

January 13, 2016

Dr. Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Opposition to FDA Recommendations to Flush Certain Medications and Harmonizing Federal Agency Messaging on Safe Medicine Disposal

Dear Commissioner Ostroff:

To protect public health and environmental quality, the signatories to this letter urge the FDA to work with the EPA, the DEA, and the White House Office of National Drug Control Policy to develop clear and consistent guidance to consumers on safe disposal of leftover household medications. We call on the FDA to end its [recommendation](#) that certain medications be disposed by flushing, and to clarify that secure medicine take-back programs provide the best disposal method for leftover household medications.

We appreciate the FDA's efforts to protect people from leftover medications that can be particularly harmful, even fatal, if abused or mistakenly consumed. However, the time has come for FDA to align its medicine disposal guidance with that of federal and local agencies who seek to protect both the public's health and our water quality.

Disposal of leftover medications by flushing contributes to pharmaceutical pollution that is harming aquatic ecosystems and entering our food web. Wastewater treatment plants are designed to remove human waste and easily degraded organics, and cannot effectively remove pharmaceuticals and other complex, synthetic chemicals. Because of this, some wastewater agencies have established laws, regulations, or guidance prohibiting flushing as a disposal method for pharmaceuticals. In these areas, FDA's recommendations infringe on wastewater districts' jurisdictional authority to protect public health.

While pharmaceuticals also enter wastewater through excretion, flushing of unwanted medication is a source that we have the ability and technology to control. The amount of leftover and expired medications in American homes is significant – estimated at 30-40% of all medications sold. It is critical to keep these pharmaceuticals from polluting our waterways by recommending secure and environmentally sound disposal through medicine take-back programs. Preventing pollution is always the most effective and least expensive option to protect public health and environmental health.

Many communities across the country now have medicine collection programs and the DEA's regulation to implement the Secure & Responsible Drug Disposal Act allows new options for take-back of prescription drugs that are controlled substances. We need clear and harmonized direction to the public and health practitioners on using medicine take-back programs, as well as ongoing efforts to increase access to secure medicine take-back programs in all communities.

Messages on medicine disposal are inconsistent between federal agencies and often in conflict with state and local regulations or guidance against flushing or trash disposal of leftover medications. This is confusing and frustrating for the public. Furthermore, the pharmaceutical industry takes advantage of inconsistencies in federal agency messaging to undermine efforts to establish local medicine take-back programs and regulations.

We therefore urge the FDA to end its “flush list” recommendation, and work to create a single disposal guidance that is endorsed by all federal agencies and consistently used on all federal websites and materials. The public should be directed to store medications securely in locked containers or cupboards, to use secure medicine take-back programs where available, never to flush medications, and to dispose of medications in the trash only as a last resort where allowed by local ordinances. We encourage adoption of the following, clear messages on safe medicine disposal:

1. To protect water quality, never flush unwanted medicine down any drain.
2. Use a community medicine take-back program for secure and safe medicine disposal. Check with local household hazardous waste, wastewater, or police departments for locations. Use the medicine manufacturer’s mail-back program if available.
3. Take leftover medicines to the Drug Enforcement Administration’s twice a year National Prescription Drug Take-back Days. Look for a site in your community at http://www.deadiversion.usdoj.gov/drug_disposal/takeback/ or contact your police department.
4. As a last resort, if there are no medicine take-back options in your community: put medicines in a sealed container in the trash after mixing the medicines with an undesirable substance, such as cat litter or used coffee grounds. Make sure the trash cannot be accessed by children, pets, or others who might be looking in garbage. Check with your local government or garbage service first, because local laws may not allow disposing of any pharmaceuticals in the trash.

We look forward to your response to our letter and to your actions to address our concerns.

Sincerely,

Potential organization signers – need to confirm all for revised text of letter.

Patricia Danielson, Vice-President
Alameda County Special District Association

John Birrer
Asepsis Bio Group, Inc.

Heidi Sanborn, Executive Director
California Product Stewardship Council

Andria Ventura,
Clean Water Action

Della Lisi Kerr, Alcohol Drug Education & Prevention Team
County of Orange Health Care Agency

Beverly Hanstrom, President
Colorado Medical Waste, Inc.

Sherrie Rubin, Founder/Director
Hope2gether Foundation



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Paul Koretz
Los Angeles City Councilmember

Patty Garbarino, President
Marin Sanitary Service

Doug Kobold, President
National Stewardship Action Council,

Frederick Mayer, CEO
Pharmacists Planning Service, Inc. (PPSI)

Greg Knell, Community Co-Chair Community Based Prevention
RxSafe Marin

Leslie Tamminen, Ocean Program Director
Seventh Generation Advisors

Graham Hamilton, West LA/Malibu Chapter Executive Committee
Chairman
Surfrider Foundation

Responded to thread- did not formally ask for sign-on:

City of Pittsburgh – Laura Wright, Administrative Officer

City of Richmond Source Control Program – Mary Phelps, Source
Control Inspector III

City of Plymouth – Sarah Hellekson, Public Works Department

County of Marin HHS – Communicable Disease Prevention & Control –
Marsha Grant, RN

Napa Sanitation District Laboratory – Mark Koekemoer, Laboratory
Supervisor

Union Sanitary District – Doug Dattawalker, Environmental Outreach
Representative

Santa Barbara County Public Works Department – Leslie Robinson,
Resource Recovery & Waste Management Division

San Francisco Department of the Environment – Jen Jackson, Toxics
Reduction & Healthy Ecosystems Programs Manager



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Department of Resources Recycling and Recovery – Burke Lucy,
Environmental Scientist

New York State Department of Environmental Conservation – Scott
Stoner, Chief, Standards and Analytical Support Section, Division of
Water

Senator Hannah-Beth Jackson, California State Senate

Individual signers, affiliation stated for purposes of identification only.
e.g Joe Smith, PharmD, Central University School of Pharmacy
Mary Smith, RN, Middleton Hospital

Cc: Administrator Gina McCarthy, U.S. Environmental Protection Agency
Director Dan Ashe, U.S. Fish & Wildlife Service
Acting Administrator Chuck Rosenberg, Drug Enforcement Administration
Director Michael Botticelli, White House Office of National Drug Control Policy