Comments on Docket No. DEA-316

(Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration) By Potomac River Basin Drinking Water Source Protection Partnership http://www.PotomacDWSPP.org

For Concerned Interest Groups:

42. What prompted you to get involved in the issue of drug disposal?

The Potomac River Basin Drinking Water Source Protection Partnership (DWSPP) is a consortium of regional water utilities and government agencies, representing over 5 million customers in the Washington, DC metropolitan area and upstream Potomac River communities. The Partnership focuses its efforts on protecting the sources of our drinking water from contaminants, including drugs, chemicals and pathogens. We have learned from research conducted by USDA and USGS along with other related contaminant occurrence studies that drugs are present at low concentrations in the Potomac River. The suspected primary source of these drugs is pass-through of substances in municipal wastewater treatment effluent. This stems from both incompletely metabolized doses ingested and excreted, and unused medicines that are flushed down the toilet as a means of disposal. While the former source cannot be readily reduced without significant and expensive changes to wastewater treatment processes at publicly owned treatment works (POTWs), eliminating or substantially decreasing the amount of unused medicine flushed down the toilet is a logical measure to reduce the presence of drugs in wastewater and ultimately in our sources of drinking water. To this end, amending DEA drug disposal rules is a valuable vehicle for reducing the amount of pharmaceuticals that eventually end up in waterways.

43. What is your group doing to address this issue?

The Potomac River DWSPP established a workgroup to focus on emerging contaminants such as pharmaceuticals. This workgroup held two workshops, one in 2005 and 2007, featuring presentations by nationally prominent experts to educate and advise DWSPP members on the occurrence and sources of contaminants such as drugs in the Potomac River. The workgroup continues to track the latest research by federal agencies such as USGS and USEPA, as well as the research conducted by drinking water advocacy and research organizations (e.g., American Water Works Association, Water Environment Federation, Water Research Foundation, Water Environment Research Foundation). The three largest drinking water utilities in DWSPP undertook a coordinated water sampling program in 2008 to test for drugs at their raw water intakes and in their finished (treated) water. This program was coordinated with the Metropolitan Washington Council of Governments. In addition, the Partnership is actively tracking take-back programs nationwide, to evaluate whether a coordinated regional program in the DC metro area would be feasible. Via our website, we also provide relevant information that is routinely updated for DWSPP members and the public.

44. What have been your successes?

The DWSPP has at least raised awareness and educated our members on these issues which will help with responding to public and media inquiries.

45. What challenges or difficulties have you encountered?

Our study of take-back programs has revealed complex, challenging and, as yet, unresolved issues for any similar program that we may elect to sponsor as a regional initiative. Challenges include selecting the appropriate locations (venues) and meeting the requirements of multiple jurisdictions; eliciting support from the medical community to identify different drugs and classify them as controlled or noncontrolled; the time investment required to coordinate with the medical community and government agencies; eliciting support from law enforcement agencies in multiple

jurisdictions to take custody of and dispose of controlled substances; and identifying sources of funding for and vendors that can dispose of noncontrolled substances.

46. If you accept medications for disposal, what records do you maintain, if any? $N\!/\!A$

47. If you accept medications for disposal, how do you store and secure these medications prior to disposal? N/A

48. If you accept medications for disposal, do you differentiate between controlled substances and noncontrolled substances? If so, how? N/A

49. What has been law enforcement's involvement in the disposal of these medications, if any?

N/A

50. What would you estimate to be the percentage, quantity, or other measurable unit of controlled substances as compared to noncontrolled substances that your disposal programs received? N/A

51. If you have a pharmaceutical disposal program in place, how is it funded? $\ensuremath{\text{N/A}}$

52. There is concern that residue from pharmaceuticals is being found in drinking water. What is your understanding of the percentage of this problem that is due to ultimate users flushing their unused or unwanted medications?

The research our group has tracked on sources of drugs in wastewater suggests that there is no consensus on the amount or percentage of drugs that enter wastewater from flushing unused medicines. However, there is evidence that the amount of drugs being sewered is significant. A 2008 Associated Press report estimates that the nation's 5,700 hospitals and 45,000 long-term care facilities annually generate at least 250 million pounds of pharmaceuticals and contaminated packaging with no way to determine the relative amounts of each (Donn, Mendoza and Pritchard, USA Today, September 14, 2008), Anecdotal evidence suggests that long-term care facilities. hospices and other non-hospital healthcare institutions typically flush unused medications. While hospitals can return undispensed drugs to a reverse distributor, medications that have been dispensed but refused or unused by patients are likely flushed as well since those drugs cannot be given to another person. Additionally, at least one state within the Potomac River Basin has a statute requiring healthcare facilities to immediately flush any remaining unused medications upon the expiration of individuals in their care. Agribusinesses and animal feeding operations may also discharge significant amounts of some drugs directly to water bodies. At the consumer level, patient survey data from published studies reveal that 35 percent of patients have rinsed medications down the sink and the number of patients flushing medications can range from 35 to 54 percent (Seehusen and Edwards, 2006, Journal of the American Board of Family Medicine, v. 19, p. 542-547; Boehringer, 2004, Pharmacist's Letter/Prescriber's Letter, v. 20, p. 1-5). However, more studies on flushed drug sources in different geographic regions, population densities, and socioeconomic environments are needed if effective education and control measures are to be taken. Further information is also needed on the efficacy of conventional and advanced wastewater treatment processes to remove or reduce the concentration of drugs that enter POTWs and what concentration are passed onto the environment in treated effluent, which ultimately contributes to drinking water sources downstream. In addition, more research is needed to evaluate the by-products of those wastewater processes (e.g., sludge/biosolids, etc.) to ensure that we are not simply transferring these contaminants from one media to another.