January 26, 2016

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

RE: FDA Recommendations to Flush Certain Medications and Harmonize 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, state 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, some in the pharmaceutical industry take 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 <u>only</u> as a <u>last resort</u> 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,

Individual signers, affiliation stated for purposes of identification only.

Irene Aguilar, MD, Colorado Senate District 32

Hannah-Beth Jackson, California State Senator

David Chiu, California State Assemblymember

Paul Koretz, Los Angeles City Councilmember

Robert F. Kennedy, Jr., Los Angeles, CA and Waterkeeper Alliance

Barbara J. Bickford, Madison, Wisconsin

Nancy Busen, Bentonville, Arkansas

Jennifer Caldwell, CalRecycle

Audrey L. Comeaux, Director-West County Wastewater District

Gary Goldbaum, Health Officer, Snohomish County, Washington

Sarah Hellekson, Solid Waste Manager, City of Plymouth, Minnesota

Heidi Mayer, Marin, California

Chris McFaul, Spokane, Washington

Nate Miley, Oakland, California

Karin North, City of Palo Alto, Watershed Protection Manager,

Carol Scianna, City of Winters, Environmental Services Manager

Ruth W. Shearer, Ph.D., Retired Toxicologist

Margaret Shield, Ph.D., Seattle, Washington

MaryAnne Sullivan, Aging in Place Facilitator, Sibert & Sullivan, LLC

Susan Strand, Environmental Specialist, City of West Sacramento

Mark Nystrom, Energy, Environment and Land Use Policy Manager, the Association of Oregon Counties Angela Goldberg, Member of the San Diego Drug Abuse Task Force Carol Bailey, Concerned Consumer and Member of California Alliance for Retired Americans Veora M. Little, Certified Registered Nurse Anesthetist, Napes, Florida Ed Gottlieb, Chair, Coalition for Safe Medication Disposal, Industrial Pretreatment Coordinator, Ithaca Area Wastewater Treatment Facility

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

Patricia Danielson, Vice-President Alameda County Special District Association

Nate Miley Alameda County Supervisor District 4



Gail Magsaysay MSN, RN, Owner Alternatives in Wellness

G. Tracy Mehan, III, Executive Director of Government Affairs American Water Works Association



John F. Birrer, President/CEO Asepsis Bio Group, Inc.

Diane VanDe Hei, Executive Director Association of Metropolitan Water Agencies



Jim Taft, Executive Director Association of State Drinking Water Administrators



Sherry Hull, Assistant Executive Director Bay Area Clean Water Agencies



Bobbi Larson, Executive Director California Association of Sanitation Agencies



Heidi Sanborn, MPA, Executive Director California Product Stewardship Council



John H. Dane, Executive Director California Resource Recovery Association



Executive Board California Water Environment Association



Melody LaBella, Pollution Prevention Program Coordinator Central Contra Costa Sanitary District



Robert Cole, Environmental Services Manager Central Marin Sanitation Agency



Comm. Mike Robinson, Chair Chisago County Minnesota Board of Commissioners



Robbin Finch, Water Quality Environmental Program Manager City of Boise Public Works



Craig M. Locke, Director of Public Works City of Chowchilla, California



Brian R. Stahl, Deputy Director, Department of Environmental Services City of Gresham, Oregon



Frankie Riddle, Director of Special Programs City of Palm Desert



Phil Bobel, Assistant Director Public Works City of Palo Alto Regional Water Quality Control Plant



Paulina Benner, Environmental Services Manager City of West Sacramento



Greg Meyer, Public Works Director City of Woodland



Greg Geist, Director Clackamas County Water Environment Services



Andria Ventura, Toxics Program Manager Clean Water Action



Curt McCormick, Owner Clean Water Act Consulting Services



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



Beverly Hanstrom, President Colorado Medical Waste, Inc.



Larry Krolikowski, Volunteer Organizer Common Ground of Southeastern Wisconsin Watershed Team



Delta Diablo Sanitation District Gary W. Darling, General Manager



Carly Gibb, Development Assistant Drug Free Collier



John Archer, Interim General Manager Dublin San Ramon Services District



Jacqueline T. Zipkin, Manager of Environmental Services East Bay Municipal Utility District



Colin Bailey, Executive Director
The Environmental Justice Coalition for Water



Violette Brown, President FillAbox Corporation



David Stitzhal, MRP, President Full Circle Environmental, Inc.



Daniel Parshley, Project Manager Glynn Environmental Coalition



Stuart Moody, Board President Green Sangha



Rachel Gibson, Director, Safer Chemicals Health Care Without Harm



John Mohoff, General Manager Healthwise Services



Sherrie Rubin, Founder/Director Hope2gether Foundation



Rodney Larson, Founding Dean Husson University School of Pharmacy



Sharon Ehrhardt, Solid Waste/Clean Sweep Specialist Jefferson County Solid Waste/Air Quality Committee



Daniel Hurley, Division Manager Lane County Waste Management



Jeff Reinhardt, Public Affairs & Communications Manager Las Virgenes Municipal Water District



David W. Pedersen, P.E., General Manager / Administering Agent Las Virgenes – Triunfo Joint Powers Authority



Mike Mohajer, Representative Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force



Amy Ziff, Founder & Executive Director MADE SAFE & NONTOXIC CERTIFIED



Aglaia Panos Pharm D, President Marin County Pharmacists Association

Patty Garbarino, President Marin Sanitary Service



Paul Sanftner MEDS Coalition, Alameda County



David St. Pierre, Executive Director Metropolitan Water Reclamation District of Greater Chicago



Kerrin O'Brien, Executive Director Michigan Recycling Coalition



Jennifer Volkman, Household Hazardous Waste Program Coordinator, MPCA Minnesota Pollution Control Agency



Timothy Healy, General Manager Napa Sanitation District



Adam Krantz, Chief Executive Officer National Association of Clean Water Agencies



April Rovero, Executive Director National Coalition Against Prescription Drug Abuse



Doug Kobold, President National Stewardship Action Council



Tiffany C Ingram, JD, Midwest Advocacy Director Natural Resources Defense Council



Kristen Anderson, Project Coordinator Nebraska MEDS Coalition



Victoria Hodge, President North American Hazardous Materials Management Association



Janet Gillaspie, Executive Director Oregon Association of Clean Water Agencies



Marti Martz, Senior Coastal Outreach Specialist Pennsylvania Sea Grant



Frederick S. Mayer, R.Ph., MPH, CEO Pharmacists Planning Service, Inc. (PPSI)



Dianna Cohen, CEO | Co-Founder Plastic Pollution Coalition



Thomas P. Jacobus, Chairman Potomac River Basin Drinking Water Source Protection Partnership - Metro Area Water Utility Committee



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



Terrie Mitchell, Manager, Legislative & Regulatory Affairs Sacramento Regional County Sanitation District



Victoria O. Conway, Head Wastewater Management Sanitation Districts of Los Angeles County



Katherine O'Dea, Executive Director Save Our Shores



Leslie Tamminen, Ocean Program Director Seventh Generation Advisors



Deborah Raphael, Director San Francisco Department of the Environment



Cynthia Stark-Wickman, Executive Coordinator San Juan Island Prevention Coalition



Stiv J. Wilson, Campaigns Director The Story of Stuff Project



Angela T. Howe, Esq. | Legal Director Surfrider Foundation, Representing 84 domestic chapters



Tina Segura, Chair Surfrider Foundation West LA/Malibu Chapter



Debbie Branch, Chair Texas Product Stewardship Council



Doug Dattawalker, Environmental Outreach Representative Union Sanitary District



Dan Tafolla, Director of Environmental Services Vallejo Sanitation & Flood Control District



Melissa Meeker, Executive Director WateReuse



Angie Rosser, Executive Director West Virginia Rivers Coalition



Nancy A. Eggleston, R.S. Environmental Health and Communicable Disease Supervisor Wood County Health Department



Steve Devine, Program Manager Zero Waste Marin

