthermore, it behooves the EPA to closely follow drug take-back programs and ensure that the recommended method—controlled, witnessed incineration—is being employed correctly to destroy UEMs. One EPA office now requires any take-back program to register with CMFPS in order to qualify for funding.

- U.S. Fishery and Wildlife Service may better monitor and predict ecological and biological effects of pharmaceuticals on aquatic life indigenous to U.S waters. Of most concern is the endocrine-disruptor class of drugs commonly found in
hormone replacement products. Concentration in parts per trillion is necessary and sufficient to disrupt specific important food chains in fishery.

- U.S. Geological Survey has been studying water quality and the presence of pharmaceutical compounds in lakes, rivers, and stream since the 1970s. UEM data can enhance its water testing and surveillance system more precisely to the expected pharmaceutical products within the sampled communities.

- The FDA is responsible for safe food and drug products and may use our UEM data to improve its adverse drug reporting system. Presently, data about significant drug problems are submitted to the FDA mostly by doctors and physicians. The Registry contains data submitted directly by patients and family members about reported side effects and drug interactions to prescribed medicines. CMFPS has taken special notice of medicines, such as Accutane with several reported side effects of *suicidal thoughts and tendency*, and the biguanide antidiabetic metformin with *severe unusual muscle pain*. Researchers believe that if the Registry were set up two years earlier, it would have easily identified the Vioxx cases. Patients apparently exhibit a very low threshold to discontinue the use of their medicines. In addition, they are comfortable in reporting side effects to the Registry and not necessarily to their doctor or pharmacist.

- The DEA and the National Drug Intelligence Center (NDIC) monitor the national drug programs and enforce federal laws to ensure strict compliance to protect the public. An independent and reliable data source for the DEA would enhance surveillance for drug diversion and trafficking. The Registry, which has one of the most accurate sampling and estimation of what kind of FCS are present in the homes and communities, may be an ideal database. Furthermore, the methods used to sample UEMs provide the best estimation of the proportion of FCS post-market. Seldom do DEA officials know how much of FCS that have been prescribed and dispensed to patients are actually present at home and are most likely to be illegally diverted from home into the streets. The DEA may use the Registry to follow the operations and progress of existing and developing drug take-back programs to ensure compliance with federal laws concerning custody and proper disposal of FCS. Drug diversion will remain a major concern for drug take-back programs when law enforcement is not involved within the drug take-back system.

- Department of Health and Human Services, particularly SAMHSA, would benefit most from studying UEM data and evaluating the effectiveness of its drug programs in mental health. If mental health patients are not using their medicines and throwing them away, new medical programs and policies may be considered to save federal healthcare dollars and resources. Patients have reported their concerns about their medicines and the reasons they chose to discontinue their medical treatment. This information is vital to learn about root causes of non-adherence and devise interventions to improve therapeutic benefits of medicines for patients who need them the most. CMFPS is now studying the pattern of drug overdose cases in the communities and the possible link between the variations of UEMs, representative of the typical drugs that individuals may choose to experiment with and consume unintentionally to result
in overdose. Furthermore, CMFPS intends to study the impact of a drug take-back program on the community by correlating the reduction in overdose cases and the success of the take-back programs.

- U.S. Congress may use UEM data to better understand healthcare policies and evaluate the effectiveness of those policies. Senator Charles Grassley, ranking member of the Senate Committee on Finance, on April 21, 2010, sent an official letter of request to every state’s Medicaid office. He requested information about the prescriptions written and billed to Medicaid, 2008 and 2009 for the following drugs: Abilify, Geoden, Seroquel, Zyprexa, Risperal, OxyContin, Roxicodone, and Xanax (Appendix 5). Maine was one of the first states to respond to this request before the deadline May 5, 2010, and provide additional data directly from the Registry to highlight the amount of each of these medicines that were thrown away. U.S. Senate Special Committee of Aging held a public hearing on Drug Waste and Disposal: When Prescriptions Become Poison, June 30, 2010. The testimony by panelist Stevan Gressitt, M.D., Founding Director, Maine Institute for Safe Medicine, Faculty Associate University of Maine, Center on Aging, was based largely on data from the Registry. To see the actual hearing, visit the website http://aging.senate.gov/hearing_detail.cfm?id=326079. Transcription of testimony from Dr. Stevan Gressitt is provided in Appendix 7.

3.3.4. Limitations of the National UEM Registry

The core and strength of the Registry is the identification of the myriad of pharmaceutical products, prescription and OTC. Researchers anticipated that some products may have been taken off the market many years ago and that some illicit drugs would be part of any drug collection and eventually reported to the Registry. Researchers constantly scan publications of the DEA, NDIC, FDA, ONDCP, and the medical and pharmaceutical communities to stay informed about new drugs and recalled drugs. Managing the vast amount of data of different types of returned medicines was the most challenging task in setting up the Registry.

A major limitation of any registry is the extent to which the data and findings may be generalized or inferred. Because data are collected only from active participants of drug take-back programs, information in the National UEM Registry is not considered representative of any population due to incomplete sampling. There is no information about non-participants and their UEMs. The findings derived from the Registry can only be generalized to that population participating in the take-back programs.

Additionally, in most cases researchers were not involved in the actual collection of UEM. Therefore, they cannot verify the accuracy of the data submitted to the Registry. For this reason, they developed the standardized data collection instrument and methods, along with a detailed Manual of Procedures to assist organizers of drug take-back programs. Detailed instructions are provided to promote a standardized data collection that would be considered “adequate” to be coded and entered into the Registry. Despite the limitations, UEM data are still important and provide valuable insights into a significant public health and patient safety problem with unwanted medicines.
4. SENIORS AS A VULNERABLE POPULATION

American citizens spent 16% of our national income on health in 2007, compared to France, Switzerland and Germany, respectively 11%, 10.8%, and 10.4% (Pearson, 2009). The cost of pharmaceuticals is a major healthcare expenditure. According to McKinsey Global Institute (2008), the average price of 181 pharmaceutical drugs in the U.S. was 30% higher than the average in other Organization for Economic Cooperation Development (OECD) countries.

The U.S. national healthcare expenditure grew 5.7 percent to $2.5 trillion in 2009 (CMS, 2009). The Center for Medicare and Medicaid (CMS), Office of the Actuary, also projected that by 2019 our national healthcare expenditure is expected to reach $4.5 trillion, approximately 19.3% of our gross domestic product (GDP). Medicare spending of $507.1 billion and Medicaid spending of $378.3 billion are projected to have increased 8.1 percent and 9.9 percent, respectively, in 2009 (CMS, 2009) due to increases in enrollment.

Spending on prescription drug in 2009 by CMS will have increased 5.2 percent, up from 3.2 percent in 2008 to reach $246.3 billion because of greater consumption of antiviral medicines and higher prices for brand-name prescription medicines (CMS, 2009). As the economy recovers, healthcare expenditures related to prescription medicines will continue to grow at 5.6 percent until this rate reaches 7.7 percent by 2019.

This Special Report highlights the growing population of seniors and the impact of this population on the national healthcare cost, particularly in the area of prescription medicines. In the Background and Rationale (Section 1), the Report discusses the general issues of UEMs originating from excess amount of medicines and the concern for non-adherence to medical treatment. These issues are further magnified for senior patients and consumers. For the vast majority, the steady accumulation of prescription and OTC medicines are the symptom—not the cause—of what is wrong. Pharmaceuticals, for better or for worse, have become the central element in the treatment of primary, acute, long-term care and all phases of chronic care (Paone et al., 1999). Longer lifespan and better quality of life for seniors are equated to better management of multiple chronic health conditions. It is a fact the seniors are the largest consumer of pharmaceutical products, and naturally they would be the ones with the greatest amount of medicines at home.

4.1. Challenges for Senior Patients

The real problem is not about an increase or decrease in the use of pharmaceuticals, but about enabling appropriate pharmaceutical management as an integrated component of primary, acute, and long-term care healthcare services (Paone et al., 1999). This procedure does not determine the real causes of seniors’ medical problems or the most appropriate intervention to use. In the situation with UEMs, seniors tend to keep their medicines whether they use them or not. They also are the ones most apt to participate in a drug take-back program, given the right information, support and encouragement.

The following statements provide an overview of the magnitude and cost associated with the use, overuse, misuse and, sometimes, abuse of prescription medicines by seniors:

- The average person over 65 or older age takes between two and seven prescription medicines daily, often for chronic conditions, such as diabetes
and heart disease. Aging changes and slows down many body processes and affects how medications are absorbed, distributed, metabolized, and excreted (Minnesota Poison Control System, 2009).

- The elderly comprise 12% of the U.S. population but represent 34% of total expenditures for prescription medicines (Mueller et al., 1997).

- Seniors represent the highest-cost, fastest-growing segment of the population served by healthcare organizations (Bringewatt, 1995).

- Seniors consume more than 30% of the four billion prescriptions filled yearly in the U.S. (Maine Benzodiazepine Study Group, University of Maine, Center on Aging, 2006).

- By 2007, seniors were predicted to waste more than $1 billion worth of drugs (Gary et al., 2004).

- Almost 40 percent of all adverse drug reactions reported each year involve people over 60 years old (Minnesota Poison Control System, 2009).

- Extensive use by seniors of multiple medicines for multiple conditions prescribed by multiple specialists often causes drug interactions, drug/food interactions, allergic reactions, and overdosing. This problem is made worse by the steadily increasing access to more than 100,000 over-the-counter (OTC) drugs that can be purchased without a prescription. Combining prescription and OTC medicines can result in adverse effects that negatively affect a person’s health and safety (Mireles, 2006).

4.2. Stockpiling of Medicines by Seniors

Seniors may not fully understand why they are taking a specific medicine or precisely how and when to take it. Polypharmacy is common among seniors who may take as many as 10-17 medicines. There are four major reasons some seniors do not receive adequate instructions from their doctor, nurse, or pharmacist. One, they are not told why the medicine was prescribed. Two, they do not ask for an explanation. Three, they forget what they were told due to anxiety, being in a hurry, or other reasons. Four, they believe they can figure out what to do when they get home.

The gradual accumulation of UEMs in the home compromises physical health and personal safety of the elderly person and also family members through: 1) underuse – failure to take all medicines as prescribed; 2) overuse – taking multiple medicines from multiple doctors for multiple conditions; 3) misuse – illegal use of prescription medicines; and 4) abuse – diversion to the streets and illegal sale.

Anytime a patient does not take medicines as prescribed by his or her doctor, the therapeutic benefits from the medicines are eliminated. For example, if a senior patient is prescribed a beta-blocker as a maintenance medicine to control high blood pressure, non-adherence to this
medical treatment may result in a stroke. All medicines should be taken strictly as prescribed by the doctor.

Seniors, particularly the baby boomer generation, have experienced times of limited resources. They tend to be conservative and, sometimes, frugal with personal properties as well as with medicines. Medicines are valued highly and are kept indefinitely for the next health episode. Some seniors even divide their medicines or ration them in order to save money or save them a visit to the doctor or pharmacy.
5. UNUSED AND EXPIRED MEDICINES AMONG SENIOR PATIENTS

5.1. Results from Safe Medicine Disposal for ME

The Safe Medicine Disposal of Maine (ME), was funded by the EPA and involved the partnership among the Center on Aging at UMaine, U.S. Postal Service (USPS) and the MDEA. See [http://www.safemeddisposal.com/](http://www.safemeddisposal.com/). This statewide program, still active in Maine, is considered one of the most successful drug take-back programs in the nation. UEM data collected from this pilot study were transmitted to CMFPS for coding, entry into our National UEM Registry, and analysis. The original report was prepared for a special request of information by State Representative Anne Perry of Calais, Maine and for a public hearing at Maine State House April 14, 2009. The entire report was presented in a combined summary report to the Center on Aging, January 31, 2010.

For this Special Report, the authors abstracted data from the Registry specific to Phase I of the pilot study, which collected returned UEMs predominantly from seniors participating in the take-back program as promoted by the Center on Aging. Approximately 800 mail packages were received with a total inventory of 1,872 items (returned UEMs in the original dispensed container or package). The analysis shows a significant pattern of non-adherence among senior patients in Maine. The UEMs were characterized by type, quantity, potential environmental impact and cost. No population-based data for a denominator (total number of seniors who participated or were eligible to participate) were available for this Report. Therefore, the rate of non-adherence could not be calculated.

5.2. Most Frequent Medicines for Non-Adherence

Table 1 shows the top 10 UEMs by brand (trade) name or generic name. The standardized data entry and primary unit of analysis for the Registry are based on the individual packaged medicine returned to a drug take-back program. A typical example is an original pill bottle with unused or expired pills or a package of unused or expired medicinal product (e.g., a used tube of ointment or gel, bottle of cream or fluid). Lisinopril in the group of angiotensin converting enzyme (ACE) inhibitors commonly prescribed to treat high blood pressure (hypertension), congestive heart failure, and to improve survival after a heart attack is the leading medicine that patients stopped using and returned for disposal in this sample. Four controlled substances, including one benzodiazepine and three narcotic pain relievers are listed in the top 10 most frequently returned UEMs among seniors in Maine.

By pill count (an estimated of the number of pills, capsules and tablets), the total number collected from 1,872 UEMs was 74,696. Table 2 shows the top 10 UEMs by pill count. The top two UEMs are the beta-blocker Metoprolol used to treat angina (chest pain) and hypertension and to treat or prevent heart attack and the ACE inhibitor Lisinopril. Together, these two UEMs comprise nearly six percent of the total collected pills, tablets and capsules. Acetaminophen-hydrocodone, the fifth most frequently returned UEM by pill count is a controlled substance of high addictive potential and is considered one of the preferred prescription medicines for abuse and drug diversion, according to the DEA. Hydrocodone is classified as Schedule-II narcotic and must be regulated and monitored closely.

Incidentally, a typical acetaminophen-hydrocodone (500mg/7.5mg) tablet sold commonly as Vicodin is worth on most days $5 to $8 per tablet on the streets illegally. On Friday and
Saturday night, the price doubles and sometimes triples depending on the demand and supply of the drug easily obtained by teens from parents and grandparents. Therefore, a crude estimated street value of the 1,370 tablets ranges from $6,850 to as high as $32,880.

### Table 1. Top 10 Returned Medicines by Brand/Generic Name

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Count by Typical Package (%)</th>
<th>Brand (Trade) Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisinopril</td>
<td>43 (2.30%)</td>
<td>LISINOPRIL, PRINIVIL, ZESTRIL</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>40 (2.14%)</td>
<td>LOPRESSOR, METOPROLOL, METOPROLOL SUCCINATE ER, TOPRO XL</td>
</tr>
<tr>
<td>Acetaminophen-hydrocodone*</td>
<td>37 (1.98%)</td>
<td>ANEXSIA, HYDROCODONE/APAP, LORCET, NORCO, VICODIN, VICODIN DS</td>
</tr>
<tr>
<td>Warfarin</td>
<td>30 (1.60%)</td>
<td>COUMADIN, JANTOVEN, WARFARIN</td>
</tr>
<tr>
<td>Lorazepam*</td>
<td>29 (1.55%)</td>
<td>ATIVAN, LORAZEPAM</td>
</tr>
<tr>
<td>Furosemide</td>
<td>27 (1.44%)</td>
<td>FUROSEMIDE, LASIX</td>
</tr>
<tr>
<td>Nitroglycerin</td>
<td>25 (1.34%)</td>
<td>NITRO-DUR, NITROGLYCERIN, NITROGLYCERIN PATCH, NITROLINGUAL, NITROQUICK, NITROSTAT</td>
</tr>
<tr>
<td>Oxycodone*</td>
<td>23 (1.23%)</td>
<td>OXYCODONE, OXYCODONE ER, OXYCODONE HCL EXTENDED RELEASE, OXYCODONE HYDROCHLORIDE, OXYCODONE SR, OXYCOTIN</td>
</tr>
<tr>
<td>Acetaminophen-oxycodone*</td>
<td>23 (1.23%)</td>
<td>ACETAMINOPHEN-OXYCODONE, ENDOCET, PERCOCET, ROXICET, TYLOX</td>
</tr>
<tr>
<td>Prednisone</td>
<td>23 (1.23%)</td>
<td>DELTASONE, LIQUID PRED, METICORTEN, ORASONE, PREDNICOEN-M, PREDNICOT, PREDISONE, PREDISONE ANHYDROUS, PREDISONE DOSE PACK, STERAPRED, STERAPRED DS</td>
</tr>
</tbody>
</table>

* Indicates product’s classification as a controlled substance defined by the Controlled Substances Act of 1974.

### 5.3. Non-Adherence by Therapeutic Category

Using the DAWN classification system, UEMs were coded according to the standardized therapeutic categories. Central nervous system (CNS) agents, such as analgesics and muscle relaxants, lead the proportion of returned items (24%), followed by cardiovascular agents (19%), such as calcium channel blocking agents, beta-adrenergic blocking agents and diuretics. Figure 7 depicts the therapeutic categories by frequency of UEMs based on the typical package of the medicines. In the Registry, each UEM is coded to two additional therapeutic subclasses when available. Others (7%) include Nutritional products, Coagulation modifiers, Miscellaneous agents, Alternative medicines, Antineoplastics, and Immunological agents. Total count of UEMs and the denominator for the percentage is 1,872 returned medicines for the pie charts.
Table 2. Top 10 Returned Medicines by Pill Count

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Pill Count (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoprolol</td>
<td>2400 (3.21%)</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>1972 (2.64%)</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>1751 (2.34%)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>1639 (2.19%)</td>
</tr>
<tr>
<td>Acetaminophen-hydrocodone*</td>
<td>1370 (1.83%)</td>
</tr>
<tr>
<td>Metformin</td>
<td>1334 (1.79%)</td>
</tr>
<tr>
<td>Tramadol</td>
<td>1284 (1.72%)</td>
</tr>
<tr>
<td>Furosemide</td>
<td>1136 (1.52%)</td>
</tr>
<tr>
<td>Naproxen</td>
<td>1133 (1.52%)</td>
</tr>
<tr>
<td>Warfarin</td>
<td>1091 (1.46%)</td>
</tr>
</tbody>
</table>

* Indicates product’s classification as a controlled substance defined by the Controlled Substances Act of 1974.

Figure 7. Therapeutic Category of UEMs, Based on DAWN Classification System
5.4. Other Characterization of Non-Adherence

Figure 8 compares the marketing status of UEMs. The majority (86%) of UEMs mailed back to the Safe Medicine Disposal for ME were coded as prescription medicine. OTC medicines comprised 11%. UEMs coded as unknown contained medicines that were unidentifiable by standard marketing status according to the FDA’s classification system. Figure 9 shows the comparison of product forms of UEMs when they were received in the mailers.

Figure 8. Marketing Status of UEMs, Based on FDA Classification System

Figure 9. Product Form of UEMs, Based on FDA Classification System
Most seniors reported in a separated survey included in the free mailers that they returned their medicines because of expiration and because their doctors discontinued the current medicines and ordered new ones. They also indicated concerns for home safety with excess medicines around, as well as environmental safety if they improperly dispose of UEMs. The Safe Medicine Disposal for ME program took advantage of two important key aspects that made this drug take-back model successful: 1) virtually everyone in Maine has access to the post office and 2) the added security of having USPS handle the shipment and delivery of the mailers conveniently from the participants’ homes.

Figure 10 shows the characterization of the UEMs by classification according to the Controlled Substance Act of 1974. Of the total 1,872 returned UEMs in this collection sample, 250 (13.35%) medicines were coded as controlled substances. Only one item was identified as a Schedule-V medicine (not shown in the Figure 9). Thirty-six items had unknown FCS classification, and the remaining 1586 items were not FCS. Seniors appeared to trust the USPS in mailing their UEMs for proper disposal. Since the mailers were provided at no cost, the incentive to participate among senior was further enhanced. Compared to other models of drug take-back programs, a direct mail back is perceived to be more secure in the safety and comfort of home and by shipment with USPS. Hence, the proportion of FCS tends to be higher in mail-back system compared to other models.

![Figure 10. Federal Controlled Substance Classification of UEMs, Based on the Controlled Substances Act of 1974 (n = 250 items)](image)

5.5. Detailed Analysis of Central Nervous System Agents

To demonstrate the capability of the Registry, researchers analyzed the most frequently returned UEMs, the CNS agents, to the sub-therapeutic classes (DAWN Classification System). Four-hundred forty-eight items (24%) were returned by mail. Table 3 shows the precise characterization of the UEMs and the generic drug names. Names in red indicate FCS.
### Table 3. Detailed Characterization of Therapeutic Class-CNS AGENTS

*(n=448, 24% of total inventory, N = 1872)*

<table>
<thead>
<tr>
<th>THERAPEUTIC CLASS (Freq)</th>
<th>THERAPEUTIC SUBCLASS 1</th>
<th>THERAPEUTIC SUBCLASS 2</th>
<th>Example Drug(s) by Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNS agents (448)</td>
<td>Analgesics 330 (73.7)</td>
<td>Antimigraine agent</td>
<td>eletriptan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cox-2 inhibitor</td>
<td>celecoxib, valdecoxib, rofecoxib</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Misc analg combo</td>
<td>tramadol, acetaminophen/diphenhydramine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nonster. Anti-infam</td>
<td>ibuprofen, meloxicam, naproxen, diclofenac</td>
</tr>
<tr>
<td></td>
<td>Analgesics, Misc Combo 6 (1.3)</td>
<td>NSC* 1 (0.2)</td>
<td>etodolac</td>
</tr>
<tr>
<td></td>
<td>Anorexiants 1 (0.2)</td>
<td>NSC 6 (1.3)</td>
<td>acetaminophen</td>
</tr>
<tr>
<td></td>
<td>Anticonvulsants 39 (8.7)</td>
<td>NSC 1 (0.2)</td>
<td>phentermine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Barbit. Anticonvuls.</td>
<td>primidon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carbonic anhydrase</td>
<td>topiramate, zonisamide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>inhibitor anticonvuls.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dibenzazepine</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>anticonvulsants</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fatty acid derivative</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>anticonvulsants</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gamma-aminobutyric</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>acid analogs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hydantoin anticonvuls.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Triazine anticonvuls.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anticonvuls, Fatty acid derivative anticonvuls. 10 (2.2)</td>
<td>NSC 10 (2.2)</td>
<td>valsartan</td>
</tr>
<tr>
<td></td>
<td>Antiemetic/antivertigo Agents 16 (3.6)</td>
<td>5HT3 receptor antag. 8 (1.8)</td>
<td>granisetron, ondansetron</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anticholinergic</td>
<td>dimenhydrinate, meclizine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>antiemetics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antiparkinson agents 10 (2.2)</td>
<td>2 (0.4)</td>
<td>benzotropine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dopaminergic antipark. agents 8 (1.8)</td>
<td>carbidopa-levodopa, pramipexole, selegiline</td>
</tr>
<tr>
<td></td>
<td>Misc. CNS agents 19 (4.2)</td>
<td>Cholinergic agonists 2 (0.4)</td>
<td>cevimeline, pilocarpine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cholinesterase inhibit. 12 (2.7)</td>
<td>donepezil, galantamine, rivastigmine</td>
</tr>
<tr>
<td></td>
<td>Misc CNS agents 5 (1.1)</td>
<td></td>
<td>memantine</td>
</tr>
<tr>
<td></td>
<td>Muscle relaxants 16 (3.6)</td>
<td>Skel muscle relaxants 16 (3.6)</td>
<td>carisoprodol, cyclobenzaprine, methocarbamol</td>
</tr>
<tr>
<td></td>
<td>Muscle relaxants, skel. mus. relaxant 1 (0.2)</td>
<td>NSC 1 (0.2)</td>
<td>metaxalone</td>
</tr>
</tbody>
</table>

| Total 448 (100%) | Total 448 (100%) | Note: Percentage may not add to 100 due to rounding error. |

*NSC = no subclass classification indicated at this therapeutic level.*
5.6. Estimated Cost and Proportion of Wasted Medicines

The estimated magnitude of healthcare cost for medicines and the estimated proportion of wasted medicines by seniors residing in Maine are important variables in a study of non-adherence. Figure 11 clearly shows the estimated waste based on the quantity received in the mailers and the estimated original quantity in the standard packsize. This estimated waste of both prescription and OTC medicines is calculated based only on the number of pills, capsules and tablets. Therefore, the figure may be subjected to errors due to incorrect or inaccurate counting. For this sample, the proportion of wasted medicines, by pill form and pill count only, is calculated by dividing the quantity returned (49,480) by the estimated standard packsize (94,700) to obtain 52%. When only prescription medicines are examined, quantity returned (35,174) divided by estimated standard packsize (82,037) results in 43% waste.

![Figure 11. Estimated Proportion (%) of Wasted Medicines, OTC and Prescription Medicines Combined—Pills, Capsules and Tablets Only](image1)

The estimated cost of UEMs returned by seniors is illustrated in Figure 12 below. This estimate is based on average wholesale price (AWP). The total cost is $83,180.14. According to conventional market price mark up for retail, which ranges between 30% and 60% above AWP, our estimated cost of wasted medicines after purchase by seniors or third-party payer is between $108,134.18 and $133,088.22.

![Figure 12. Estimated Cost of Returned Medicines (US Dollars)](image2)
6. CONCLUSIONS

6.1. Unused and Expired Medicines as a Symptom of Systems Failure

Rarely does a new phenomenon afford researchers a peek into the operational status and weaknesses of the healthcare system. The national UEM study conducted by CMFPS since 2005 has provided researchers a fortuitous vantage point to observe and record some of the most perplexing problems related to manufacturing, distributing, marketing, using, stockpiling, and discarding prescription medicines in the U.S. The authors, at least, are certain this problem is not unique only to the U.S.

The study has been exploratory, mostly fact finding and hypothesis generating. As a natural experiment, the study has allowed researchers to observe the cause and effect relationship with various independent variables, such as interventions with new legislations, policies and community-based drug take-back programs. Researchers are now beginning the daunting task of analyzing and making sense of the dependent variables—patterns of drugs, behavior, cases of accidental poisoning, cases of drug overdose, number of arrest related to prescription medicine crime, amount of controlled substances in the neighborhood, types and amount of API in local waters, wasted medicines, loss in healthcare dollars, etc.

Pharmaceutical care is an essential component of the modern healthcare system. Medical treatment is an appropriate practice to prevent, cure and restore health. At the same, the cost of pharmaceuticals to improve, save and extend lives is a significant driver of the total U.S. healthcare expenditure. In fact, the total cost of pharmaceuticals is about 10% of the overall national healthcare expenditure. In 2008, this expenditure grew to $2.3 trillion or approximately 16.2% of our gross domestic product (GDP). No other country spends more on health care than the U.S.

U.S. healthcare system is considered the most technologically advanced and expensive healthcare system in the world, but it consistently ranks at the bottom among other industrialized nations. Experts are studying the dichotomy between cost and health outcomes. Rising healthcare costs and increasing health premiums rates coupled with high number of uninsured people (about 47 million Americans or 16% of the total U.S. population) are among the significant factors contributing to the need of health reform today. Health reform is viewed as an initiative towards improving the current system by fixing the parts attributable to poor quality, inefficiency, poor health outcomes and growing healthcare costs.

According to the Center for Medicare and Medicaid (CMS, 2010), Medicare spending grew 8.6% to $469.2 billion in 2008, or 20% of the total national healthcare expenditure. Medicaid spending rose 4.7% to $344.3 billion in the same year, or 15% of total national healthcare expenditure. The authors have taken a systems approach to their analysis that focuses on the pharmaceutical component of the healthcare system. In this Special Report, they provide insight and better awareness and understanding of the challenges faced by many senior patients regarding the adherence to medical treatment.

The fact that the elderly comprise 12% of our population but represent 34% of total healthcare expenditures relative to prescription medicines (Mueller et al., 1997) underscore the demand for affordable, effective and safe medicines. For seniors, having access to Medicare and Medicaid as primary payer of expensive medicines does not translate perfectly into appropriate utilization of medicines or adherence to treatment. Even with a catastrophic coverage with a modest
copayment required after the initial deductible and standard coverage through Part D, many are left unable to afford to fill needed prescriptions. Hoadley et al. (2008) discovered that in 2007, 15% of Part D enrollees in the coverage gap using prescription medicines in one or more of eight major drug classes stopped taking their medication. The authors believe their estimate will be significantly higher based on the findings of our study in Maine.

Non-adherence to medical treatment is a complicated problem for patients and caregivers. It also may be indicative of a failure of an important part of our expensive and highly complex healthcare system. At the individual level, it may be obvious that a patient chooses to discontinue his or her medicines prescribed by a doctor. However, the real reason for non-adherence can be as simple as poor patient-physician communication and relationship or as involved as with unexpected side effects or drug interaction. On the organizational level, researchers must examine this problem as a true symptom for something ominously wrong when costly medicines are prescribed, dispensed and never used by the intended patient. Based on data abstraction from the Registry, it is estimated that the rate of wasted prescription medicine is 43%—medicines that were literally thrown away.

6.2. Senior Patients and the Aging American Population

Based on U.S. census data, as of July 1, 2004, 12% or 36.3 million people were 65 or older and 4.9 million people were 85 or older. By the year 2050, 21% or 86.7 million Americans will be 65 or older. Even more alarming is that in the 65-and-over population, projected percentage increases between 2000 and 2050 will be 147% compared with an overall population growth of just 49%. The aging of our population is a trend seen across the globe as life expectancy increases for the majority of the people on this planet. In some nations, this situation can be disastrous when the birth rate cannot balance the quickly aging population. These nations must find a way to maintain and sustain their workforce and economic base, which requires younger, able citizens.

The care of elderly citizens would place a tremendous burden on the society in terms of demanded healthcare and economic resources. Issues of health access, quality, safety and disparity among senior patients surely would categorize this growing group as a vulnerable population. If younger people are viewed as more important and should be protected, health prevention and services may be redirected and provided more to children and young adults. For example, Europe is considering a new health policy to immunize only young schoolchildren against influenza given limited supply of the vaccine and the goal of protecting the population at greatest risk.

Elderly citizens and patients may become marginalized or disenfranchised by the healthcare system when resources become finite and restricted. Age has become a critical factor and determinant in medical decisions regarding certain surgical procedures, treatments, therapies and even certain diagnosis of a disease. In some cultures, the diagnosis of a particular cancer may not be disclosed to an elderly patient when a treatment plan is not considered a viable option because of the patient’s age, mental competency and demonstrative support network.

Cumulative lifetime exposure to environmental toxicants and the possible numerous co-morbidities already present in this age group make this population vulnerable for avoidance and neglect. Elderly patients may be easily viewed as complicated cases to treat and manage. One simple practice in the healthcare system is to prescribe more medicines to treat various conditions.
symptoms of co-morbidities, as witnessed in the growing trend today. It is known that a terminal elderly patient can be transferred to a hospice facility with more than four or five doctors still prescribe maintenance medicines, according to one gerontologist.

Non-adherence will remain a patient safety concern for elderly patients as long as they are required to manage the numerous prescription medicines by themselves or with some assistance. Regulations for nursing homes and most assisted-living facilities are highly restricted with how medicines are routinely administered to senior patients and by whom. In some settings, patients may go without medicines if a licensed nurse or doctor is not present to administer them and the patients cannot take medicines by themselves due to physical or mental dysfunction. State laws vary.

For the majority of seniors, most will enjoy good health and quality of life independently and in small community group settings. While the market and healthcare system provide an ample source of prescription medicines, seniors often choose not to adhere to the prescribed medical treatment simply because they do not understand completely why they are taking the medicines. To reiterate, the threshold for non-adherence due to an unpleasant side effect or drug interaction from a new medicine is very low. Some have suggested that senior patients may experience a cascading chain of side effects from different medicines, knowingly or unbeknownst to them. For example, a newly prescribed medicine caused a migraine headache. The patient sees a different doctor who prescribes an analgesic that causes a gastro-intestinal problem, and so on. For some desperate patients, being sick and seen by a doctor offers an opportunity to receive needed attention and care when other social support is weak or absent.

The study by the Center on Aging, UMaine has shown a concern for senior patients who must deal with a multitude of medicines to manage their health conditions. The over-abundance of prescription medicines for seniors will continue to pose a patient safety risk to them. Without proper assistance and appropriate resources, the behavior associated with non-adherence will magnify resulting in more wasted medicines and healthcare dollars.

6.3. The Ideal Drug Take-Back System

Considering the wealth of data that have been reviewed, most gathered for the first time by CMFPS, researchers are confident in comparing and evaluating different models of drug take-back systems. Information in the Registry has provided the opportunity to study various designs and to compare outcomes of many of the programs. The attributes of an ideal drug take-back system are:

- Convenience for participants in terms of accessibility and use
- Open to all members of the community
- User-friendly format and instructions
- Safety and security during collection and transfer of UEMs
- Widely-promoted and supported by and within the community
- Compliance to all state and federal regulations, particularly those pertaining to FCS and hazardous waste
- Involvement of law enforcement to minimize the possibility of drug diversion and ensure strict custody of FCS
- Sustainability with mission, vision, personnel and funds
- Strong partnership with community stakeholders and leaders
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- Standardized data collection system
- Research based
- Ability for replication and scaling
- Proper documentation and monitoring
- Destruction of UEMs by approved, efficient and effective method, such as incineration, and
- Ability to report and share new findings, including special alerts about unusual or new side effects or drug interactions, as well as identified best practices

From the annual survey conducted by CMFPS, most existing take-back programs do not have all the desired attributes. Many are considered experimental and ad hoc; most will quietly disappear as the competition among programs grows. The authors have termed this period of our data collection as the “trial-and-error window” or the “wait-and-see time” of a natural experiment as an opportunity to witness and study the emergence and evolution of drug take-back systems.

The authors predict that eventually only the strongest and most resilient program will persist and perhaps monopolize the manner by which all consumers’ unwanted drugs are returned and destroyed. The dominant programs will achieve some degree of recognition and will have some political support in term of funding. While mounting evidence suggests that the private sector will lead the development of a national drug take-back system under an ambitious vision of an integrated waste management system, the authors also suspect that state and federal government would soon intercede by introducing new legislations to maintain oversight of such a national system.

The consensus of the research team is that the direct mail-back model is the most superior model compared to others. Although further refinement and modification of the operational procedures and sampling methods to collect needed information about UEM will be required, the direct mail-back system, such as the Safe Medicine Disposal for ME, stands in a class by itself as an exemplary model. See Section 2.5.

The Safe Medicine Disposal for ME has allowed drugs to be returned from patients and consumers, particularly senior patients, directly to one state agency, which reduced coordination costs and provides for secure collection and consolidation of the collected UEMs. In Maine, the MDEA has statewide jurisdiction and was involved from the outset in concept development to solidify the law enforcement participation and support. This partnership with MDEA already has facilitated a closer review and subsequent approval of this program by the federal DEA. The statewide mail-back model offers an unmatched, centralized coordination feature, ensures the element of confidentiality and anonymity not found with in-person, drop-off models. Overall, the direct mail-back system demonstrates the least burdensome of all take-back models in terms of perceived security, convenience and reliability from participants, namely senior citizens and patients. Furthermore, the collaboration with the USPS strengthens the program’s structure by including another federal group in the system. Mailing letters and boxes is an all too-familiar exercise for seniors on a daily or weekly basis. Yet, the most impressive aspect of this statewide mail-back system is that there is no cost to the patients, for now. Among seniors, this attribute alone appears to be adequately sufficient to generate the degree of support and participation, as reported in the response rate or return rate of the distributed free mailers at 42%.
7. RECOMMENDATIONS

Problems and concerns among patients, particularly senior patients, discussed in this Special Report have existed for many years, and, without immediate intervention, will only worsen in the years ahead. Experts are calling this problem “pandemic” because of the global burden placed on society, healthcare infrastructure and the environment as more people live longer and would demand improved quality of life (Mireles 2007). Unfortunately, the magnitude of these problems and efforts required to create and implement alternative ways to effectively deal with these problems is both time consuming and expensive. However, a systems or macro perspective considers the entire sequences of events in the prescribing process, from beginning to end. In this way, symptoms of the problem are easily separated from the real problems, allowing the actual problems to be clearly identified and resolved in a timely manner. The premise is based on the observation that UEMs are an indicator or symptom of a systemic failure of the U.S. healthcare system.

7.1. Healthcare Innovations to Address UEMs

From years of investigation, literature review, consultation with healthcare authorities, and prominent stakeholders in addressing UEM, the authors offer six innovative ideas and recommendations to immediately alleviate the burden on our healthcare system with wasted medicine and lost healthcare dollars. Forward thinkers and progressive visionaries in healthcare and beyond are now seriously contemplating the following five innovations, which have a compelling rationale embedded with principles and values of patient safety and healthcare quality. These innovations are provocative yet sensible to further challenge individuals and organizations to re-evaluate our attitude and behavior concerning medicines in general and specifically UEMs at the end-of-life cycle for these products.

7.1.1. Integrated Pharmaceutical Care

The need to integrate pharmaceutical care into seniors’ overall healthcare plans would reduce duplication of medicines taken on a regular basis and reduce unexpected, possibly harmful effects, such as overdose or forgetting to take medicines both prescription and OTC.

The vision and framework for a systems-based model for pharmaceutical care based on the belief that the full value of pharmaceutical therapy is best achieved by organizing care around the person is clearly outlined by Paone et al (1999). The Institute of Medicine (2000) and our Foundation strongly believe and support the inclusiveness and practice of patient-centered medicine. This type of care focuses on disability prevention, health maintenance, and extends smoothly across setting, across providers, and over time.

Although this model has yet to be fully implemented, progress is being made on integrating pharmaceutical care with all other care decisions in order to improve the effectiveness of therapy. When diseases can be diagnosed and related conditions identified at an earlier stage, appropriate therapies can be prescribed more quickly. Thus, further physical and mental deterioration and time needed to perform or resume normal activities of daily living and both time and associated costs are reduced.
Specifically related to UEM issues, seniors should be afforded a drug take-back system, such as Safe Medicine Disposal for ME. To manage excess medicines and unwanted medicines through an integrated pharmaceutical care that emphasizes improved communication among senior patients, doctors and pharmacists, a drug take-back system is needed to remove UEMs from home and out of the neighborhood. This system must be convenient, safe and extremely user friendly for seniors.

7.1.2. Patient-Centered Medical Home

Medical Home is not a location. It is a well-researched and documented method to build relationships with personal physicians that uses a whole person orientation. In 1967, the Medical Home was introduced by the American Academy of Pediatrics (AAP) to set up a central location to archive a child's medical record. In 2002, AAP expanded the concept to include accessible, continuous, comprehensive, family-centered, coordinated, and culturally effective care. In 2004, the American Academy of Family Physicians (AAFP) introduced “medical home”. In 2006, the American College of Physicians (ACP) introduced “advanced medical home”.

The joint principles in key concepts of Medical Homes issued by the AAP, AAFP, ACP, and the American Osteopathic Association (AOA) extend to all children, youth, and adults. This holistic approach emphasizes:

- Ongoing relationship with personal physicians
- Physician-directed medical practice
- Whole person orientation
- Coordinated care across the health system
- Quality and safety
- Enhanced access to care

With appropriate leadership and a supportive organizational culture of patient safety, Medical home could be readily implemented in any medical community. Size is not a limiting factor. Pertaining to UEMs, patient-centered medical home is a good model to provide a comprehensive and continuous care for senior patients that include strict management of medicines prescribed by a healthcare team working together to benefit the patients. The goal is to reduce the number of prescription medicines to only those medicines that must be taken in order to restore health and to maintain the quality of health.

7.1.3. Patient-Centered Healthcare Community

While the patient-centered medical home emphasizes continuity of care, our patient-centered healthcare community elevates this concept of care to the community and society. Using the original concept of Community of Competence™ (CC™) and CMFPS’s community education and outreach concept of C.A.R.E. with the four basic educational goals and strategies (build the Community, increase Awareness, instill Responsibility, and Empower individuals), issues in healthcare must be addressed on the social and organizational levels. The primary objective of the patient-centered healthcare community is health and wellness by incorporating the following premises (Mireles and Smith, 2010):
• Foundation based on CC™ and the intrinsic values of community and competency to create, support and sustain an environment for healing, restoring health and maintaining the quality of life
• All patients (individuals) need more than a home; they need a community—we all belong to a larger community
• Key strategies include primary prevention, education and empowerment

In taking the public health approach, sickness is not an isolated phenomenon. It is a larger experience of the individual and the community. Social and health determinants (biological, environmental, lifestyle and healthcare organization) play an enormous part in how and why a person becomes sick or injured (LaDonde, 1974). The traditional view of the biomedical healthcare system has to change in order for us to improve health outcomes.

Environmental conditions and factors contribute significantly to a person’s health. Clusters of certain cancers can be seen in the physical environment of some communities. Neighborhoods plagued with the social environment of domestic violence, physical abuse and neglect also see the highest rate of homicide and trauma. Symptoms of poverty, violence, ignorance and incompetence are determinants and predictors of poor health and premature death. Yet, these symptoms are seldom, if ever, taken into account when a person is diagnosed with an illness or injury.

In this sense, UEMs, too, are only a symptom of a systemic problem in the healthcare system. Drug take-back programs should be considered a temporary solution to a larger, more complex problem within an already complex system. UEMs are certainly an important health concern and a significant patient safety issue, immediately (accidental poisoning) or in the long term (chronic low-level exposure to API).

A patient-centered healthcare community would allow and encourage any member of the patient’s healthcare team, including the patient and family members, to participate and contribute their expertise and knowledge. This community also satisfies our fundamental needs for a true community where we feel comfortable, are supported, and can engage in worthwhile, rewarding activities, regardless of our current health status. Open discussion about medicine should be the norm of this healthcare community. Over-prescription or inappropriate prescription (duplicates or drug interaction from multiple prescriptions) would be prevented when all parties come together and communicate what is best for the patient, and best for the community.

Communities such as this would support and sustain an environment for healing, restoring health, and achieving and maintaining a higher quality of life. Social and emotional support could be provided by other community members and by outside support systems of family, friends, and other caregivers. Benefits of a patient-centered healthcare community include:

• Emphasis on integration and continuity of care within a nurturing community of competent caregivers and patients
• Advantages in sociometric and social support
• Better use of human and healthcare resources
• Access to experts and available services
• Cradle to grave monitoring
• Network with other medical communities (global)
• Ability to learn, share new knowledge faster
Save healthcare dollars and lives

The logical focus of the patient-centered healthcare community may begin with healing a sick person and restoring good health. An ideal healthcare community really focuses on health and wellness. It also strongly promotes a new paradigm that an illness or injury to person is a larger experience and has some impact on others within the community. If it takes a village to raise a child, it also takes a village to care for a sick or injured person.

7.1.4. A National Drug Take-Back System

An operational national drug take-back system, similar to those in Europe, is the logical next step in the solution for UEMs. Federal authorities should examine closely the success of Safe Medicine for ME and evaluate other models of drug take-back systems.

A unified and standardized system to return UEMs would be an essential aspect of an integrated pharmaceutical care system. Such a system may help detect immediately the type of medicines that are not used by patients so doctors may adjust the prescription. A national drug take-back system should be adequately funded and promoted consistently with the same message highlighting the benefits of getting rid of UEMs. Moreover, this public message should emphasize primary prevention to reduce excess medicines at home and work.

A vital part of this national drug take-back system is a well-designed database or data repository to record UEM data for research and surveillance. The best model of this database is the National Unused and Expired Medicines Registry. A national drug take-back system may build upon the enormous databank stored within the Registry and begin to look at patterns and trends and do state by state or regional comparison.

Despite current discussions among experts of a possible multi-state drug take-back system or a combination of drug take-back programs, the authors strongly believe one primary national drug take-system would be more cost effective, logistically manageable and efficient in collecting and destroying UEMs. This decision most likely would be dictated by the federal funds and political oversight from the leading federal agency. However, several private corporations have contacted CMFPS within the past several months with great interest in the Registry and their preliminary plan and possible intention of leading this national effort.

7.1.5. A National Center for Safe Drug Disposal

To oversee and direct the design, implementation and operation of a national drug take-back system, a national center for safe drug disposal must be considered and established. Similar in purpose and functions as the prescription medicine-monitoring program, this national center can provide an independent prescription medicine surveillance system to detect abuse and waste. The nascent Maine Institute for Safe Medicine is a logical model. The authors support Stevan Gressitt, M.D., as founder director of this Institute and the location in Maine for this Institute, where the annual international symposia on safe drug disposal are held. Again, Maine has been the outstanding leader in this field. The Maine Institute for Safe Medicine can also serve as a working model of a state and federal, private and public collaborative enterprise for other countries closely following the progress in the U.S.
The Maine Institute for Safe Medicine may serve as permanent repository for CMFPS’s National UEM Registry. The Maine Institute, providing a national model for responsible collection and disposal, and data gathering, could be replicated in other countries to facilitate cross-national comparison of medicine consumption and non-adherence. For example, it could produce world-class research and facilitate policy-making opportunities, encourage and support dialog between federal and state regulatory entities, and build credibility beyond the governmental level.

The Maine Institute for Safe Medicine may collaborate directly with a number of federal agencies, such as the EPA, FDA, ONDCP and DEA, as a field data collection site for information about post-market pattern and trend of certain drugs of interest. Data gathered and compiled by the Maine Institute will be used for research and policy development. UEM research through academia, pharmaceutical companies, government, and nonprofits would be enhanced with data made publicly available and accessible, given sufficient funding and political support.

One important first study that may be conducted by the Maine Institute is the high rate of non-adherence among seniors. This Special Report shows that seniors waste approximately 50% of their prescription medicines should be of great interest to CMS and other agencies involved with payment for prescription medicines. This situation is not likely to change or improve any time soon. Funding to establish the Maine Institute for Safe Medicine is critical, and it must be initiated as soon as possible.

7.1.6. Change in Legislations

New legislations could be enacted, or current ones could be modified to promote and support drug take-back programs in the U.S. At the state level, enabling laws are necessary to highlight the benefits of a safe and legal drug return system, but legislations to ensure adequate funding of such a system are more crucial to demonstrate the commitment, stewardship and commitment to constituents of the state.

Nationally, the federal government must exhibit some leadership to endorse and guide the development of a unified drug take-back system with a standardized data collection. Unlike other countries, U.S. government has involved law enforcement in a close-loop pharmaceutical system in order to monitor controlled substances. The DEA plays a unique role in this pharmaceutical system and has tremendous influence over who can and cannot handle, receive and possess controlled substances.

One effective recommendation for immediate consideration is the modification of DEA exemption regulation for first registrants: Code of Federal Regulations (21 CFR Part 1300), Section 1301.24: Exemption of Law Enforcement Officials. Presently, this exemption allows law enforcement officers to engage in activities related to the collection, transportation and destruction of controlled substances. This law can be modified to extend the same authority and privileges to non-law enforcement agents and agencies.
7.2. What Can We as a Community Do Together?

In general, three major ways to effectively deal with the steadily increasing use of medicines and proper handling of UEM:

- Take personal responsibility to learn as much as possible about the medicines prescribed and make intelligent, informed decisions about usage and disposal. Then, tell others what you have learned and encourage them to tell others.
- Actively spread the word about the major problems and concerns regarding inappropriate personal use and disposal of UEM.
- Be knowledgeable about and openly discuss and demonstrate concerns about the hazards UEM pose to our environment.

7.3. Individual’s Responsibility

An informed, cautious person makes intelligent decisions about their own safe use of prescription medicines and often shares what they have learned with others. Suggestions for everyone, not just seniors:

- Establish open, two-way communication with your doctor, nurse, pharmacist, and supporting healthcare professionals. Ask questions about the need for medicines, benefits, possible side effects, adverse reactions, and expected therapeutic outcomes. Read available handouts, take notes, and write reminders to ensure you take your medicines exactly as prescribed.
- Before getting a new prescription or renewing existing prescriptions, discuss with your doctor or pharmacist the plusses and minuses of medicine that may be prescribed.
- Discuss with your doctor or pharmacist the merits and possible limitations of non-prescription alternatives, such over-the-counter medicines, nutrition, exercise, or other proven therapies, or regimens, and use of alternative medicines, such as herbal supplements.
- Be aware of the symptoms and signs of under use, overuse, misuse and abuse among family and friends and suggest referral to impartial, trusted health professionals for help.
- Continuously monitor medicine being taken to minimize risk of under use (failure to take medicine as prescribed), overuse, misuse, and abuse.

7.4. Environmental Stewardship

Harmful chemical ingredients from UEM may seep into our drinking water supplies when flushed or discarded in the trash or disposed in landfills. Eventually, UEM end up in streams, lakes, or other bodies of water. Up to 90% of every drug taken is excreted unchanged and may end up in
ground water. No local, state, or federal government agency is equipped or funded to measure and document the type, amount, or potentially harmful chemicals in UEMs that have the potential to damage the environment or pollute drinking water.

Ways to minimize environmental impact and increase public awareness:

- Become active in grass roots efforts to learn more about UEMs and appropriate take-back programs. Become involved in credible, environmentally responsible, or “green” programs.

- Learn about and educate others about the “precautionary principle” and “environmental stewardship”. Health education and promotion are key components in any preventive program or intervention designed to change the status quo.

- Develop programs designed to improve the current behavior, thinking, and common practices associated with prescribing, dispensing, and consuming medicines.

- Speak out for and endorse CMFPS’s guidelines and recommendations to discourage any attempt to collect UEMs, especially from the home for the purpose of recycling and/or donating the medicines from home to anyone. Such donations are considered illegal and unethical based on the standard of care and safety.

- Support, as does CMFPS, legally monitored, controlled, witnessed incineration of UEMs by law enforcement or other legal, authorized groups. Although currently expensive, controlled incineration will increase the likelihood that harmful chemicals in UEM will be consumed and minimize contamination of landfills, land or water.

- Endorse ideas that promote the values and principles of product stewardship to reduce the health and environmental impacts of consumer products, including medicines. Adopt the common-sense approach to solving waste management problems associated with UEMs by advocating better and safer product design changes and support communication among stakeholders in order to encourage drug manufacturers to take increasing responsibility to reduce the entire life-cycle impacts of a pharmaceutical product and its packaging – energy and materials consumption, impact on air and water, the amount of toxicants in the product, worker safety and waste disposal.

- Learn about and practice green pharmacy and green health care that take product stewardship, personal health, medical practice and pharmaceutical waste management into one concept of sustainability for the patient, community, and environment. Physicians and patients must be made aware of options in medicines that place a lower burden of harm to aquatic life. Ultimately, to minimize wasted medicines, we must diligently reduce over-prescribing, over-reliance, and over-consumption of medicines.
7.5. Some Predictions and Closing Thoughts

This Special Report contains important facts and health statistics that are alarming. It is indeed concerning to know that U.S. citizens consume nearly half of the world’s supply of manufactured prescription medicines, and even more alarming that seniors consume 34% of the total expenditures for prescription medicines (Mueller et al., 1997). The authors cautiously predict that this steadily growing pandemic in the use and nonuse of prescription medicines, particularly among seniors, will eventually be curtailed naturally through social responsibility or by legislative intervention.

When the pendulum swings too far toward what is considered a crisis, such as the current expansion in the creation of new drugs, doctors’ prescribing rationale, and the perceived or actual need to take more and more prescription medicines, the pendulum always swings back to a less extreme position. History has proven that given enough accurate, readily available, timely information, most concerned people will accept social responsibility as the morally correct action, and do what is good for themselves and then for business. Social responsibility encompasses people, planet, and profits, and is part of the “new wave” of thinking, or must be part of the equation for sustainability.

The authors are the first to openly admit that it is impossible to accurately predict the future, discuss possible scenarios, and provide realistic suggestions and solutions without starting with the facts. Changing our highly bureaucratic, top-down, 150-year old, profit-centered healthcare model will be difficult. The healthcare system must be reformed from within, starting with patients and their families, the only true customers of health care, not with insurance or other third party payers. Longstanding silos or barriers endemic to health care and government can be broken down through improved and effective communication, collaboration, and sharing knowledge and “best” practices.

To change our status quo, it is necessary to take a new, holistic approach that provides both a framework for change and the energy or motivation to implement change. Patscot, Vice-President of human resources for General Electric Healthcare Americas, states the two essential elements in change strategy are the technical components in management, such as planning, budgeting … problem solving, and the cultural components of leadership involved with aligning organizational culture (Donahue & Yelton, 2010). A cultural strategy reinforces effective, lasting change by engaging and aligning key stakeholders shown in Figure 1 with a shared vision for the future and then mobilizing and motivating them to make that vision a reality. The shared vision of safely and legally removing UEMs from the home, workplace, and other locations will reduce adverse effects resulting from misuse, overuse and abuse. Wasted medicines and healthcare dollars can be reduced by directly and boldly addressing the true problems of non-adherence, and not just the symptoms of a systems failure.

The real problems clearly identified in this Special Report can be resolved by visionary leaders who make informed decisions using lessons learned from leading industries, researchers, patients, families, and healthcare practitioners. These visionary leaders must involve as many stakeholders as possible in creating a wide range of scenarios or ways to address and solve problems facing our healthcare communities. Undisputable facts presented in the report and summarized below should be used in all planning and implementation efforts. Proposed actions should be reviewed and the “best” scenarios selected for further examination and critical evaluation before action plans are created, implemented, and accepted. It is important to use the iterative process of planning, implementing, checking, and reviewing solutions in order to
continuously modify and improve results. What can be learned in this process may produce new ideas that can be incorporated into sustainable and cost-effective solutions. The authors have offered six previously described outstanding, provocative innovations to begin the journey to change.

Some modest predictions are based and constructed on the best-scenario situation in health care in the decades ahead:

- Despite the constant concern with the shortage of nurses and doctors, especially geriatricians, the authors anticipate a shift in the empowerment of patients, families, and individuals in general toward a more positive attitude and behavior regarding their health status. Initiatives, like the C.A.R.E. campaign, are being expanded and adopted by true communities of responsible, engaged, and civic-minded members.

- The new organizational concept of Communities of Competence™ is providing the framework and roadmap for necessary changes in health care. Community is a metaphor for group or organization. Everyone belongs to a community no matter how it is defined, constructed, and utilized for change. Additionally, members will demonstrate their expertise, unique talents, leadership and competencies in ways that would benefit the community. These new healthcare communities will be global, connected by a shared vision and desire to be safe and healthy in a world challenged with disparities and limited natural resources (e.g. clean water, food, and energy).

- Medical decisions will eventually involve the true customers of healthcare—the patients. These decisions will be shared and based on respect of the patient and accurate information that can be understood by the patient and family members. In many cases, patients and their families are the only ones who have most of the information about their health status and their ability and desire to adhere to a medical treatment.

- Medical technology and future breakthroughs will transform healthcare faster than at any time in the past. Pharmaceutical care some day may be tailored and customized for a single patient. Medicines may be made on the spot using nanotechnology and genetic engineering to ensure the highest level of safety and efficacy. Polypharmacy may be a concept soon to be forgotten when medicines are indicated and used appropriately and judiciously for the right reasons.

- Health information technology will provide around-the-clock care and management of senior patients. New diagnostic and treatment procedures may become automated giving patients ready access and control of their health decisions and options. We expect the best model of an electronic medical record system will be designed and introduced by patients themselves. Health information is expected to become the domain of the individuals, within a well-developed network of sophisticated data points, nodes and repositories that caregivers and healthcare organizations may access. CMFPS is leading the development of a patient safety recording system where patients can connect, learn from each other, and offer advice and support.
The real health reform and achievement will be measured in the satisfaction of patients and caregivers. The enduring changes will be seen in a paradigm shift or cultural realignment of values and purpose of a new and improved healthcare system, one that is truly patient-centric, compassionate, effective, and safe. More attention will be given to “taking care of the caregivers” thereby allowing healthcare professionals to perform their important duties of care as competently and professionally as possible. Part of this prediction is based on the fact that seniors will be working longer; some will never retire. Older nurses and doctors will continue to practice given the right work environment, support and motivation to stay as productive as possible.

Patients, in particular seniors, will create new social communities to extend family and friends based largely on the CC™. Instead of isolation and loneliness, seniors will galvanize toward a life of continued independence and self-reliance within support groups. These groups will organize and expand to teach and learn from each other. Peer-to-peer education and information sharing and social networking that value and care for each member will increasingly become the foundation of the communities. The essence of community will be demonstrated by these groups committed to growing and maintaining the quality of life and productivity among seniors.

A new wave of stewardship and a transformation of the attitude about medicines would be realized as patients advocate and adopt the practice of holistic or comprehensive health care that includes environmental conservation and protection. New therapies and natural healing processes will be discovered that allow patients to incorporate their health beliefs, spirituality, culture, personal values and experience in their overall health management. Primary prevention of a disease and injury slowly becomes the rule, not the exception. Some are putting the “compression of morbidity” into practice by engaging in prudent lifestyles and reducing risky behavior. It is very possible that seniors will enjoy their lives with minimum episodes of illness until they reach the end of life.

Finally, the authors predict with great hope that the epidemic of UEMs will eventually be resolved when caregivers, patients, families, and communities come together and work cohesively to address the real health problems. Improved communication and relationship between patients and caregivers will result in a more humane health care, ultimately reducing medical lawsuits, healthcare fraud, and healthcare waste.

The authors are confident that within their lifetime, a national drug take-back system will be designed and implemented. The efforts of courageous individuals who will develop and operate this system will be recognized. Problems, such as non-adherence as measured by the amount of returned UEMs, would be quickly detected and corrected. The system will be regarded as a surveillance model, a national healthcare database, a foundation for continued research and discoveries, and a learning tool to remind U.S. patients and our society that there is a good possibility that Americans really may not be that sick, compared to the rest of the planet. UEMs are a modern problem that requires combined efforts and commitment from all communities working together and sharing responsibilities. Everyone must be involved and must work toward the same solution.
8. REFERENCES


Mireles MC and Smith EA (2010). *The medical home model: A new approach and innovation to patient-centered care or just another patient safety hype?.* Presentation at the Elizabeth A. Smith Patient Safety Colloquium, Texas Woman’s University, Texas Medical Center, Houston, TX, April 20, 2010.


Appendix 1: Glossary of Terms

**Aging Initiative** – a special outreach program of the U.S Environmental Protection Agency (EPA) to protect the environmental health of older persons. A major goal of the Aging Initiative is the development of a National Agenda for the Environment and the Aging. The National Agenda will prioritize environmental health hazards that affect older persons, examine the environmental impact of an aging population in a smart growth context, and encourage civic involvement among older persons in their communities to reduce hazards.

**Annual Drug Take-Back Survey** – a one-page hardcopy or electronic data collection instrument distributed in 2007 - 2009 to identify active community-based drug take-back programs in the U.S.; results from the Survey are summarized and published in *the National Directory of Drug Take-Back and Disposal Programs, First Edition, 2008*.

**Anonymous** – not identified, named or acknowledged in order to protect the privacy of a person.

**Benzodiazepine** – a category of depressants that are used therapeutically to produce sedation, induce sleep, relieve anxiety and muscle spasms, and to prevent seizures. In general, benzodiazepines act as hypnotics in high doses, anxiolytics in moderate doses, and sedatives in low doses.

**Bioaccumulation** – the concentration of a substance in adipose tissue of aquatic organisms; technically, bioaccumulation is assessed according to the OECD based on the partition coefficient n-octanol/water (Pow), in which substances with log Pow>3 are judged to be potentially bioaccumulating (OECD test 107 or 117).

**Center on Aging, UMaine** – a university-wide, interdisciplinary center at the University of Maine, specializing in aging education, research and community service. The mission of the Center is to promote and facilitate activities on aging in the areas of education, research and evaluation, and community service to maximize the quality of life of older citizens and their families in Maine and beyond.

**Community of Competence™** – a new organizational framework and methodology to describe, assess, and combine separate strengths and core competencies of individuals, groups and organizations into a meaningful whole to solve a problem or complete a project. The methods and framework of Community of Competence™ is used in all of our research, educational, and outreach programs. Trademarked by Elizabeth A. Smith, November 8, 2005.

**Community Medical Foundation for Patient Safety (CMFPS)** – established in December 2003 as a nonprofit 501 (c)(3) tax-exempt, active learning organization based in the Houston area and a leader in patient safety research and education. Its mission is to promote and support patient safety through research, education and the demonstrated practice of patient-centered health care. On behalf of the Secretary of the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality has recognized and listed Community Medical Foundation for Patient Safety as Patient Safety Organization #29.
Glossary of Terms (Cont.)

**Environmental hazard** – the inherent potential of a substance to damage the environment, assessed by three variables: persistence in the aquatic environment (P), bioaccumulation in aquatic life (B) and toxicity (T) in water; each variable is assigned a numerical value (0–3). The total of these values constitutes the PBT index for the substance.

**Environmental risk** – the acute toxic danger to the aquatic environment, based on the ratio between predicted environmental concentration of the substance (PEC) and the highest concentration of the substance that does not have a harmful effect in the environment (PNEC).

**Federally controlled substance** – the classification of a pharmaceutical product by the U.S. Drug Enforcement Administration according to the Controlled Substances Act of 1974, based largely on the addictive property of that pharmaceutical product or major active ingredient(s) of that product and the propensity of the product to be abused and diverted from appropriate use and custody of the product.

**Medical Home** – introduced in 1967 by the American Academy of Pediatrics, medical home was set up as a central location for archiving a child’s medical record. This concept has expanded to include a whole person orientation to coordinate care across the health system that facilitates ongoing relationships with personal physicians. This concept is further described on the body of this report. Note, medical home is not meant to be “home”, but a way to coordinate and all forms of healthcare delivered by doctors and to facilitate communication and record keeping.

**Medicare Part D** – administered by the Center for Medicare and Medicaid Services, Part D allows seniors to receive their prescription drugs at a reduced cost. Common prescription medications are covered in part or in full, through the use of generics or name brand medications that are commonly prescribed to seniors. For instance, the plan covers 75% of the prescription costs above $250 per year. Specific calculations are made for other levels of costs.

**Medicine or medication** – the overall term used to describe any type and form of a prescription and non-prescription substance or product indicated for treating an illness. “Medicine” is used through this report includes all forms: pills, capsules, labels, inhalants, gels, ointment, salves, lotions, and other substances used for therapeutic purposes.

**National Directory of Drug Take-Back and Disposal Programs, First Edition** (2008) – 91 pages, was published by CMFPS. Our one-page 2009 Annual survey was sent electronically to individuals, groups, and organizations known to be directly involved in take-back programs, 66 of whom responded. Responses to a the following survey questions were presented in tabular form: 1) collection methods, 2) collection schedules, 3) type of destruction, 4) involvement of law enforcement, 5) type of program, 6) primary purpose of program, 7) funding sources, 8) UEM classification, and 9) participation on the National UEM Registry and other variables. The National Directory also lists the 84 commercial reverse distributors by state and other useful resources for drug take-back programs.
**Glossary of Terms (Cont.)**

**National Patient Safety Directory, First Edition** (May 2010) – 127 pages, published by CMFPS. From March 2008 to March 2010, the Foundation conducted a survey of patient safety programs and organizations in the U.S. Results of this survey include official lists of patient safety programs; Patient Safety Organizations (PSOs); selected U.S. and European healthcare organizations, associations, and agencies; U.S. Health Departments; hospital associations; medical, nursing, and pharmacy review boards; and a calendar of patient safety and health observances.

**National Unused and Expired Medicines Registry** – a national repository of data concerning unused and expired medicine, established in 2005 by CMFPS. A standardized data collection method and format is used to improve the consistency and uniformity of information gathered from community-based drug take-back programs. Currently, the Registry contains nearly 30,000 items with an estimated total pill count of approximately 3 million.

**Prevention** – the espoused goal of health care and public health to promote, preserve and restore health and minimize suffering and distress, namely by minimizing the probability and risk of disease and injury.

**Over-the-counter medicine or non-prescription medicines** – all forms of medicine that does not require a prescription.

**PBT Index** – an environment hazard rating scale (0 to 9) developed by Stockholm County Council and Apoteket AB (The National Corporation of Swedish Pharmacies) in 2003. The hazard model of this index is based on three variables: persistence in the aquatic environment (P), bioaccumulation in aquatic life (B) and toxicity (T) in water; index is used as an indication of the active substance's inherent danger to the environment; it is the standard environmental hazard classification system of the National Unused and Expired Medicines Registry.

**Patient safety** – freedom from preventable injuries caused by medical care; prevention of harm caused by errors of commission (doing what is believed to be right that leads to an undesirable outcome or significant potential, often due to poor communication or lack of training) and omission (failing to do the right thing that leads to an undesirable outcome or significant potential for harm, such as failure to prescribe a proven medication having major benefits for an eligible patient).

**Patient** – any individual who has been diagnosed and determined by a physician or an authority with similar medical credentials to be ill or injured.

**Patient Safety Checklists®** – a comprehensive listing of important facts, guidelines, and warnings in various health care areas designed to guide and teach patients to think before taking action (be proactive) and to remind them of behaviors affecting health status in negative and positive ways. CMFPS has developed more than 40 Patient Safety Checklists®. Nine checklists were specifically designed to minimize the abuse, overuse, misuse, and underuse of prescription medicines and over-the-counter medicines and encourage safe, intelligent use of all medicines (Mireles, 2006).
Glossary of Terms (Cont.)

Persistence – ability to resist degradation in the aquatic environment; biodegradability as measure of persistence is assessed based on criteria for ready biodegradation according to the OECD’s test guidelines (test 301) or another equivalent test of biodegradability.

Pharming – a colloquial term used to describe the abuse of prescription medicine among teens who steal the medicines from home, family members or friends and experiment with the medicines to get high.

Polypharmacy – a trend in prescribing by physicians and consuming by patients a combination of prescription medicine (usually consider eight or more individual prescriptions) to treat multiple health conditions. However, this somewhat loosely used term classifies individuals other than seniors who may not be taking as many as eight or medicines, but a significant number of prescribed medicines.

Precautionary principle – promotes responsible and conservative use of resources with the protection of the physical environment for current and future generations. Protecting and preserving the environment requires stewardship of our communities.

Prescription medicine – medications that require a prescription to be sold. These are usually more potent than those sold over-the-counter (OTC) and may have more serious side effects if inappropriately used.

Registry – a systematic, ongoing data collection and registration of information pertaining to a specific population or research questions, to include births, deaths, specific diseases, such as cancer and motor vehicle accidents. In this paper, Registry refers to the National Unused and Expired Medicine Registry specifically developed by our Foundation in 2006 to collect data on unused and expired medicines accumulating at home and in the workplace.

Superordinate goal – the highest level of mission or purpose usually assigned by the consensus of a defined community in its effort to address a highly complex, multi-disciplinary, technological problem, issue or endeavor. In the 1960s, the superordinate goal for the nation was to put a man on the moon and return him safely before the end of the decade.

Toxicity – pertaining to PBT Index, the potential to poison aquatic organisms; technically, toxicity for aquatic organisms is assessed based on the results of toxicity tests including three trophic levels; fish, Daphnia and algae (OECD test guidelines 203, 202 and 201, or equivalent). Data for the most sensitive organisms are used in the assessment.

Unused and expired medicines (UEMs) – unwanted prescription and over-the-counter medicines kept at home or workplace because they are not used or have exceeded the expiration date.

Additional terms or expanded definitions of terms of this Special Report may be found in the Dictionary of Patient Safety, www.comofo.com
## Appendix 2: Abbreviations Used in this Report

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AAP</td>
<td>American Academy of Pediatrics</td>
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<tr>
<td>AAFP</td>
<td>American Academy of Family Physicians</td>
</tr>
<tr>
<td>ACP</td>
<td>American College of Physicians</td>
</tr>
<tr>
<td>AOA</td>
<td>American Osteopathic Association</td>
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<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
</tr>
<tr>
<td>API</td>
<td>Active pharmaceutical ingredients</td>
</tr>
<tr>
<td>AWP</td>
<td>Average wholesale price</td>
</tr>
<tr>
<td>CARE</td>
<td>Community, Awareness, Responsibility and Empowerment</td>
</tr>
<tr>
<td>CC™</td>
<td>Community of Competence™</td>
</tr>
<tr>
<td>CC™ UEMs</td>
<td>Community of Competence™ for Unused and Expired Medicines.</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CMFPS</td>
<td>Community Medical Foundation for Patient Safety</td>
</tr>
<tr>
<td>CMS</td>
<td>Center for Medicare and Medicaid Services</td>
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<tr>
<td>COA</td>
<td>Center on Aging</td>
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<tr>
<td>DAWN</td>
<td>Drug Abuse Warning Network</td>
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<tr>
<td>DEA</td>
<td>U.S. Drug Enforcement Administration</td>
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<tr>
<td>EPA</td>
<td>U.S. Environmental Protection Agency</td>
</tr>
<tr>
<td>EIRS</td>
<td>Environmental impact rating score</td>
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<tr>
<td>FCS</td>
<td>Federal controlled substance</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
</tr>
<tr>
<td>GROUP</td>
<td>Get Rid of Unused Pharmaceuticals®</td>
</tr>
<tr>
<td>HHS</td>
<td>U.S. Department of Health and Human Services</td>
</tr>
<tr>
<td>MBSG</td>
<td>Maine Benzodiazepine Study Group</td>
</tr>
<tr>
<td>MDEA</td>
<td>Maine Drug Enforcement Administration</td>
</tr>
<tr>
<td>MEPA</td>
<td>Maine Environmental Protection Agency</td>
</tr>
<tr>
<td>MISM</td>
<td>Maine Institute for Safe Medicine</td>
</tr>
<tr>
<td>NADDI</td>
<td>National Association of Drug Diversion Investigators</td>
</tr>
<tr>
<td>NCPIE</td>
<td>National Center for Patient Information and Education</td>
</tr>
<tr>
<td>NDIC</td>
<td>National Drug Intelligence Center</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute of Occupational Safety and Health</td>
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<tr>
<td>NOE</td>
<td>Northeast Occupational Exchange</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Cooperation Development</td>
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</tbody>
</table>
### Abbreviations Used in this Report (Cont.)

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONDCP</td>
<td>Office of National Drug Control and Policy</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>OTC</td>
<td>Over-the-counter</td>
</tr>
<tr>
<td>PCHC</td>
<td>Patient-Centered Healthcare Community</td>
</tr>
<tr>
<td>PCPCC</td>
<td>Patient-Centered Primary Care Collaborative</td>
</tr>
<tr>
<td>PPCP</td>
<td>Pharmaceuticals and personal care products</td>
</tr>
<tr>
<td>SAMHSA</td>
<td>Substance Abuse Mental Health Services Administration</td>
</tr>
<tr>
<td>UEM</td>
<td>Unused and expired medicine(s)</td>
</tr>
<tr>
<td>USGS</td>
<td>U.S. Geological Survey</td>
</tr>
<tr>
<td>USPS</td>
<td>U.S. Postal Service</td>
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</tbody>
</table>

Additional abbreviations and acronyms used in this Special Report may be found in the *Dictionary of Patient Safety*, www.comofcom.com
Appendix 3: State of Maine Proclamation by Governor

WHEREAS, unused and unwanted consumer pharmaceuticals have a negative impact on public health and the environment and the lack of effective and efficient methods of drug disposal has resulted in unwelcome social, cultural, ecological and global effects; and

WHEREAS, theft and social use, misuse, and abuse of pharmaceuticals by teenagers, adults and older adults has increased; and

WHEREAS, increasing poly-pharmacy, non-adherence to prescriptions and medication errors contributes to accumulation and poor patient outcomes; and

WHEREAS, potential deleterious effects on wildlife and humans due to drug disposition in surface and ground waters are a result of improper disposal; and

WHEREAS, unused medications represent wasted health care dollars to both consumers, insurance carriers and tax payers;

NOW, THEREFORE, I, JOHN E. BALDACCI, Governor of the State of Maine, do hereby proclaim October 31, 2008 as

PROPER DRUG DISPOSAL DAY

throughout the State of Maine, and urge all citizens to recognize the need for proper adherence to medication and appropriate drug disposal across the State of Maine.

In testimony whereof, I have caused the Great Seal of the State to be hereunto affixed GIVEN under my hand at Augusta this fifth day of September in the Year of our Lord Two Thousand and Eight.

John E. Baldacci
Governor

Matthew Dunlap
Secretary of State
TRUE ATTESTED COPY
Appendix 4: The Athens Declaration

THE ATHENS DECLARATION as unanimously voted on August 3rd, 2007 at the 2nd International Conference on Environment in the City of Athens Cultural Center is as follows:

We, an international group, support the following six reasons to address citizen unused drug disposal:

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
6. To eliminate waste in the international health care systems of all countries

We call upon governments, NGO’s, and citizens everywhere to correct policies and practices that foster waste in the health care systems of all countries and endanger humans, animals, and our physical environment.

We call upon all countries to renew their support of WHO Guidelines on Drug Donations and the WHO Guidelines on Drug Disposal, and strive to improve on these.

We call upon health care providers worldwide to appropriately prescribe medicines to patients in the most effective form and quantity.

We call upon health care organizations to refrain from policies that promote excessive dispensing.

We call upon patients worldwide to recognize the need for medicine to be taken as intended if it is to be effective.

We call upon governments, NGO’s, and citizens worldwide to refrain immediately from improper drug donations either as humanitarian aid following disasters or in general practice.

We call upon others to endorse these principles with us for the betterment of the health of the environment and patients worldwide.

In North America:
Maine Benzodiazepine Study Group
Stever Gressitt, M.D.
207-441-0291
Gressitt@uninets.net
www.mainebenzo.org

Athens, Greece
August 3rd, 2007
Appendix 5: Letter from U.S. Senator Charles Grassley

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510-4200

April 21, 2010

Via Electronic Transmission

Tony Marple
Director
Maine Office of MaineCare Services
State of Maine
11 State House Station
Augusta, ME 04333

Dear Director Marple:

In the United States, the federal and state governments spend roughly $317 billion every year on the Medicaid program. As Ranking Member of the Senate Committee on Finance, I have an obligation to ensure that taxpayer dollars are appropriately spent on federal health care programs. Like the Medicare program, Medicaid suffers from systemic weaknesses that lead to fraud, waste, and abuse across the program, resulting in higher costs and less health care to those who are in need. The overutilization of prescription drugs, whether through drug abuse or outright fraud, plays a significant role in the rising cost of our healthcare system. The purpose of this letter is to request information regarding certain outliers in Maine’s Medicaid program and what steps Maine takes to monitor rates of utilization.

In recent inquiries, I have asked the U.S. Department of Health and Human Services about physicians prescribing mental health drugs at astonishingly high rates. In addition to these concerns, a recent CNN report detailed the increasing abuse of OxyContin, Roxicodone, and Xanax. Specifically, the report described the role some pain management clinics and physicians play in the black market for these drugs. I write today to better ascertain how high rates of both mental health and pain medication utilization are affecting the Medicaid program, as well as how Maine’s rates compare to the national rates.

To that end, please provide charts that list the top ten Medicaid prescribers of the following drugs for the years 2008 and 2009. For each prescriber, please provide his/her prescriber identifier, and the number of prescriptions written per drug per year, and the total amount billed to Medicaid per drug, separated for each year.

- Abilify;
- Geodon;
- Seroquel;
- Zyprexa;
Appendix 5: Letter from U.S. Senator Charles Grassley (Cont.)

- Risperdal;
- OxyContin;
- Roxicodone; and
- Xanax.

I thank you in advance for your cooperation and request that you provide the requested documents and written responses by no later than May 5, 2010. In your reply, please format information into a chart like the examples provided below. All formal correspondence should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov or via facsimile to (202) 228-2131. Of course should you wish to discuss this matter further, please do not hesitate to contact Christopher Armstrong of my Committee staff at (202) 224-4515.

Sincerely,

Chuck Grassley
Charles E. Grassley
Ranking Member

Attachment
### Appendix 5: Letter from U.S. Senator Charles Grassley (Cont.)

<table>
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<th>Total Prescriptions</th>
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### Appendix 6: Standardized Medicine Return Form (CMFPS)

<table>
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<tr>
<th>Date (mm/dd/yy)</th>
<th>Drug Name (Example: Aspirin)</th>
<th>Drug Strength</th>
<th>Quantity</th>
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<tr>
<td>________________</td>
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**Discrepancies/Corrections**

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<th>ID</th>
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</table>

**Get Rid of Unused Pharmaceuticals (GROUP) Program**

- Standardized Unused and Expired Medicines Return Form®
- Dispensed or prescribed
- Patient do not want it
- Patient died or moved
- Patient refuses to take
- Patient on alternate therapy
- Expiration date
- Multiple bottles
- Expired or damaged
- Other

**Where did you get this drug?**

- Pharmacy
- Mail order

**Why are you returning this drug?**

- Ineffective as prescribed
- Wrong strength
- Expiration date
- Overdose (trapped pill)
- Family or child

**Are you recording this drug?**

- Yes

**For official use only**

- Receiving Date
- Lot Number
- Quality check
- All matched
- Missing data
Appendix 7: Public Testimony of Stevan Gressitt, M.D. at Special Committee on Aging, U.S. Senate Hearing on Prescription Drug Disposal, June 30, 2010

Statement of
Stevan Gressitt, M.D.
Faculty Associate, University of Maine Center on Aging
Founding Director, Maine Institute for Safe Medicine
University of New England, College of Pharmacy
Department of Pharmaceutical Sciences
Associate Professor of Clinical Psychiatry, University of New England,
College of Osteopathic Medicine

Co-Principal Investigator of U.S. E.P.A. Grant # CH-83336001-0
(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
Appendix 7: Public Testimony of Stevan Gressitt, M.D. at Special Committee on Aging, U.S. Senate Hearing on Prescription Drug Disposal, June 30, 2010. (Cont.)

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.
Appendix 7: Public Testimony of Stevan Gressitt, M.D. at Special Committee on Aging, U.S. Senate Hearing on Prescription Drug Disposal, June 30, 2010. (Cont.)

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 Vicodin, rose by 750%. The number of impairment cases involving oxycodone rose by 450% and cases involving methadone, 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 2005 (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 identified3,4,5:

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.
Appendix 7: Public Testimony of Stevan Gressitt, M.D. at Special Committee on Aging, U.S. Senate Hearing on Prescription Drug Disposal, June 30, 2010. (Cont.)

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 Aging. 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.
Appendix 7: Public Testimony of Stevan Gressitt, M.D. at Special Committee on Aging, U.S. Senate Hearing on Prescription Drug Disposal, June 30, 2010. (Cont.)

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 (27.5%)
- 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 calculated to $18.79 per unit mailer. Subsequent mailer costs (Phase III) are calculated at $7.50 per unit mailer. 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
Appendix 7: Public Testimony of Stevan Gressitt, M.D. at Special Committee on Aging, U.S. Senate Hearing on Prescription Drug Disposal, June 30, 2010. (Cont.)

...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 2005, the United States Pharmacopeia passed a resolution to address unused medicine and reiterated this position at the 2010 Convention. Within the past month the American Medical Association House of Delegates passed Substitute Resolution 515 which states:
RESOLVED. That our A.M.A. support initiatives designed to promote and facilitate the safe and appropriate disposal of unused medications. (New House of Delegates Policy) [1]

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.

References:
Appendix 7: Public Testimony of Stevan Gressitt, M.D. at Special Committee on Aging, U.S. Senate Hearing on Prescription Drug Disposal, June 30, 2010. (Cont.)

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11. AMA Resolution # 515, 2010 (quoted on page 7 above)
12. Additional material from the Maine Medical Association

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