Written Testimony
House Subcommittee on Insular Affairs, Oceans and Wildlife
Submitted by State Representative Anne Perry
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Madam Chair and Members of the House Subcommittee on Insular Affairs, Oceans and Wildlife, my name is Anne Perry, and I am the State Representative from Maine's House District #31, representing Baileyville, Baring, Calais, Charlotte, Passamaquoddy Indian Township, Passamaquoddy Pleasant Point, Perry and Robbinston, plus part of the unorganized territory of North Washington. I am House Chair of the Joint Standing Committee of Health and Human Services and a practicing Family Nurse Practitioner.

In my 62-year lifetime, the practice of medicine has changed greatly. Over 40 years ago, oral contraceptives were introduced. Oral medications for diabetes were approved by the U.S. Food and Drug Administration about 15 years ago. The list goes on. There are oral medications for heart disease, hypertension, cancer and many other chronic diseases. We are living longer and the majority of our elderly take an average of two to five medications daily. In 2008, according its Prescription Monitoring Program, Maine dispensed 2,299,736 prescriptions of schedule II-IV drugs, the equivalent of 1.75 medications per person, and this does not include hypertensive, diabetic and other such medications.

The abundance of medications creates two issues that affect our environment – proper disposal of unused pharmaceuticals and proper use.

Pharmaceuticals in our environment come from two sources – unused waste and human waste. Most of us have had to decide how to discard an out-of-date or discontinued medication. The bottle keeps getting pushed around the medicine cabinet, but what do you do with the remaining pills? Historically, we have been instructed to flush unwanted pharmaceuticals. Water treatment plants do not monitor for, nor do they have the technology to filter out, pharmaceutical compounds found in medicines, which leads to contamination of surface waters, ground waters, and biosolids.

Even at small concentrations, a few parts per billion, there is concern about exposure of chemicals such as antibiotics, antidepressants and hormones to aquatic organisms. Some classes of drugs can act as endocrine disruptors, and have been linked to abnormalities and impaired reproductive performance in fish, amphibians and other aquatic species. People are starting to understand that flushing is not the way to go, but the question remains: What do you do?

Just like flushing, we all know, or can infer, that trash disposal is not the answer either. Trash disposal can lead to drug diversion and abuse or accidental poisonings. Major pharmaceutical companies suggest that misuse and abuse from medication stolen from trash cans can be avoided by contaminating the medication with such things as kitty litter or coffee grounds, but it does not stop the potential, eventual leachate into the ground water for lack of appropriate solid waste management options.

So what do we do?

I am not an environmental scientist, or a biologist. My answers to this question stems from my work in the Maine State Legislature on legislation aimed at proper drug disposal and from my

career as a family nurse practitioner and, more importantly, as a prescriber of many of these pharmaceuticals.

Given the environmental, drug enforcement and health impacts of improper drug disposal, Maine has decided to do something to address household pharmaceutical waste. Under the leadership of Dr. Stevan Gressit, who organized a group around benzodiazepine use and unused pharmaceuticals, the Maine Legislature took action. In 2003, Maine passed its first of many laws addressing proper drug disposal. Maine Public Law 2003 Chapter 679 (ATTACHMENT 1), to be administered by MDEA, created the Maine Drug Return Implementation Group, a study commission to look at the best way to create a state wide disposal program.

The Group also learned that household pharmaceutical waste is exempt from laws governing hazardous waste disposal. Once prescription drugs are separated from household waste and accumulated from more than one household, they must then be disposed of under federal regulations for hazardous waste. The U.S. Drug Enforcement Agency (DEA) chain of custody rules follow the distribution of pharmaceuticals from manufacturer to consumer. However, these rules prohibit any return of medications to pharmacy, physician or hospital leaving consumers in the present quandary – what do I do with unused medication? This led the Maine Drug Return Implementation Group to recommend:

- Mail-in program
- Packaging for Mailing
- Mail receipt, storage and disposal
- Funding – no State general funding.
- Starting date changed to July 2006
- Product stewardship – responsibility of manufacturer
- General Recommendations
- Redistribution program for unneeded pharmaceuticals of health facilities, drug manufacturers, drug wholesale & terminal distributers and hospitals.

In the meantime local community groups lead by local AARP organizations began take back programs. In order to do this they required the presence of a police officer who is the only one who could legally handle the collected pharmaceuticals maintaining DEA rules. These drugs are brought to the Maine DEA (MDEA) for proper disposal.

In 2006, the Office of National Drug Control Policy issued "Synthetic Drug Control Strategy," which mentioned the importance of encouraging the proper disposal of unneeded prescription medications in order to keep them out of the hands of those who would divert them. And also, mentioned meeting with pharmaceutical companies about encouraging proper disposal of unwanted drugs. Historically, ONDCP guidelines have recommended flushing unused pharmaceuticals.

2007: ONDCP ISSUES NEW GUIDELINES FOR PROPER DISPOSAL OF PRESCRIPTION DRUGS :

- Take unused, unneeded, or expired prescription drugs out of their original containers and mix the prescription drugs with an undesirable substance, like used coffee grounds or kitty litter, and put them in impermeable, non-descript containers, such as empty cans or sealable bags, further ensuring that the drugs are not diverted or accidentally ingested by children or pets; then throw these containers in the trash

- Flush prescription drugs down the toilet only if the accompanying patient information specifically instructs it is safe to do so
- Return unused, unneeded, or expired prescription drugs to pharmaceutical take-back locations that allow the public to bring unused drugs to a central location for safe disposal.

In 2007, at the Second International Conference on the Environment in Athens, Greece, The Athens Declaration was unanimously voted to address pharmaceutical waste and drug disposal internationally (ATTACHMENT 2). Also in 2007, the UMaine Center on Aging received a $150,000 grant from the U.S. Environmental Protection Agency for developing a drug return program. This was matched by another $150,000 from the State of Maine's Fund for a Healthy Maine.

The Safe Disposal for Maine pilot program was formed in conjunction with the Agency on Aging and the MDEA. In January of 2008, pharmacies in two rural and two urban counties were selected to distribute prepaid Merchandise Return Service First class prepaid mailers to begin the pilot program. In March of 2008, USPS and MDEA executed a two-year Operational Test Agreement for the mail back service. In May 2008, 1,800 mailers were distributed from 11 drug stores to homeowners. In November 2008, state-wide distribution began with 100 distribution centers.

Mailers were obtained by participants through a designated pharmacy. Unused drugs were packed into the envelopes according to instructions that accompanied the mailer. Envelopes were then mailed through the postal service to MDEA. The MDEA is responsible for delivering returned medications to disposal plants. By April 2009 of 9,000 mailers available to public, 7,230 had been distributed and 2,264 returned (reflecting a 31.3% response rate).

The pilot also hired a pharmacist and assistants to do periodic quantity and medication counts to quantify what is being discarded. A preliminary report (ATTACHMENTS 3, 4, 5) of the pilot with only 70% of the data set shows a total of 74,696 pills, capsules, and tablets for prescription and over-the-counter medicines, 52% were never used by the patients/consumers.

Below is a tally of the top ten medications returned by generic name:

Metoprolol 2400 (3.21%)
Lisinopril 1972 (2.64%)
Ibuprofen 1751 (2.34%)
Aspirin 1639 (2.19%)
Acetaminophen-hydrocodone** 1370 (1.83%)
Metformin 1334 (1.79%)
Tramadol 1284 (1.72%)
Furosemide 1136 (1.52%)
Naproxen 1133 (1.52%)
Warfarin 1091 (1.46%)

Although the pilot will continue through the summer, we have been impressed with the reception and success of the program. As a result, I introduced LD 821 **An Act to Support Collection and Proper Disposal of Unwanted Drugs** (ATTACHMENT 6), in coordination with the Maine Department of Environmental Protection, Department of Health and Human Services and Maine DEA. The bill is based on a product stewardship model that would result in the shared

responsibility for safe drug disposal among consumers, government, health care entities, pharmacies and the manufacturers. Attached is a copy of the proposed legislation. It is being carried over to allow for negotiations with manufacturers around implementation and what the program should look like.

Under product stewardship concepts, all product lifecycle costs – from using resources, to reducing health and environmental impacts throughout the production process, to managing products at the end-of-life – should be included in the total product cost. Manufacturers should thus have a direct financial incentive to redesign their products to reduce these costs. These policies should also create incentives for the development of a sustainable and environmentally-sound system to collect and dispose of unwanted products, in this case millions of pounds of unwanted drugs.

The drug manufacturers are collecting and disposing of unwanted drugs in Europe and many Canadian provinces. I feel it is time for the US to have a similar program, financed and administered by these same manufacturers.

I would also add that product stewardship is only a part of the solution. We need to:

1. increase public and health care provider education regarding disposal of unused prescription drugs and the availability of disposal programs;
2. continue efforts with policymakers to address laws and regulations governing controlled substances that currently impede implementation of comprehensive drug take-back programs; and
3. encourage EPA, FDA and ONDCP to revise the federal guidelines on drug disposal to further discourage flushing of any drugs. And more specifically, address the U.S. DEA rules that make it difficult to return unwanted drugs for proper disposal.

As a care provider, my answer is that we need to prescribe better. We need to address unused medication at the front end. The Community Medical Foundation for Patient Safety, located in Bellaire, Texas, created the national Unused and Expired Medicines Registry in 2004 to collect and analyze information on unused medications. National samples of pill count reveal that approximately 40% of prescription medicines were never used and would have been thrown away.

As a prescriber of medications, I am distinctly aware that an important way to reduce household pharmaceutical waste, and ultimately reduce environmental impact, is to work on preventing waste at the front end of the process. This session, I introduced LD 191 **An Act Regarding Insurance Copayments for Short-term Prescriptions** (ATTACHMENT 7), which would permit pro-rated copays for short term prescriptions at the initiation of or change in medication. While the bill was defeated in committee, it developed enough interest by insurance companies and pharmacists to create a discussion group for continued work. We need to do general education for prescribers around pharmaceutical waste and work with changing prescribing habits. It is also important make insurance companies aware of the waste issues around the push to dispense large quantities at inappropriate times.

I would add that we need to educate the public on buying habits of over the counter drugs. I am sure many of you have stood in the aisle comparing the 50-pill bottle at 43 cents per unit and the

500-pill bottle at 25 cents per unit. We as consumers need to rethink the way we buy in bulk, especially when it comes to medication – we need to stop the cycle of buying large quantities, using a few pills, then having to throw out the rest because the next time it is needed the medication is out of date.

This issue cannot be solved by a single solution. The blanket of proper drug disposal covers the environment, drug enforcement, health care, and financial savings. If we address proper drug disposal at all levels, we will lower risks to aquatic species and human health through environmental contamination. We will reduce the quantity of *unwanted* pharmaceuticals in our nation's medicine cabinets and, therefore, reduce the chances for illegal diversion and accidental poisoning. Despite an ever-expanding range of available drugs, reducing over-prescribing on the front end will bring down costs.

The solution will be multi-faceted and will include product stewardship and education. It will involve manufacturers, government officials, prescribers and consumers.