



**COMMENTS OF THE GENERIC PHARMACEUTICAL ASSOCIATION ON IMPLEMENTING
PRODUCT STEWARDSHIP IN MAINE: 2011 REPORT TO THE JOINT STANDING
COMMITTEE ON NATURAL RESOURCES**

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The Generic Pharmaceutical Association (GPhA) thanks the Maine Department of Environmental Protection (DEP) for this opportunity to share the generic industry's views. GPhA is a non-profit trade association representing the manufacturers and distributors of finished generic pharmaceutical products. GPhA members manufacture more than 90% of all generic pharmaceuticals dispensed in the United States. According to IMS Health, the generic industry currently fills 75% of the prescriptions dispensed for only 22% of the total amount spent on prescription drugs in the U.S. Through competition, generic manufacturers drive down the costs of medicine and support public health by providing access to affordable medicine.

Generics provide enormous cost savings to Maine consumers and the State, and deliver the same quality medicine as their brand equivalents. Currently, on average, a generic prescription costs \$35.22 versus an average cost of \$137.90 for brands. In fact, in the Maine State Medicaid program alone, for every 1% increase in generic utilization, generics save \$1.6M for Maine taxpayers (not including the savings to the Federal Government). Because generic medicines are generally sold at commodity prices, and generic manufacturers supply a wide variety of products that bear extremely thin profit margins they cannot afford to absorb the costs of pharmaceutical take back programs. Inevitably, such costs will increase the cost of health care.

To address concerns over unwanted or unused medicines, such as diversion and accidental poisonings, GPhA supports efforts to educate consumers on proper disposal methods. GPhA believes that concerns over unwanted and unused medicines can be addressed with effective and affordable pharmaceutical take back programs without mandating manufacturer-funded programs that risk increasing health care costs.

COST OF TAKE BACK PROGRAMS

A pharmaceutical take back program proposed in Maine was projected to cost \$1.5M annually for 3 years, after which the annual cost would be unlimited. This legislation was wisely rejected by Maine's legislature and similar legislation failed to pass in many other states including Minnesota and Washington. Furthermore, Maine's proposal did not include any requirement for consumers to participate, resulting in a costly program that would do little if anything to reduce the unwanted drugs being flushed, put in landfills, or left in medicine cabinets.



The program proposed in Maine included a “mail back” component. Based on reported data from the mail back pilot program conducted by the Maine Center on Aging, the costs were \$7.50 per envelope. Other estimates on the cost were as high as \$17 per envelope. For generic medicines that often retail at \$4 for a 1-month supply, these costs would be unsustainable if extrapolated to a state-wide program. Given the current budget situation, where states like Maine are facing enormous cost burdens to pay for expanded health care, further increasing costs to manufacturers, and the subsequent prices charged to consumers, will be detrimental to public health.

ENVIRONMENTAL CONCERNS

FDA’s Environmental Assessment Expert, Raanan Bloom, Ph. D., notes regarding concerns about trace levels of drug residues found in surface water that “the main way drug residues enter water systems is by people taking medications and then naturally passing them through their bodies.”¹ It is estimated that well over 90% of the trace medicines found in surface water is excreted, rather than discarded or flushed. Thus, even if a costly program were 100% effective, it would do little if anything to impact the amount of pharmaceuticals entering water systems. In addition, experts agree that there is no scientific evidence to demonstrate that the traces of pharmaceuticals (measured in parts per trillion) detected in water have any impact to humans.

CONCLUSION

Prescription medications are critical to maintaining health and improving the quality of life for millions of Americans. For a variety of reasons not all medicines dispensed to patients are consumed. GPhA remains committed to educating consumers on proper methods of disposal for such products. However, mandating costly take back programs that will ultimately increase the cost of medicine at a time when Maine and other states are struggling to manage historical budget deficits, and in particular health care costs, would be misguided. GPhA implores the DEP and the Joint Standing Committee on Natural Resources to consider these factors in addressing unused pharmaceuticals.

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¹ Available at www.fda.gov/consumer/updates/drug_disposal062308.html