The Unused Pharmaceutical Disposal Program of Maine

The Problem

Prescription drug overdoses have become the major source of drug-related deaths in Maine. Childhood toxic events, household diversion, and elderly compliance issues, as well as environmental concerns, have led to this proposal. No current disposal program approved by the DEA and EPA exists for the general public for unused or expired pharmaceuticals, either DEA scheduled or not.

In the case of accidental drug overdoses in the State of Maine, only half of the decedents had a documented prescription for at least one drug that was listed in the cause of death. The lack of documented prescriptions for many drugs listed in the cause of death suggests they have been diverted from other sources.

Young children continue to be a group which accidentally ingests pharmaceuticals, as documented by Poison Control calls.

Law enforcement is seeing an increase in today's youth raiding accessible medicine cabinets for unused prescription drugs and either abusing them, selling them, or sharing them at parties. The effects of these pharmaceuticals are often unknown to the user, and when used in combination with other drugs often have tragic results. Prosecutions by the Office of the Attorney General for prescription drug abuse charges have more than doubled in three years.

The elderly have become targets of break-ins for their medications.

An increasing amount of pharmaceuticals is being detected in the water supply and environment, making disposal a growing issue and one with which the EPA and Maine DEP now are quite concerned. No environmental surveys have been published yet regarding Maine. Throwing prescription drugs in the trash creates more opportunity for access to the drugs by wildlife and "dumpster divers." Pharmaceutical contamination of estuaries is a growing national problem and one which could have profound economic impact on the State of Maine.

Potential Assistance for Maine's Prescription Drug Problem

Senator Lynn Bromley (D-Cape Elizabeth) has introduced legislation which would create the Unused Pharmaceutical Disposal Program to voluntarily encourage Mainers to safely clean out their medicine cabinets. This bill has bipartisan support and broader federal legislation is about to be presented by Senator Collins.

The bill creates a system under which individuals may mail their unused or expired prescription drugs in a pre-paid mailer to a post office box under authority of the Maine Drug Enforcement Agency (MDEA). The MDEA would collect the mailers and destroy them by approved incineration. The MDEA currently destroys drug evidence by DEP approved high-temperature incineration when it is no longer needed in the judicial system. This bill would simply change the volume of disposal.

Individuals would obtain these pre-paid mailers from a variety of places, such as pharmacies, schools, health care providers' offices, etc.

Details regarding the proposed use of the funds

Technical assistance is requested to assess what would be returned, as there will be a higher than usual incidence of counterfeit pharmaceuticals. Note is taken of the fact that Maine is the source of the first counterfeit medication suit over Lipitor, currently in Missouri Federal Court.

No data exists in the U.S. comparable to what this program could provide. Technical assistance would require (as necessary) identification, assay, sampling specifics, laboratory selection, and testing specifications, and pharmacoeconomic evaluation. It is expected that the information from this survey would help provide better patient compliance education and assist with targeting campaigns for patient education. We expect the structure of this

specific pilot project to serve as an option for those seeking to achieve the same goals, without violating EPA or DEA regulations.

With the State of Maine facing a current budget crisis of an immediate \$109 million shortfall, and an expected two-year budget shortfall of over \$200 million, this Program cannot expect to receive State Money for its implementation. Advocates of the Program are asking for technical assistance. We are also asking for funding from your organization. We believe that a partnership between Program advocates and the pharmaceutical industry can be beneficial to limit accidental misuse of prescription drugs, household diversion, or inadvertent self-administration by our elders or mentally disabled.

We believe that the 5 year partnership in Prince Edward Island, Canada between several pharmaceutical manufacturers, pharmacists, the provincial environment department, Health Canada and the Provincial Government with no onerous legislation and on a strictly voluntary basis has led to a workable system. The technical specifics, however in PEI, are not tolerable by the U.S. DEA and hence our proposed design. Estimates of the cost of starting this program run from \$250,000-\$900,000, depending upon the level of investment in motivating individuals to participate.

Funding

Funding would be used for the following:

The time of one licensed state police officer at the Maine Drug Enforcement Agency to handle the content of the post office box through the incineration process. One additional licensed state police officer will be necessary occasionally to provide the two-officer sign-off to document transfer/destruction and counts for the internal control system to assess internal diversion.

Purchase and Printing of mailers

Postage for mailers

Audit of returns, for pharmaceutical, quantity, fraudulence

Exploration of alternative long-term funding such as grants for specific elements, consumer self-pay envelopes, rebate inducement, and alternative self-pay mechanisms.

Support of the Program

Support for this program comes from the medical community, including the Maine Medical Association and the Maine Psychiatric Association, law enforcement, the environmental community, pharmacies, the substance abuse community, the Maine Association for Substance Abuse Programs, advocates for children, mental health centers, individual physicians, the Maine Bureau of Health, the Office of the Maine Attorney General, Maine Rivers, the Maine Children's Alliance, and many more. This broad and bipartisan coalition of environmental, medical, and substance abuse providers is committed to this Program.