HUNTON& WILLIAMS

WATER ALERT

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Public Fears Spur Increased Scrutiny of Drugs in Nation's Drinking Water

This week, the Associated Press began a series of reports on the presence of trace amounts of pharmaceutical products in the drinking water supplies of 41 million Americans. Based on a five-month inquiry, the AP identified 56 pharmaceutical and personal care products ("PPCPs") in treated drinking water, including common household drugs such as birth control, antidepressants, pain killers, antibiotics, steroids and fragrances. Headlines such as "Meds Lurk in Drinking Water" were obviously aimed at stirring public emotion and fear. On the same day the story broke, Senators Boxer (CA) and Lautenberg (NJ) announced their plan to hold hearings on the matter. According to Benjamin Grumbles, the head of the U.S. Environmental Protection Agency's (EPA) water program "we recognize it is a growing concern and we're taking it very seriously." While there have been calls by some for immediate action, the EPA has found there is "no evidence of adverse human health effects from PPCPs in the environment." http://epa.gov/ppcp/fag.html

PPCPs are ubiquitous and among a larger cast of chemicals referred to by the EPA as "emerging contaminants," which are generally characterized as unregulated chemicals found in the environment (often in low concentrations) and whose effects on the environment and human health are not well understood. PPCPs enter the

water through a number of sources, but primarily through the public's everyday use and disposal of pharmaceutical products in sinks or toilets, which ultimately are discharged through waste treatment plants and septic systems. Other sources are believed to include storm water discharges that come into contact with pet and agricultural wastes containing veterinarian products.

Since the late 1990s, federal scientists have studied the extent of PPCPs in water bodies and their potential effects as environmental stressors. Also, over the last several years the EPA, the Food and Drug Administration, the Drug Enforcement Agency, the U.S. Geological Survey, and the pharmaceutical industry have worked cooperatively to identify the gaps in our scientific understanding, to evaluate the regulatory challenges to reducing PPCPs in the environment, and to establish "take back" programs for unused drugs. According to Brent Fewell, the former deputy assistant administrator for EPA's office of water, who is now counsel at Hunton & Williams, "the pharma industry has been and continues to be a very important partner in helping the Agency better understand the issue and promote important programs aimed at educating consumers about safe and proper disposal practices."

Although there is no new news in the AP story, the close scrutiny and heightened attention will invariably reinvigorate calls for new regulations or legislation, and an accelerated timetable for regulatory decisions and increased monitoring efforts. It may also spawn activist litigation against producers, users and dischargers of PPCPs, and possibly against water providers. In July, the USGS is also expected to release the Phase I results of a similar (yet more comprehensive) study that evaluates the potential presence of 270 compounds at numerous drinking water plants around the country. Ultimately, to successfully

manage the risks and liabilities of PPCPs will require a keen understanding of the interdisciplinary nature of the challenges and of the complexity of the divergent regulatory programs at play, including the Safe Drinking Water Act, Clean Water Act, the Toxic Substances Control Act, the Federal Insecticide, Fungicide, and Rodenticide Act and the Food Quality Protection Act.

The Water Practice Group at Hunton & Williams has extensive experience identifying and handling water-related disputes across a wide variety of statutes and industries, including the application to pharmaceuticals of the

divergent programs of the Clean Water Act, the Safe Drinking Water Act, the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act. Hunton & Williams' water practice lawyers have represented clients in administrative and judicial enforcement litigation and civil suits throughout the United States for more than 25 years, since the inception of the Clean Water Act and other environmental legislation.

For more information, please visit our <u>Water Quality</u>, <u>FDA</u> and <u>Products</u> <u>Liability</u> Practice Pages.

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