12-2012

Comment: Emerging EPA Regulation of Pharmaceuticals in the Environment

Gabriel Eckstein
Texas A&M University School of Law, gabrieleckstein@law.tamu.edu

Emerging EPA Regulation of Pharmaceuticals in the Environment

by Gabriel Eckstein

Gabriel Eckstein is a Professor of Law, Texas Wesleyan University, and Of Counsel, Sullivan & Worcester.

A recent report by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA) criticized EPA for failing to take regulatory action regarding pharmaceuticals found in the nation's freshwater resources. The May 25, 2012, report—entitled *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal* (OIG Report)[1]—disapproved of EPA's lack of progress in determining whether certain pharmaceuticals found in surface, ground, and drinking water qualify as hazardous waste, as well as in establishing an evaluation and regulatory process for pharmaceutical wastes. As a result of the report, EPA is now considering mechanisms for assessing and regulating the presence of certain pharmaceutical products in the environment as hazardous wastes under the Resource Conservation and Recovery Act (RCRA).[2]

I. Background

In recent years, serious questions have been raised regarding the environmental and health impacts of the multitudes of pharmaceutical and personal care products (PPCPs) that have accumulated in the nation's freshwater resources. Numerous studies have suggested that exposure to certain PPCPS, such as antibiotics and endocrine disruptors, may result in a variety of adverse health impacts in humans; other research has more conclusively established the detrimental effects that even minute concentrations of certain drugs can have on aquatic species. The most obvious pathway by which humans can be exposed to PPCPs is by consuming contaminated water. Exposure, however, may also occur through the consumption of fish and shellfish that have bioaccumulated PPCPs, or through swimming or bathing in water containing PPCPs.

The wastewater discharge and treatment communities have been increasingly concerned about PPCPs in light of their ability to persist or only partially degrade in water and during the wastewater treatment process and, as a result, the growing presence of PPCPs in treated wastewater effluent that reaches streams, lakes, groundwater, and seawater. Similarly, freshwater treatment operators are becoming alarmed about their ability to provide safe freshwater to the nation's population and the steps they may have to take to ensure water quality. Moreover, producers of PPCPs and generators of large quantities of PPCP wastes, such as hospitals and nursing homes, are also becoming concerned about the regulation of these wastes.

PPCPs are an extremely diverse group of chemicals used in health care, cosmetics, hygiene, veterinary medicine, and agriculture. Researchers have estimated that the number of commercially available PPCP substances worldwide may be as high as six million. PPCPs are ubiquitous pollutants, entering the environment worldwide due to widely dispersed usage in industry and agriculture, as well as by individuals at home. Sources of PPCPs include human and animal feces and urine, hospital and medical wastes, wastes from industrial and agricultural processes, the inappropriate disposal of unwanted PPCPs products, urban runoff, and leachate from landfills. These contaminants are rarely treated or removed in the wastewater treatment process and typically remain in waters discharged from wastewater treatment plants into receiving streams and lakes, as well as in solid and liquid wastes applied to lands designated as application sites.

II. Regulating Pharmaceutical Waste

The U.S. Congress has not adopted legislation specifically aimed at PPCPs generally, or pharmaceutical products solid waste streams specifically. Nevertheless, certain pharmaceutical wastes are subject to regulation under RCRA. Under that statute, EPA (or a state agency authorized by EPA) regulates the generation, storage, transportation, treatment, and disposal of solid wastes that are deemed to be *hazardous*. Facilities, including hospitals, nursing homes, pharmaceutical dispensers, and other health-related operations that generate

1. Rep. No. 12-P-0508, *available at* http://www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf.
2. 42 U.S.C. §§6901-6992k, ELR Stat. RCRA §§1001-11011.

between 100-1,000 kilograms (kg) (220-2,200 pounds (lbs.)) of hazardous waste per month, or up to 1 kg (2.2 lbs.) of *acute* hazardous waste per month, must comply with RCRA's hazardous waste provisions. Those include approved containers for transporting hazardous wastes, transport by designated hazardous waste transporters, and disposal by permitted hazardous waste disposal facilities. Facilities that generate 1,000 kg (2,200 lbs.) or more of hazardous waste per month, or 1 kg (2.2 lbs.) or more of acute hazardous waste per month, are subject to additional requirements. Disposal of hazardous waste in municipal waste landfills, municipal incinerators, or medical waste plants is strictly prohibited under RCRA.

EPA's RCRA regulations set forth a number of tests for identifying wastes as hazardous. Wastes may be classified as hazardous if they are found to be ignitable, corrosive, toxic, or reactive. While most PPCP waste products are not ignitable, some substances (like solvents) can be corrosive, numerous PPCPs have been found toxic to humans as well as plants and animals, and many PPCPs react with other substances to produce toxic or otherwise harmful compounds. EPA can also classify wastes as hazardous by identifying those that can be fatal to humans or animals above certain thresholds or doses (P-list substances), and those that either exhibit any of the four hazardous characteristics noted above or contain a toxic constituent (e.g., chemical compounds or elements that have been shown to have toxic, carcinogenic, mutagenic, or teratogenic effects on humans or other life forms) capable of posing a "substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed"[3] (U-list substances). Unfortunately, the vast majority of PPCPs have yet to be evaluated for any hazardous qualities.

According to the OIG Report, EPA in 1980 identified 31 pharmaceutical substances that met the hazardous waste criteria for listing under RCRA.[4] Since that initial designation, while the Food and Drug Administration approved hundreds of new drugs (an average of 30 drugs each year since 1996), EPA has not updated its RCRA pharmaceuticals list. Moreover, EPA has not established a process for regularly identifying and reviewing new or existing pharmaceuticals that may qualify for regulation as hazardous waste products. In contrast, the National Institute for Occupational Safety and Health (NIOSH) has identified more than 160 drugs that it states should be handled as hazardous materials,[5] while the Occupational Safety and Health Administration (OSHA) lists 61 pharmaceuticals on its own hazardous drug list.[6] According to the OIG:

> RCRA hazardous waste regulations are not keeping up with drug development and the potential hazards they may pose if mismanaged and disposed without the necessary protections to human health and the environment. Without an established process to review pharmaceuticals, EPA cannot ensure that it has identified pharmaceutical contaminants that may pose a hazardous risk to human health and the environment.[7]

In 2008, EPA attempted to address this deficiency by proposing to add hazardous waste pharmaceuticals to the Universal Waste Rule (UWR) under RCRA. The UWR is an EPA program designed to streamline the management and disposal of some of the more commonly occurring hazardous wastes, like spent batteries, pesticides, and mercury-containing equipment. EPA believed that adding hazardous waste pharmaceuticals to this program would "facilitate better management of pharmaceutical wastes by streamlining the generator requirements and encouraging generators of hazardous pharmaceutical wastes to manage them under the provisions of the UWR, which ensures that these hazardous pharmaceutical wastes are properly disposed of and treated as hazardous wastes."[8] Following substantial negative comments, the Agency withdrew the proposal, concluding that it would have to repropose a new rule to adequately respond to the various concerns. EPA has yet to follow through on this effort.

III. The OIG's Concerns

In its report evaluating EPA pharmaceutical-related activities, the OIG faulted the Agency for failing to update its list of pharmaceuticals that met the hazardous waste criteria under RCRA, as well as for failing to establish a process by which the Agency can regularly assess and identify new or existing pharmaceuticals that may qualify for regulation. Highlighting the efforts of the NIOSH and OSHA and considering those agencies' lists as a valid starting point, the OIG identified eight chemicals found in certain pharmaceuticals that were not regulated by EPA, but that met EPA criteria for regulation as "acute hazardous waste." It also identified three pharmaceuticals currently regulated by EPA under RCRA's "toxic" criteria (U-list), but that actually met RCRA's "acutely" toxic standards (P-list). The OIG also distinguished 21 other pharmaceuticals that currently are not regulated by EPA, but which may qualify as "toxic" under EPA's RCRA criteria.

In addition, the OIG Report noted that according to EPA itself, many "health care workers, retail pharmacy

3. 42 U.S.C. §6903(5), ELR Stat. RCRA §6903(5).
4. According to the Health Care Environmental Resources Center (*available at* http://www.hercenter.org/hazmat/pharma.cfm#listed), seven pharmaceutical substances are found under EPA's P-list (Arsenic trioxide, Epinephrine, Nicotine, Nitroglycerin, Physostigmine, Physostigmine salicylate, and Warfarin >0.3%), and 24 are included in the Agency's U-list (Chloral Hydrate, Chlorambucil, Chloroform, Cyclophosphamide, Daunomycin, Dichlorodifluromethane, Diethylstilbestrol, Formaldehyde, Hexachlorophene, Lindane, Melphalan, Mercury, Mitomycin C, Paraldehyde, Phenacetin, Phenol, Reserpine, Resorcinol, Saccharin, Selenium sulfide, Streptozotocin, Trichloromonofluromethane, Uracil mustard, Warfarin <0.3%).
5. U.S. Department of Health & Human Services, NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012, *available at* http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf.
6. U.S. Department of Labor, OSHA Technical Manual (OTM), Section VI: Ch. 2, App. VI: 2-1, http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.
7. *Supra* note 1, at 7.
8. 73 Fed. Reg. 73519 (Dec. 2, 2008).

employees, and other pharmaceutical generators are often unfamiliar with or confused by RCRA hazardous waste management requirements, prompting them to improperly dispose of hazardous pharmaceuticals as municipal or bulk wastes."[9] While the lack of awareness and understanding may be the product of an inadequate, inefficient, and/or antiquated system, it has not stopped some states and EPA regional offices from imposing fines and citations. In April 2012, for example, California settled with retail drugstore giant CVS Pharmacy for $13.75 million on claims that the national chain illegally disposed of pharmaceutical and other hazardous waste. Two months later, California settled with Costco for $3.6 million on similar allegations. In 2010, the New York Attorney General settled with five health care facilities after investigations showed that they released pharmaceutical waste into the New York City Watershed. In 2009, EPA Region 7 issued a $50,000 fine to a hospital and required the facility to implement programs to manage pharmaceutical and other waste at a cost of nearly $500,000. In 2003 and 2004, EPA Region 2 issued fines ranging from $40,000 to $280,000 after identifying violations at a number of health care facilities. Similar enforcement and outreach efforts appear to be on the rise elsewhere across the country.

IV. The OIG's Recommendations

In its conclusion, the OIG asserted: "If EPA's hazardous waste rules do not keep up with new drug development or ensure that regulated entities understand and comply with their obligations, uncertainties about human health and environmental risks from hazardous pharmaceuticals are likely to grow."[10] Accordingly, it recommended that EPA's Assistant Administrator for Solid Waste and Emergency Response identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste, as well as to establish a process for reviewing new pharmaceuticals to determine whether they qualify for regulation as hazardous waste. In addition, it advised the Agency to develop a nationally consistent outreach and compliance assistance plan to help states address challenges that health care and other facilities may have in complying with RCRA regulations for managing hazardous waste pharmaceuticals.

V. EPA's Response[11]

In its response to the OIG's Report, EPA contended that the OIG failed to fully appreciate the complexities of listing a chemical as a commercial chemical product. It also suggested that resources to evaluate whether new drugs and other substances qualify for regulations, as well as to update existing and formulate new regulations, are becoming more limited given the ever-increasing pace of technology and development. Nevertheless, the Agency agreed "that pharmaceuticals are a category of chemicals that need attention."[12]

With regard to the OIG's recommendations, however, EPA's response was somewhat noncommittal. It stated that the Agency "will consider the appropriate next steps to take given significant resource constraints and competing priorities"[13] and that further actions the Agency could pursue may include a process to review newly developed pharmaceuticals as well as to "propose revisions to RCRA regulations to more effectively address hazardous waste pharmaceuticals in the health care sector."[14] In responding to the OIG's third recommendation pertaining to outreach and compliance assistance programs, EPA stated that it is now "developing major revisions to the hazardous waste regulations to make them more effective for the health care sector and the hazardous waste pharmaceuticals they generate" with the aim of helping "states with implementation and the regulated community with compliance with the RCRA regulations for hazardous waste pharmaceuticals."[15] Whether those major revisions will address the OIG's concerns related to the identification and evaluation of existing and new pharmaceuticals or only implementation and compliance with the existing program remains to be seen. The Agency anticipates that it will publish a proposed rule in March 2013.

VI. Concluding Thoughts

Given the current trends, it is very likely that pharmaceutical wastes will be subject to more regulations in the near future. The presence and fate of such substances in the nation's waters is raising serious concerns nationwide that are not likely to subside. EPA is currently attempting to formulate processes and mechanisms to respond to this apparent threat and to build on the existing, albeit limited, RCRA program. It is also possible that EPA will revisit its 2008 effort, which focused on the UWR under RCRA, as part of its regulatory efforts. Whatever the Agency formulates will be of significant interest to numerous industries and sectors, particularly the water discharge and treatment communities, producers of pharmaceuticals, and generators of pharmaceutical wastes. EPA, however, also will be watched closely by the producers of personal care products and generators of personal care product wastes, as well as the general public and the various states who have already indicated their growing concerns with the potential health and environmental threats posed by these contaminants.

Nevertheless, as EPA (and, potentially, Congress and state legislatures across the country) considers the vari-

9. *Supra* note 1, at 9.
10. *Supra* note 1, at 9.
11. Memorandum, Response to EPA Office of Inspector General Report, *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal* (Rep. No. 12-P-0508, May 25, 2012), Aug. 24, 2012, *available at* http://www.epa.gov/oig/reports/2012/12-P-0508_Agency%20Response.pdf.
12. *Id.* at 1.
13. *Id.* at 2.
14. *Id.*
15. *Supra* note 1, at 18.

ous programmatic and regulatory options that might be pursued, it may be prudent to take a step back and ask a number of rather simplistic but obvious questions. Is it truly possible to develop a coherent regulatory process that will adequately assess whether the tens of thousands of pharmaceutical waste products (let alone the millions of different PPCP substances and waste products) require regulation? If yes, could a regulatory program like RCRA devise, implement, and monitor the multitude of disparate disposal, removal, and treatment mechanisms that will have to be developed for each of the multitude of classes and categories of pharmaceuticals or personal care products? The magnitude of the challenge is daunting.

It is noteworthy that RCRA is not the only potentially relevant federal statute for regulating the presence and fate of PPCPs in the environment. Other statutes that may be applicable include the Clean Water Act (CWA),[16] the Safe Drinking Water Act (SDWA),[17] and the Toxic Substances Control Act (TSCA).[18] While each of these approaches may have its own allures and virtues, and each one offers unique mechanisms intended to protect human and environmental health, like RCRA, all of them suffer from the tremendous challenge of regulating the massive quantity of disparate PPCP substances and wastes that now infest the nation's freshwater resources. Additionally, even assuming that large-scale wastewater or freshwater treatment techniques and systems can be developed to comply with any of these statutory schemes as a means of controlling the plethora of PPCPs, the cost could be staggering. As one researcher noted: "Although the public may want pure water, people are not prepared to pay what it would actually cost even if sufficient technology did exist."[19]

In a recent report—"Alternative Strategies for Addressing the Presence and Effects of Pharmaceutical and Personal Care Products in Fresh Water Resources"[20]—published in the *Denver Water Law Review*, the present author and a colleague offer an alternative or supplementary approach to the regulation of PPCP wastes. Rather than solely focusing on the presence of PPCPs in the environment through regulations limiting such contamination, the relevant PPCP industries and professions, as well as various regulatory bodies, should investigate actions designed to remove or minimize the presence of PPCPs *before* they reach the environment. For example, drugs and personal care products could be designed to minimize the human and animal excretion of PPCP wastes, which would then minimize the volume of PPCPs that enter the environment. Likewise, changing the delivery mechanisms or tailoring dosages to individual patients could reduce excreted PPCPs. In addition, greater efforts could be made for the proper disposal of PPCPs amongst the regulated community as well as the general public. Other options include reducing the need for PPCPs through the use of non-PPCP alternative as well as nutrition and health maintenance programs.

The presence and fate of PPCPs in the environment, and especially in surface, ground, and drinking water resources, is a complicated problem that will not be quickly addressed. Responding to the various concerns will likely require multiple, complementary solutions, including reducing PPCPs in various products, treating PPCP wastes prior to discharge into the waste stream and the environment, proper disposal programs, monitoring systems, and even changing peoples' habits. Whether these can be implemented through industry and community efforts, or through the regulatory process, remains to be seen. Given the massive numbers of PPCPs produced globally, the complexities involved in determining whether any particular PPCP or combination of PPCPs may be harmful to people or the environment, and the scientific and political challenges of formulating appropriate responses, it is safe to say that this issue will be with us for years to come.

16. 33 U.S.C. §§1251-1387, ELR Stat. FWPCA §§101-607.
17. 42 U.S.C. §§300f to 300j-26, ELR Stat. SDWA §§1401-1465.
18. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.
19. Keith J. Jones, *Endocrine Disruptors and Risk Assessment: Potential for a Big Mistake*, 17 Vill. Envtl. L.J. 357, 386 (2006).
20. Gabriel Eckstein & George William Sherk, *Alternative Strategies for Addressing the Presence and Effects of Pharmaceutical and Personal Care Products in Fresh Water Resources*, 15(2) Denv. Water L. Rev. 369-445 (2012).