Challenges in Pharmaceutical Waste Management: "First, Do No Harm"

John Johnson, Greg Blount, Karlie Clemons, and Hahnah Williams

The regulated community and policymakers are grappling with how best to manage pharmaceutical waste, now and in the future. In some ways, they may best be guided by the Hippocratic admonition: Do no harm. Otherwise, unintended consequences could interfere with the vital flow of medication to and from dispensing facilities. Pharmaceutical waste management presents major challenges for hospitals, clinics, physicians' offices, and retail pharmacies. The implications of pharmaceutical waste management are far ranging and changes in the requirements can substantially impact pharmaceutical supply chain logistics. With an increased focus on potential environmental impacts of pharmaceutical waste disposal, federal and state officials have become increasingly aggressive in inspecting businesses that dispense pharmaceuticals and taking enforcement action for alleged violations of the hazardous waste regulations. For instance, in 2009, a hospital agreed to pay the U.S. Environmental Protection Agency (EPA), Region 7, $51,501 in civil penalties, and agreed to spend nearly $500,000 on a plan to manage pharmaceutical and other wastes. That same year, a California court assessed a civil penalty totaling $8,650,000 against a national retail company for alleged hazardous waste violations, including mismanagement of pharmaceutical waste.

The foregoing enforcement actions were taken pursuant to alleged violations of federal hazardous waste regulations and state hazardous waste regulations, respectively. The federal hazardous waste regulations, promulgated pursuant to the Resource Conservation and Recovery Act (RCRA), are primarily designed to address the proper management of industrial waste, rather than pharmaceuticals, which typically comprise a relatively low-volume, but discrete and variable waste stream that includes such items as tablets, capsules, and injectables. Nevertheless, under the current regulatory framework, pharmaceutical waste generators—from the rural retail pharmacy to the major metropolitan hospital and all scenarios in between—are held to the same detailed, often stringent standards that are applied to generators of industrial waste. Thus, when any of a broad array of pharmaceuticals, including newly manufactured pharmaceuticals, becomes a waste, generators are obligated to determine whether or not the pharmaceutical must be managed as a hazardous waste. Further complicating the process (as discussed below) is the question of when a pharmaceutical becomes a "waste," an unsettled issue in some jurisdictions, especially as it relates to the reverse distribution of pharmaceuticals.

To determine whether a pharmaceutical waste is RCRA hazardous, generators must consider two primary questions: (1) whether the pharmaceutical has a sole active ingredient listed on RCRA's P- or U-list as an acute (P-list) or toxic (U-list) hazardous waste, as codified at 40 C.F.R. § 261.33; and (2) whether the pharmaceutical exhibits one or more of the RCRA hazardous waste characteristics (ignitability, corrosivity, reactivity, and toxicity), as codified at 40 C.F.R. Part 261 Subpart C. This can be a complex undertaking for dispensers of pharmaceuticals, given the wide variety of chemical names, active ingredients, and formulations of the pharmaceuticals that they stock. There are a few federal and state reference sources that identify some pharmaceuticals as hazardous, but the federal government has not made a pharmaceutical hazardous waste identification system available to generators.

In addition to managing pharmaceuticals as hazardous, generators may also be required to manage the residue in pharmaceutical waste containers as hazardous. Under RCRA, residue in containers that previously held a P- or U-listed hazardous pharmaceutical waste must be managed as hazardous waste unless the container is "RCRA-empty." To be considered RCRA-empty, a container that previously held a P-listed waste must be triple rinsed with an appropriate solvent or cleaned by an equivalent, scientifically proven method. 40 C.F.R. § 261.7(b)(3). A container that previously held a U-listed waste is RCRA-empty if the contents have been removed using practices commonly employed to remove materials from the container and no more than one inch of residue remains in the container or, if the container is less than or equal to 119 gallons in size, 3 percent by weight of the total capacity of the container remains in the container. 40 C.F.R. § 261.7(b)(1). Under RCRA, any rinsate that comes into contact with these containers must also be managed as a hazardous waste, making the option of rinsing the containers infeasible for most generators.

RCRA requires generators to follow specific requirements when storing, packaging, labeling, transporting, and disposing of their hazardous pharmaceutical waste. These requirements vary depending on the amount of waste (pharmaceutical and otherwise) a facility generates. A party is considered a Large

Mr. Johnson and Mr. Blount are partners, and Ms. Clemons and Ms. Williams are associates in the Environmental and Natural Resources Practice Group of Troutman Sanders LLP. Mr. Johnson can be reached at john.johnson@troutmansanders.com, Mr. Blount can be reached at greg.blount@troutmansanders.com, Ms. Clemons can be reached at karlie.clemons@troutmansanders.com and Ms. Williams can be reached at hahnah.williams@troutmansanders.com.

Quantity Generator (LQG) at a site if it generates 2,200 pounds or more of hazardous waste in a calendar month or generates more than 2.2 pounds of acute (P-listed) hazardous waste in a calendar month, or accumulates that amount of acute (P-listed) hazardous waste at any time. It is considered a Small Quantity Generator (SQG) if it generates more than 220 pounds of hazardous waste per calendar month, but less than 2,200 pounds of hazardous waste per calendar month, and generates or accumulates no more than 2.2 pounds of acute (P-listed) hazardous waste in a calendar month or at any time, respectively. 40 C.F.R. § 261.7(b)(1). Parties that generate no more than 220 pounds of hazardous waste per calendar month, and generate or accumulate no more than 2.2 pounds of acute (P-listed) hazardous waste per calendar month, or at any time respectively, are considered Conditionally Exempt Small Quantity Generators (CESQG). 40 C.F.R. § 264.5(a).

LQGs must comply with the full range of RCRA generator regulations, which include waste storage requirements (LQGs may store waste for up to 90 days without obtaining a RCRA permit, provided certain storage requirements are met.); container labeling and management requirements; hazardous waste storage area closure requirements; manifesting and reporting requirements; contingency planning and emergency procedures; and training requirements. In addition, a LQG must obtain an EPA identification number, which establishes the facility in a hazardous waste generator database that does not distinguish between industrial facilities that generate a large volume of hazardous waste and pharmaceutical dispensers that do not. SQGs are subject to fewer requirements than LQGs. CESQGs are not subject to the RCRA hazardous waste regulations, other than being able to verify that they are a CESQG based on the volume of hazardous waste generated. However, state laws may place additional requirements on generators in all categories.

While healthcare facilities and retail pharmacies typically generate a small volume of hazardous pharmaceutical waste, they nonetheless can be subjected to the full array of RCRA hazardous waste requirements applicable to LQGs based on their of the generation of P-listed pharmaceutical waste such as Warfarin, a commonly used blood thinner, in excess of 2.2 pounds. Under RCRA, because P-listed pharmaceutical waste residue must be managed as a hazardous waste, containers holding the residue must also effectively be managed as a hazardous waste. The weight of the residue typically would be negligible. However, if the weight of the containers were included in calculating the volume of hazardous waste generated, this 2.2 pound threshold could be exceeded, for example, if a facility generated a relatively small number of Warfarin bottles containing residue. EPA has recently attempted to provide some relief to the regulated community through issuance of a November 4, 2011, guidance document entitled Containers that Once Held P-Listed Pharmaceuticals. In this guidance document, EPA provided helpful clarification in specifying that "it is only the residue in the non-RCRA-empty container that is considered a P-listed hazardous waste; the container itself is not a hazardous waste." EPA goes on to state, "[a]ccordingly, it is only the weight of the residue in the container that needs to be counted toward generator status; the weight of the container does not need to be counted toward generator status." EPA then outlined the following three approaches to managing pharmaceutical waste residue in containers that previously held P-listed waste: (1) Count only the weight of the residue toward generator status; (2) demonstrate an equivalent removal method to render containers RCRA empty; or (3) for Warfarin containers, show that the Warfarin concentration in the residue is below P-listed concentrations. As EPA points out, this guidance may enable many pharmaceutical waste generators to be classified as CESQG rather than LQGs. However, such is not the case for generators that generate other acute hazardous wastes in a month that, combined with the P-listed container residues, cause the facility to exceed the 2.2 pound threshold, triggering LQG standards. In addition, as discussed below, states are free to adopt more stringent hazardous waste requirements than EPA, and, therefore, may take the position that containers holding a P-listed residue to be included in determinations of waste generator status.

EPA has also issued guidance documents that exclude certain pharmaceutical waste from regulation as hazardous waste. For example, EPA has clarified that epinephrine salts are not included in the epinephrine P042 hazardous waste listing. As such, waste epinephrine salts would be hazardous only if they exhibited one or more of the hazardous waste characteristics. EPA has also stated that wastes classified as a P- or U-listed hazardous waste solely based on the characteristic of ignitability, corrosivity, or reactivity are not regulated as hazardous waste if they do not exhibit the characteristic on which the listing is based. On this basis, EPA has reasoned that medicinal nitroglycerin is excluded from regulation as a hazardous waste because it does not exhibit the characteristic of reactivity in that formulation. In addition, EPA has interpreted the RCRA regulations to exclude used syringes containing residual P- or U-listed pharmaceuticals from hazardous waste regulation as long as they do not exhibit a hazardous waste characteristic.

Under RCRA, states can develop and implement a hazardous waste program in lieu of the federal hazardous waste program, subject to EPA's approval and ability to enforce the state program, if necessary. All states, except Alaska and Iowa, have EPA-authorized hazardous waste management programs. State-authorized programs are allowed by RCRA to be broader and more (but not less) stringent than the federal program, and many state programs do, in fact, differ significantly from the federal program. The adoption of state-specific hazardous waste programs has resulted in significant variation in the regulation of pharmaceutical waste between states and EPA and among the states. These differences in compliance requirements have created substantial difficulties for regulated entities seeking to implement pharmaceutical waste compliance programs at facilities across multiple states. While by no means exhaustive, key variations in state regulatory programs include the following: state-specific hazardous waste, regulated in addition to RCRA hazardous waste; reverse distribution policies; and state universal pharmaceutical waste rules.

State-Specific Hazardous Waste

A number of states have adopted regulations that designate waste as hazardous, even though the waste is not regulated as hazardous waste under RCRA. For example, the Rhode Island hazardous waste program includes "Rhode Island Wastes," which are regulated as hazardous wastes. Similarly, Michigan has adopted additional U-listed hazardous wastes; Vermont has designated certain wastes as Vermont-only hazardous wastes; Connecticut has adopted additional waste codes for non-RCRA hazardous waste, known as "Connecticut-Regulated Waste"; and Oregon has designated certain wastes as Oregon-only hazardous wastes.

Other state-specific hazardous waste regulations take different forms. Minnesota has expanded its state list of hazardous waste characteristics to include lethality, in addition to the four RCRA characteristics. In Colorado, if a formulation has more than one active ingredient on the P- or U-list, the formulation is deemed to still meet the listing description. In Washington, if pharmaceutical waste meets certain criteria, the waste is classified as "dangerous waste." Washington's program, which varies significantly from the federal program, provides several regulatory options for management of state-only dangerous waste. California has adopted the California Medical Waste Management Act (MWMA), which regulates various non-RCRA-regulated pharmaceuticals as California-only hazardous wastes. Under the MWMA, these California-only hazardous wastes are termed "biohazardous waste," a subset of "medical waste." The MWMA includes additional criteria regarding the characteristic of toxicity, which are not included under RCRA. For example, if a waste contains a substance listed in the California Code of Regulations sections 66261.24(a)(1)–(2), regarding the characteristic of toxicity, the waste is regulated as a hazardous waste in California.

Additionally, there is inconsistency among states with regard to adoption of the EPA regulatory interpretations regarding certain pharmaceutical waste exclusions, as states are not required to adopt these exclusions as interpreted by EPA. While many states have adopted EPA's exclusions in their entirety, others have refused to recognize some or all of them. For example, Connecticut and Michigan have not adopted either the epinephrine or nitroglycerine federal exclusions, and Washington has not adopted EPA's exclusion for used, P-listed syringes. In California, while used syringes containing residue of P- or U-listed pharmaceuticals are excluded from RCRA, they must be managed as medical waste under California's Medical Waste Management Act.

States may also vary in their definitions of "empty" for purposes of determining whether a container that previously held P- or U-listed pharmaceutical wastes is regulated as hazardous waste. For example, in Florida, some Warfarin containers do not require triple rinsing to be considered "empty." This applies to Warfarin containers that previously contained at least 50 coated tablets/capsules at a dosage of 10 milligrams (mg) and Warfarin containers that previously contained at least 110 coated tablets/capsules at a dosage of 1 mg. These bottles are considered empty if (1) all the waste has been removed using practices commonly employed to remove materials from that type of container; and (2) no more than 1 inch of residue remains on the bottom of the container; or no more than 3 percent by weight of the container capacity remains in the container if the container is less than or equal to 119 gallons in size; or no more than 0.3 percent by weight of the container capacity remains in the container if the container is greater than 119 gallons in size.

In Michigan, consistent with RCRA, a container that previously held an acutely hazardous pharmaceutical waste is considered "empty" if it has been triple rinsed with an appropriate solvent or cleaned by an equivalent, scientifically proven method. However, Michigan defines "empty" differently when it comes to containers that have held acutely hazardous pharmaceutical containers listed solely for a hazardous waste characteristic (e.g., nitroglycerin). Those containers are "empty" if (1) all waste has been removed using practices commonly employed to remove materials from the container; and (2) not more than one inch of residue remains on the bottom of the container or inner liner or either (i) not more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size, or (ii) not more than 0.3 percent by weight of the total capacity container remains in the container or inner liner if the container is more than 119 gallons in size. California's hazardous waste regulations are consistent with federal regulations with respect to "empty" containers, except that in addition to requiring triple rinsing for containers that held acute hazardous waste, containers or inner liners that once held waste that is "extremely hazardous" pursuant to California regulations must also be triple rinsed.

Reverse Distribution of Pharmaceuticals

Reverse distribution is the process by which dispensers of pharmaceuticals return expired, damaged, recalled, or discontinued pharmaceutical products to manufacturers, wholesalers, or to third-party service companies that facilitate the processing and disposition of the returned products. In processing the items, the reverse distributor determines if the items are eligible to receive a monetary credit from the manufacturer. In published guidance documents, EPA has taken the position that pharmaceutical products returned via the reverse distribution process do not become wastes until a determination is made to discard them. Shipping waste-like items to a reverse distributor is, however, prohibited. Under EPA guidance issued in 1991, EPA indicated that a pharmaceutical product returned through reverse distribution with a reasonable expectation of being recycled (e.g., reused, reclaimed, or sold overseas) is not a waste under RCRA. In the preamble to EPA's 2008 proposed Universal Pharmaceutical Waste Rule, EPA took the position that unused or expired pharmaceuticals that are being returned for possible manufacturer credit still have potential value and thus are not considered waste. Under this guidance, generators may return unused pharmaceutical products that the generator reasonably expects will be cred-

ited, whether the pharmaceuticals will be recycled or not.

Reverse distributors usually consult with manufacturers when deciding whether a pharmaceutical is credit worthy, and the reverse distributor is responsible for properly disposing of credit-worthy pharmaceuticals that the manufacturer will not take back. Items not returned to the manufacturer or recycled are sent by the reverse distributor for incineration at solid or hazardous wastes facilities, as appropriate. Under the federal framework, reverse distribution of pharmaceuticals allows dispensers to manage pharmaceuticals safely and effectively without having to adhere to complex and burdensome hazardous waste requirements. Most states appear to embrace (or at least not object to) EPA's position on reverse distribution of pharmaceuticals. However, a handful of states either reject the position altogether or have adopted approaches that differ substantially from the federal position. The Connecticut and Minnesota programs exemplify approaches that are considerably more stringent than the EPA's position.

Although Connecticut has not promulgated regulations or a formal policy on the issue, the state expressed its position in public comments submitted by the Connecticut Department of Environmental Protection (CDEP) (now the Connecticut Department of Energy and Environmental Protection) to EPA on March 4, 2009, regarding the federal proposed universal pharmaceutical waste rule. Connecticut took the position that pharmaceuticals should be regulated as a waste at the store level unless a determination is made at that point that they will be reused or recycled. Connecticut stated:

> CTDEP believes that EPA should not consider unused or expired pharmaceuticals that are sent to return centers as being exempt from solid and hazardous waste requirements. Rather, CTDEP believes that these pharmaceuticals should be subject to regulation from the point that they are determined to be unwanted or unusable by the generating facility.

Connecticut further took the position that a manufacturer's credit should have no bearing on waste status.

Minnesota's policy on reverse distribution of pharmaceuticals is set forth in a May 6, 2011, "Program Management Decision (PMD) Memo" issued by the Minnesota Pollution Control Agency (MPCA) and a subsequent June 2011 guidance document. Under the PMD, generators may manage their used pharmaceuticals through a reverse distribution system only if certain criteria are met. In the PMD Memo, the MPCA explained, "In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a waste." The agency further explained, "Whether a pharmaceutical is eligible for return credit does not affect its product or waste status." Rather, a generator should "[a]ssume a waste pharmaceutical is hazardous unless you have evaluated it and have documentation showing it to be nonhazardous." Generators must comply with various requirements to be eligible to manage unevaluated or hazardous waste pharmaceuticals through a reverse distributor. Among other requirements, the generator must "[d]ocument that all pharmaceuticals that (1) have not been evaluated or (2) would be hazardous waste in Minnesota will be disposed of according to hazardous waste disposal requirements." This documentation must include "(a) an agreement between the generator and reverse distributor stipulating that disposal of those pharmaceuticals will meet hazardous waste disposal requirements; and (b) a management plan from the reverse distributor listing the identity and location of the hazardous waste disposal facility or facilities that will ultimately manage those pharmaceuticals."

State Universal Pharmaceutical Waste Rules

The RCRA regulations establish streamlined management requirements for certain common, widely generated and dispersed hazardous waste, known as "universal waste," to facilitate the proper collection and recycling of those wastes. Currently, the federal universal waste program applies to certain batteries, pesticides, mercury-containing equipment and lamps. 40 C.F.R. Part 273. However, the federal program allows states that have adopted the universal waste program to petition EPA to include and manage other hazardous waste as universal waste. 40 C.F.R. § 273.80. To date, two states—Florida and Michigan—have adopted and implemented universal waste rules for pharmaceutical hazardous waste. These rules provide benefits not afforded currently under federal or other state hazardous waste regulations. These benefits include (1) storing pharmaceutical wastes for a longer period of time; (2) not having to count pharmaceutical wastes in determining a facility's hazardous waste generator status; and (3) utilizing relaxed manifesting requirements for the transportation and disposal of the universal pharmaceutical waste. Fla. Admin. Code Ann. R. 62-730.186 and Mich. Admin. Code r. 299.9228.

The downside to these state universal pharmaceutical waste rules is that they only apply while pharmaceuticals are being managed in the state. For example, when pharmaceuticals are transported outside of Florida they become subject to the hazardous waste requirements of all the states through and to which the pharmaceutical waste is routed. As Florida has no facilities permitted to incinerate pharmaceutical waste, the benefits that attach to the waste in Florida have no relevance once the waste leaves the state.

Options Moving Forward

There is a consensus among regulators and the regulated community that pharmaceuticals must be managed and disposed of responsibly. Currently, however, national pharmaceutical dispensers must adhere to myriad and various pharmaceutical waste regulations in each state in which they operate and in which the pharmaceutical waste comes to be located. National retailers face the challenge of maintaining compliance programs that both require consistent practices and accommodate these various state programs. In view of the ill-suitedness of EPA's current hazardous waste management program to the management of pharmaceutical waste and the lack of consistency among state regulatory programs and

federal regulations, pharmaceutical dispensers are struggling to accommodate the various regulatory schemes.

Based on these regulatory challenges, it is apparent that a national, more uniform pharmaceutical waste regulatory program is warranted. One option is for EPA to move forward with a universal pharmaceutical waste rule. EPA proposed such a rule on December 2, 2008, to provide a simplified, streamlined alternate system for the management of hazardous pharmaceutical wastes. The comment period for the proposed rule ended on March 4, 2009, but the Agency does not have a projected date for finalizing the rule. According to EPA's website, the Agency is "considering additional regulatory options to address the notification and tracking concerns as well as other issues that surround the proper management and disposal of hazardous pharmaceutical wastes." However, while an EPA universal pharmaceutical waste rule would provide a basis for needed flexibility and uniformity, it would have to be proactively adopted by the 48 states with authorized hazardous waste programs to take effect in those states. Given the elaborate pharmaceutical waste management programs currently in effect in a number of states, it is unlikely that the rule would be adopted in some of those jurisdictions. Furthermore, even if an authorized state were to adopt the rule, the state would be free at any time to establish more stringent pharmaceutical waste management requirements. Accordingly, a federal universal pharmaceutical waste rule would not guarantee greater uniformity and flexibility.

EPA might consider another option for establishing pharmaceutical waste regulations that, once effective, would automatically be applicable to pharmaceutical waste in every state, without states having to proactively adopt the Federal program. For example, promulgation of pharmaceutical waste management standards under 40 C.F.R. Part 266 (which contains standards for specific hazardous waste) would provide EPA with a mechanism to regulate pharmaceutical waste in a uniform fashion, leaving states only the option of adopting more stringent regulations. As a model, EPA could consider its regulation of lead-acid batteries under 40 C.F.R. Part 266, Subpart G. Part 266 contains limited requirements for generators that manage spent lead-acid batteries that are eventually reclaimed. Under Subpart G, these generators are not required to obtain an EPA identification number, include the batteries when determining hazardous waste generator status, manifest the batteries, or use hazardous waste transporters to transport the waste. A similar approach could be utilized for generators of hazardous pharmaceutical waste to be disposed of in specific ways, such as by incineration. Unlike EPA's proposed universal pharmaceutical waste rule, regulation under Part 266 would provide EPA the ability to immediately enforce those regulations in every state. While states could eventually adopt more stringent pharmaceutical waste regulation, Part 266 regulation would at least, even if temporarily, enable EPA to establish a uniform, national system specifically designed for pharmaceutical waste management.

Another option for establishing or supplementing uniform pharmaceutical waste regulation would be for Congress to enact appropriate legislation. Legislation that has been enacted for batteries could also provide a model for pharmaceuticals. For example, in 1996 Congress passed the Mercury-Containing and Rechargeable Battery Management Act. Public Law 104-142 (May 13, 1996), 1996 Stat. 1329. The legislation addressed a range of batteries, including lead-acid batteries not otherwise covered by Part 266, Subpart G. The legislation required states to adopt provisions for collection, storage, and transportation that are identical to the universal waste requirements for those batteries. Although states may still adopt more stringent requirements for recycling and disposal of batteries, the standards for collection, storage, and transportation must be consistent with the federal framework.

Similar to the legislative approach used for batteries, Congress could pass legislation directly applicable to pharmaceuticals management. Congress could supplement (to the extent EPA does, in fact, adopt) Part 266 pharmaceutical regulations and a universal pharmaceutical waste rule. For example, Congress could require that states adopt regulations for pharmaceutical waste identical to federal regulations for the collection, storage, and transportation of pharmaceutical hazardous waste, while still allowing states flexibility to adopt more stringent regulations with respect to the disposal of such waste.

Conclusion

There are a variety of options available to legislators and regulators, but each will require a balancing of regulatory controls with maintenance of the efficient flow of pharmaceuticals as articles of commerce and a means for healing. The current evolving patchwork of regulatory controls is becoming increasingly unworkable for implementation on a national or regional scale. Leadership on these issues is evident in states such as Florida and in EPA's recent guidance on pharmaceutical containers. Continuing this momentum will be critical to finding a reasonable balance of all interests before these regulations do, in fact, result in greater harm than good.