

## Environmental Law

### The Hazards of Pharmaceutical Disposal: Emerging Environmental Issues of Concern

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**R**ecent studies revealing the presence of pharmaceuticals in our nation's waterways arising from a variety of sources, particularly hospitals, has brought the topic of pharmaceutical waste disposal to the forefront of environmental and public health issues. New technology has permitted more comprehensive studies which indicate that the prior practice of discharging waste pharmaceuticals down the drain, while generally accepted and legal, has been contaminating our waterways. Although harmful chemicals can enter water sources through various means, hospitals and health care facilities are authorized to flush or pour certain wastes and products directly into drains. From there, these products typically flow into sewage treatment plants or septic systems which have been discovered to be ill-

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equipped to remove all pharmaceuticals, resulting in these medications filtering into our waterways. Consequently, regulatory agencies are now looking to enact stricter environmental laws governing the disposal of pharmaceuticals.

Although laws governing the disposal of hazardous wastes have existed for years, there has been a lack of definitive regulations at either the federal or state level with respect to the proper disposal of pharmaceutical wastes and prescription medications. Generally, hazardous wastes consist of any waste with properties that make it dangerous or capable of having a harmful effect on human health or the environment. This definition excludes certain solids and many chemicals which are classified as 'pharmaceutical wastes' but deemed nonhazardous. Regulatory agencies fear that absent a cohesive and coherent policy governing disposal of pharmaceutical wastes, uncertainty regarding the appropriate methods for disposal will lead to a further contamination of waterways. As a result, the Environmental Protection Agency and New Jersey Department of Environmental Protection are actively reviewing existing policies governing the disposal of pharmaceutical wastes, as well as other hazardous and potentially hazard-

ous chemicals, particularly as they pertain to hospitals and health care facilities.

Wastes typically disposed of by health care facilities consist of pharmaceuticals and contaminated packaging. Pharmaceutical and personal care pollutants can consist of both hazardous and nonhazardous materials. They include an expansive and varied category of chemical substances ranging from prescription to over-the-counter (OTC) medications, nutraceuticals, hormones, antidepressants and biopharmaceuticals, among others. Generally, epinephrine (Waste Code 042) is by far the most common hazardous drug waste generated in a health care setting. Proponents of change to the existing laws contend that although priority should be given to the management of hazardous pharmaceutical waste, this should not preclude consideration and implementation of adequate procedures for the disposal and management of nonhazardous pharmaceutical waste.

Currently, disposal of unused pharmaceuticals by health care facilities is governed by the provisions of the Resource Conservation and Recovery Act (RCRA) and Controlled Substance Act (CSA). RCRA controls the management and disposal of hazardous pharmaceutical

wastes and ensures they are managed in an environmentally sound manner. Under RCRA, a waste is considered "hazardous" if specifically listed as such by the EPA or if it exhibits one or more of the specified characteristics required to render it as hazardous under its provisions. However, RCRA regulations have not been updated since being enacted in 1976. Thus many pharmaceuticals currently evoking concern, such as hormones, antibiotics, antidepressants and other potent drugs and trace chemotherapy waste, are not covered by its provisions.

The CSA consolidates numerous laws regulating the manufacture and distribution of controlled substances. Under the CSA, registrants of the act may dispose of harmful controlled substances through several permitted means, including reverse distribution, destruction in accordance with applicable state law, returning unused products to manufacturers or flushing. Disposal by use of reverse distribution companies which track manufacturer return policies and facilitate a return of any unused or expired drugs for potential credit from the manufacturer is an option which has been approved by the EPA for close to three decades through letters of interpretation. However, not all products are eligible for credit and those which cannot be returned are frequently thrown away or flushed. Additionally, since most long-term care facilities are not CSA registrants, they are not eligible to return pharmaceuticals to manufacturers or utilize reverse distributors.

As concern over pharmaceutical waste and its impact on the environment and human health continues to escalate, federal and state agencies have demonstrated increased vigilance in inspecting waste disposal policies at hospitals and health care facilities. A wave of enforcement actions by government officials against many unsuspecting health care facilities has resulted, despite the lack of clear-cut disposal policies at either the state or federal level. A prime example of this is the recent actions of the New York State Office of Attorney General ("OAG") which initiated investigations against 15 small hospitals and nursing homes in New York's watershed region. In accordance

with generally acceptable practices in the industry, these facilities had been flushing certain waste solvents and pharmaceuticals into sinks and toilets. Fines and penalties and adverse publicity were imposed on the unsuspecting health care providers who agreed, although not required by law, to stop flushing wastes and to direct all their pharmaceutical wastes to incinerators. Strong criticism was levied against the OAG for its actions.

In order to address the criticism expressed by many regarding the lack of adequate regulations, state and federal agencies are seeking to revisit current policies for the disposal of all harmful pharmaceutical wastes, including those which are not currently covered by RCRA. To that end, the EPA has proposed to add hazardous pharmaceutical wastes to the federal universal waste program by April of 2011. Adding pharmaceuticals to the universal waste category will provide definitive regulations which govern their disposal. However, there is no guarantee that the more lenient practice of including waste pharmaceuticals as universal waste will be accepted by the states.

Additionally, the EPA is also developing 'best practices' for managing unused pharmaceuticals at health care facilities, which it anticipates will be published by October. The study is aimed at understanding the factors which contribute to pharmaceuticals entering the water. As part of this process, the EPA has initiated a study of unused pharmaceutical practices at hospitals and health care facilities. It focuses primarily on medical facilities which are believed to dispose of the largest quantities of unused pharmaceuticals directly into water. Generally, health care facilities discharge their wastewater to publicly owned treatment works (POTWs). However, traditional wastewater treatment is not designed to remove pharmaceuticals. While some of the upgraded facilities have more advanced treatment technologies, even these facilities are not specifically designed to remove pharmaceuticals. Thus, most pharmaceutical waste passes through without being filtered, which results in the waste ultimately passing through into our waterways. Based on these findings, the EPA has issued an interim report indicating its preliminary

observations regarding existing disposal practices.

New Jersey has recently undertaken strong initiatives to impose more stringent disposal requirements for pharmaceuticals. New Jersey's existing framework for the regulation of contaminants, although stricter than federal guidelines, provides for their regulation on a chemical-by-chemical basis. Thus, it can take several years before standards for emerging contaminants are set. Contaminants are tested extensively and evaluated on an individual basis to determine the level at which no unacceptable risk to human health is present. Adequate information regarding their toxicology and concentration levels in the state's waterways must be obtained before a determination can be made as to whether their inclusion on New Jersey's Right to Know Hazardous Substance List (RTKHSL) is necessary. Currently, New Jersey's RTKHSL contains over 3,000 hazardous substances, including those defined as carcinogenic, mutagenic, teratogenic, corrosive, flammable and reactive substances. However, while this approach may be sufficient to address concerns relating to a single, high-concentration contaminant, it may not be suitable for addressing low-level contamination occurring as a result of pharmaceuticals or multiple, combined chemicals.

Other studies conducted in New Jersey by the DEP, in collaboration with the U.S. Geological Survey, Rutgers University, UMDNJ and the federal Centers for Disease Control, have revealed that the State's ground and surface waters, as well as drinking water, contain low levels of various chemical compounds, including pharmaceuticals. In order to address this issue, the DEP is considering regulating organic contaminants as a class of contaminants as opposed to individual chemicals. The change would require the development of "treatment techniques" for the removal of contaminants from drinking water. The hiring of consultants to conduct comprehensive reviews on available treatment processes have already commenced in furtherance of these options.

Legislative changes have also been proposed which would prohibit health care institutions, their employees and/or staff

from flushing or pouring any unused medication into a sewer system or septic system. Additionally, the state's legislature has proposed that a New Jersey Water Supply and Pharmaceutical Product Study Commission be established which would investigate, quantify and evaluate the risks of pharmaceutical products in the water supply of New Jersey. If approved, the commission would be charged with developing recommendations for proper disposal methods and potential filtering techniques which would adequately remove pharmaceutical products from New Jersey's waste

streams.

The issue of proper disposal of pharmaceuticals is complex and has become a growing cause of concern among the health care and environmental communities alike. It is likely that significant changes to existing disposal policies and regulations will be made at both the federal and state level. In the interim, health care entities should focus on reviewing their existing disposal practices and engage legal and consulting professionals to evaluate their current practices which might subject them to exposure or penalties for violations of existing regu-

lations under either state or federal laws. To the extent a safer, viable alternative is available for disposal which is in compliance with federal and state regulations; all efforts should be made to implement alternatives, particularly where flushing is the existing method of disposal. As is evident by the actions of federal and state regulatory agencies, previously accepted methods of disposal will no longer be tolerated. Accordingly, hospitals and health care facilities must be proactive with their disposal policies and enact alternatives before the need arises. ■