

EXECUTIVE COMMITTEE

PRESIDENT

Kevin L. Shafer

Executive Director

Milwaukee Metropolitan

Sewerage District

Milwaukee, WI

VICE PRESIDENT

Jeff Theerman

Executive Director

Metropolitan St. Louis

Sewer District

Saint Louis, MO

TREASURER

David R. Williams

Director of Wastewater

East Bay Municipal

Utility District

Oakland, CA

SECRETARY

Suzanne E. Goss

Government Relations Specialist

JEA (Electric, Water & Sewer)

Jacksonville, FL

PAST PRESIDENT

Marian A. Orfeo

Director of Planning

& Coordination

Massachusetts Water

Resources Authority

Boston, MA

EXECUTIVE DIRECTOR

Ken Kirk

January 6, 2010

Suzanne Rudzinski

Deputy Director

Office of Science and Technology

Office of Water

U.S. Environmental Protection Agency

Washington, D.C.

Via Electronic Mail

Dear Suzanne,

Given your involvement in many of the Office of Water's efforts on emerging contaminants and the role of the Office of Science and Technology (OST) in evaluating the need for Clean Water Act controls on these contaminants, NACWA wants to express its concern about a new set of recommendations from the Food and Drug Administration (FDA) on the disposal of unused pharmaceuticals. Specifically, NACWA is concerned about a new online fact sheet developed by the FDA's Office of Training and Communication that provides an overview of the issues surrounding the disposal of unused pharmaceuticals, a series of frequently asked questions, and a list of drugs recommended for flushing. Most troubling are the broad statements about the lack of impacts these unused drugs are having on the environment. NACWA's members continue to work tirelessly to educate their communities on the importance of source control and the availability of other, more environmentally friendly alternative for the disposal of unused pharmaceuticals and these FDA guidelines will only further complicate these efforts. We would appreciate your feedback on this issue and your assistance in working with FDA to revise their guidelines.

As you know, a few years ago the Office of National Drug Control Policy (ONDCP) developed a set of recommendations on the disposal of unused pharmaceuticals in cooperation with EPA and other federal agencies to ensure they adequately addressed environmental concerns. At that time, the ONDCP felt obliged to publish a list of pharmaceuticals that are recommended for flushing, based on input from the FDA. The ONDCP, based on comments from NACWA and other stakeholders, made changes to the recommendations to underscore that flushing was ***an option of last resort*** and that there were better management options. The new FDA guidelines do



January 6, 2010

Page 2

not appear to have been developed in collaboration with other federal agencies and draw the conclusion that the risk posed by accidental ingestion outweighs any environmental impacts from flushing these pharmaceuticals.

NACWA is also writing to the FDA to express these same concerns, but believes that the FDA's assertion that there is little or no human health or environmental impact from the flushing of these pharmaceuticals is a finding that must ultimately be made by EPA in consultation with its sister agencies, not by FDA alone. The FDA guidelines state that any human health or environmental risk posed by the flushing is outweighed by the "real possibility of life-threatening risks from accidental ingestion of these medicines." While NACWA understands the very real potential for accidents or diversion of prescription medication for illicit use, making such broad statements of relative risk and basing national guidelines on those statements is problematic unless all of the necessary analyses have been done to truly evaluate the risks. EPA's water quality standards program generally does not consider relative risk and it is clear that the potential exists for a situation where one federal agency will recommend the flushing of pharmaceuticals while another federal agency mandates that clean water agencies install technology to remove those same pharmaceuticals from their wastewater or solids.

The clean water community is being looked to for solutions as public awareness of the emerging contaminants issue grows. EPA has made it clear that it has the authority and tools to mandate controls for these contaminants if warranted. NACWA continues to believe that the best solution is pollution prevention. The public will not remember which drugs are recommended for flushing and will not draw the fine distinctions the FDA is drawing, so any recommendation for flushing will cause added confusion. What is most needed is a consistent message regarding disposal. If a risk tradeoff is truly needed, accepting potential environmental impacts to prevent accidental ingestion, then all federal agencies need to make this decision together and ensure it is applied consistently.

NACWA requests that EPA address these concerns and assist in working with FDA to revise their guidelines. Please don't hesitate to contact me if you have any questions or would like to discuss further.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Hornback", written in a cursive style.

Chris Hornback
Senior Director, Regulatory Affairs