



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

LOCAL GOVERNMENT
ADVISORY COMMITTEE

DEC 18 2008

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Administrator Stephen Johnson
US Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Dear Administrator Johnson:

On behalf of USEPA's Local Government Advisory Committee (LGAC), we would like to forward the LGAC's recommendations on the growing public health and environmental concerns posed by carelessly discarded unused pharmaceuticals. Public awareness of significant levels of pharmaceuticals found in drinking water and in our nation's surface and groundwater constitute a growing public concern about public health and environmental impacts -- as well as demand for convenient, safe, and secure disposal options.

State and local officials are on the frontline of this issue and we are being called upon to take quick, decisive action. Many states and communities have started collection programs, but face regulatory obstacles which inhibit their effectiveness. The LGAC urges USEPA to assist state and local governments by setting a workable national policy for safe disposal of pharmaceuticals in order to minimize the risk of environmental harm, illegal diversion, and accidental poisoning.

The LGAC believes a product stewardship approach is an efficient, cost-effective solution. Product stewardship means that those who design, sell, or use a product are responsible for the product's disposal, recycling, and/or reuse, as well as for minimizing the product's environmental and public health impacts throughout the product's lifecycle. In the case of pharmaceuticals (and as demonstrated in British Columbia, Canada), a product stewardship program provided by drug companies could be both convenient and effective. The product stewardship concept is gaining momentum at the state and local level, and the LGAC believes that adopting such an approach at the national level would be the most logical way of bringing consistency to these efforts.

Background: Why We Are Concerned?

Unused and unreturned prescription medicines pose significant public health risks for poisoning, abuse, and contamination to the environment.

Frances Eargle
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The Center for Disease Control reports that in 1993, pharmaceutical drugs caused 94.3% of poisoning deaths.

Further, prescription drug abuse has risen in this country, and the Office of National Drug Control Policy reported that prescription drugs ranked as the most prevalent illegal drug problem in the nation. Every prescription that is no longer needed or which has expired poses a household risk that is avoidable.

Unused pharmaceuticals also pose a threat to the environment. Eighty percent (80%) of one hundred thirty nine (139) streams assessed by the U.S. Geological Survey contained one or more of ninety five (95) different chemicals used in pharmaceuticals. Of these ninety-five (95) chemicals, thirty-three (33) are suspected to have hormonal effects which potentially affect human health and adversely impact aquatic life.

While some pharmaceutical contamination is the result of excretion, the problem is exacerbated by disposal of unwanted pharmaceuticals through flushing or landfills. Disposal in landfills simply delays entry of pharmaceuticals into streams and the water-shed since most landfill leachate is treated at waste-water facilities. These facilities thus far are not equipped to remove chemicals found in pharmaceuticals; in fact, most facilities do not even test for them. Ironically, the risks from flushed or disposed pharmaceuticals are preventable if national regulations allowed for viable take-back and disposal programs.

LGAC Recommendations

The LGAC urges EPA to consider and act on the following recommendations put forth by consensus of the LGAC:

- **National Product Stewardship-** The LGAC strongly believes that USEPA should promote a national policy framework for product stewardship of pharmaceuticals that will assist state and local governments in promoting prudent, reasonable, and economic approaches to this problem. We need widespread and effective collection and destruction of pharmaceuticals, but local governments cannot afford to pay for comprehensive collection programs. Product stewardship has proven to be an effective approach to pharmaceutical disposal in many state pilot programs.
- **Department of Justice Drug Enforcement Agency (DEA) Rule Making-** The LGAC urges USEPA to influence the DEA's rule-making proceeding on pharmaceuticals. Existing DEA rules create barriers to practical, economic, and secure product stewardship and take-back programs. Rule revisions are under consideration but without the involvement of state and local governments.

The LGAC notes that some state and local governments are seeking to implement innovative solutions to promote product stewardship and create

effective drug return programs. Such efforts are under way in California, Maine, Minnesota, Oregon and Washington. However, these advances may be significantly hindered by the DEA's proposed rule-making if rule changes require cataloging of each returned pill and/or other impractical measures. The LGAC believes this would institute a highly overburdened, bureaucratic, and costly process that would preclude collection and disposal of unused and unwanted pharmaceuticals in a safe manner. It would effectively prevent manufacturers, retail pharmacies, and state and local governments from establishing viable and effective pharmaceutical take-back programs.

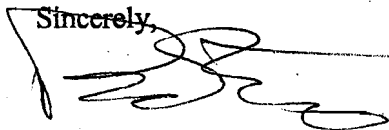
The LGAC believes that the new Federalism directive clearly recognizes the role of local governments in the rule-making process and the need for early consultation. While USEPA is not proposing the new rule, we believe there is too much at stake to ignore the proceeding and its potential effect on USEPA's role in protecting the environment. The LGAC therefore urges USEPA to enter into inter-agency discussions about the rule-making and to utilize the product stewardship approach as part of its policy framework.

Not only should local governments be consulted and involved in this issue initially, but local governments should have more influence in how policy is shaped to address this growing problem. The environmental effects of pharmaceutical contamination pose potentially huge burdens on state and local budgets. Further, we believe that USEPA is in a unique position to facilitate partnerships that would provide incentives to enhance product stewardship initiatives for pharmaceutical collection and disposal across the country.


In conclusion, the LGAC calls upon the USEPA to show leadership in three areas: 1) encourage and promote product stewardship principles where appropriate; 2) promote partnerships at the state and local level to address this issue; and, 3) work at the interagency level with Department of Justice's Drug Enforcement Agency to revise rules to allow for viable pharmaceutical take-back programs.

The LGAC looks forward to working with USEPA to promote product stewardship for collection and take-back of pharmaceuticals. We believe this approach will significantly reduce the public health and environmental hazards. Thank you for consideration of our recommendations and the interest that you have demonstrated in working with the LGAC.

Sincerely,



Roy Prescott
Chair



Jim Gitz, Chair
Solid Waste Workgroup