

January 4, 2010

Octavia Conerly  
US EPA Office of Water (4304T)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N. W.  
Washington, DC 20460

Dear Octavia Conerly,

The New England Interstate Water Pollution Control Commission (NEIWPC), on behalf of the New England States and New York State, is writing to urge the US EPA Office of Water to coordinate with other federal agencies to better incorporate green chemistry concepts into the lifecycle of pharmaceuticals and personal care products (PPCPs). There is a strong need for federal leadership and inter-agency collaboration on this issue and in this letter we propose a management structure for PPCPs that focuses on a holistic lifecycle (e.g. green chemistry) approach to design, production, consumption, and disposal of these compounds. We urge federal agencies to better collaborate on solutions that address the defined environmental, aquatic, and human impacts of PPCPs.

Published studies have detected trace concentrations of pharmaceuticals in our nation's waters and demonstrated harmful effects in aquatic organisms from exposure to these compounds. As awareness of PPCPs increases, states, the public, and water utilities among others are searching for solutions to keep these chemicals out of our nation's waters. The following comments were developed with the input of NEIWPC's Pharmaceuticals and Personal Care Products Workgroup. NEIWPC's role is to coordinate and assist the efforts of our seven member states to improve and maintain water quality and the health of aquatic environments and ecosystems.

### **Impacts of PPCPs**

Pharmaceuticals and personal care products have been found in our nation's waters as well our wastewater and drinking water treatment facilities. These compounds enter the aquatic environment through a variety of routes, including (1) disposal of unused or unwanted medications by flushing, (2) direct release to open waters via washing, bathing, and/or swimming, and (3) release through excretion (human or animal). These compounds have been shown to adversely affect organisms, for example endocrine disrupting compounds have been shown to cause genetic malformation in aquatic organisms such as the development of intersex fish. An accumulation of antibiotics and anti-bacterial soaps and lotions "could have detrimental effects on the most sensitive species such as bacteria or algae,"<sup>1</sup> the backbone of the aquatic food web.

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<sup>1</sup> Segura PA, François M, Gagnon C, Sauvé S. 2009. Review of the Occurrence of Anti-infectives in Contaminated Wastewaters and Natural and Drinking Waters. *Env Health Perspectives* 117(5):675-684.

Wastewater effluent is one of the most significant vehicles by which PPCPs enter the aquatic environment and, as a result, wastewater treatment processes are being targeted to mitigate PPCP transport. Conventional treatment processes, however, were not designed for PPCP removal and are only partially effective in doing so. To further complicate matters, wastewater treatment processes can break down PPCPs into different compounds that are sometimes more potent than the parent compound.<sup>2</sup>

### **Current Federal Action and Involvement**

Across the country, federal agencies are addressing pharmaceuticals and personal care products in the environment by conducting research, evaluating pharmaceutical disposal techniques, and providing product information.

*Research:* The United States Geological Survey (USGS) and Environmental Protection Agency (EPA) are conducting research to “provide information on these compounds for evaluation of their potential threat to environmental and human health.”<sup>3</sup> Research includes developing analytical methods, characterizing sources, and evaluating drinking and wastewater treatment as well as environmental transport, occurrence, and fate.

*Risk:* Databases provide tools to assess aquatic and human risk - the National Ocean and Atmospheric Administration (NOAA) tracks information on the general chemistry and toxicology of potential environmental levels of pharmaceuticals.<sup>4</sup> The Department of Health and Human Services (DHHS) provides consumers with brand and manufacturer information, health effects, handling/disposal procedures, and ingredients of common personal care products.<sup>5</sup>

*Disposal:* The EPA and Drug Enforcement Administration (DEA) are involved in pharmaceutical disposal, requesting information on current management practices as well as revisiting existing regulations in light of emerging drug return, or “take-back” programs. The White House Office of National Drug Control Policy (ONDCP) released federal guidelines on the “Proper Disposal of Prescription Drugs” recommending techniques for drug disposal.

These efforts, successful in defining the scale of the problem, serve only as a starting point. Federal agencies need to collaborate on solutions that address the defined environmental, aquatic, and human impacts of PPCPs.

### **The Next Step – Green Chemistry**

The costs associated with the production and use of PPCPs have been externalized onto the aquatic environment, water utilities, and state and federal governments. Pharmaceutical and personal care

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<sup>2</sup> Reckhow D, Arcaro K. “Pharmaceuticals, Personal Care Products, and Endocrine Disrupting Compounds in Drinking Waters.” Regional Science Council Seminar. Webinar, May 13, 2009.

<sup>3</sup> USGS Toxic Substances Hydrology Program: Research Projects – Emerging Contaminants <http://toxics.usgs.gov/regional/emc/> Accessed July 16, 2009.

<sup>4</sup> NOAA’s NCCOS: Pharmaceuticals in the Environment, Information for Assessing Risk <http://www.chbr.noaa.gov/peiar/> Accessed July 16, 2009.

<sup>5</sup> US DHHS Household Products Database <http://hpd.nlm.nih.gov/index.htm> Accessed July 16, 2009.

products should be initially designed so those responsible for the disposal and subsequent removal of PPCPs from the natural environment are not solely shouldering the burden. It is vital to evaluate the entire lifecycle of a compound and design something that works within our existing framework rather than having to compromise or change our framework to fit a compound.

### **What Needs to Be Done?**

Green chemistry is the design of chemical products and processes that reduces or eliminates the use and generation of hazardous substances. Examining a compound's lifecycle and how each phase can be altered and "greened" to lessen their adverse downstream impacts is an important next step in addressing PPCPs in our waters. Below are examples of how green lifecycle changes can decrease downstream impacts.

#### *Discovery and Development*

- Maintain chemical efficacy while adjusting design to have little or no toxicity to humans and the environment
- Incorporate chemical practices that minimize waste and energy use
- Create pharmaceuticals that fully (or to the greatest extent possible) metabolize in a patient's body to reduce the amount of pharmaceuticals excreted into the wastewater stream, and/or design compounds to be rendered innocuous by conventional wastewater treatment processes
- Develop a "rating system" for raw materials and compounds to allow chemical manufacturers to make more informed choices about the products they develop

#### *Prescribing*

- Prescribers should practice prudent prescribing, including the use of trial medication packs to minimize the distribution of unnecessary pharmaceuticals
- Increase patient education regarding effective medical practices and environmental consequences of overprescribing

#### *Disposal and Treatment*

- Better understand how current wastewater treatment processes interact with PPCPs (including byproducts and daughter products) and support the development of treatment technologies that effectively remove PPCP compounds
- Encourage proper disposal of PPCPs through minimizing flushing and promoting takeback programs

Aside from addressing the chemistry behind PPCPs, it is also important for US EPA Office of Water to raise awareness of the need for and methods available for change within the chemistry community. Providing recognition to encourage changes, like the Presidential Green Chemistry Challenge Awards Program, is vital to the success of these changes being incorporated into mainstream chemical production.

#### *Federal Collaboration and Cooperation*

NEIWPCC's PPCP Workgroup is encouraging federal PPCP stakeholders to form a cross-agency task force to better coordinate the application of green chemistry to PPCP compounds and processes. Federal agencies need to synthesize PPCP occurrence and treatment data with risk and toxicology data to determine which compounds are prime candidates for a lifecycle reevaluation and work with FDA to determine best

management practices for implementing “green” manufacturing practices. Agencies need to utilize data (and encourage more research) from the USGS, NOAA, DHHS, and CDC to make informed decisions. The EPA’s Office of Prevention, Pesticides, and Toxic Substances (OPPTS) has developed a Green Chemistry Program that “recognizes and supports chemical technologies that reduce or eliminate the use or generation of hazardous substances during the design, manufacture, and use of chemical products and processes.”<sup>6</sup> Federal agencies need to tap into the efforts of this program and incorporate as much green chemistry as possible into their PPCP efforts.

The Federal Interagency Work Group on Pharmaceuticals in the Environment is co-chaired by the USGS, EPA, and FDA and comprised of 11 federal agencies. The Work Group, established in 2006, was charged with developing a research strategy that addressed topic areas and data needs for risk assessments as well as recommend areas for federal collaboration. While individual agencies are pursuing PPCP activities and research, the Work Group has yet to release a research strategy. If this Work Group is to be an effective vehicle for fostering interagency communication and cooperation, we would like to see the group take a more active role in the implementation of PPCP lifecycle management and green chemistry goals.

NEIWPCC greatly appreciates your consideration of the comments and suggestions in this letter. We look forward to continuing this conversation with US EPA Office of Water staff in the future. If you have any questions, please do not hesitate to contact me or Sarah Peters of my staff at (978) 323-7929.

Sincerely,



Ronald F. Poltak  
Executive Director

Cc: NEIWPCC Executive Committee  
NEIWPCC Pharmaceuticals and Personal Care Products Workgroup  
Susan Sullivan, Rebecca Weidman, and Sarah Peters, NEIWPCC

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<sup>6</sup> EPA OPPTS: Green Chemistry <http://www.epa.gov/greenchemistry/index.html> Accessed July 16, 2009.