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ASTSWMO POSITION PAPER

A NEW REGULATORY APPROACH TO PHARMACEUTICAL WASTE MANAGEMENT

INTRODUCTION

Many studies have demonstrated that pharmaceutical compounds are making their way into the environment. Although little can be done to prevent some pharmaceuticals from reaching environmental receptors, the destiny of *waste* pharmaceuticals can be controlled. The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) understands that the U.S. Environmental Protection Agency (EPA) Office of Resource Conservation and Recovery is developing new regulations for management of pharmaceutical wastes to replace the December 2008 proposal that would have allowed those pharmaceutical wastes already regulated as hazardous waste under Subtitle C of the Resource Conservation and Recovery Act (RCRA) to be managed as universal wastes. ASTSWMO also understands that while EPA's forthcoming proposal will be designed to offer flexibility to health care facilities that manage pharmaceutical wastes; it too will only apply to those pharmaceuticals currently regulated as a hazardous waste under RCRA. This Position Paper outlines a more holistic management approach that could apply to all post-manufacturing pharmaceutical wastes, not only those regulated as a hazardous waste.[1] In developing this Paper, several articles and publications were reviewed. A complete bibliography of those reviewed is included.

BACKGROUND

Significantly, concerns about the detrimental effects of pharmaceuticals in the environment were identified at least as far back as the late 1970s—nearly 35 years ago. Many recent studies have shown that a wide variety of pharmaceuticals are reaching environmental receptors (e.g. ground water, surface water, and tissues of aquatic life) through pathways such as discharges from wastewater treatment plants, which are not designed to remove pharmaceutical compounds during the treatment process, or discharges from animal feeding operations. Other studies have shown that pharmaceuticals are present in significant concentrations in landfill leachate, which is frequently treated using wastewater treatment technologies that do not remove pharmaceutical compounds. Finally, there is some evidence, though apparently not as

1 ASTSWMO recognizes that the approach outlined in this Paper may not be feasible for all generators of pharmaceutical wastes, and it may be more cost-effective for them to dispose of non-hazardous pharmaceuticals through another EPA/State-approved method while still handling the RCRA hazardous pharmaceutical wastes in accordance with current regulations.

thoroughly studied, of pharmaceuticals making their way into surface or ground waters from septic systems. It seems clear to ASTSWMO that the current RCRA regulatory framework for managing pharmaceutical wastes, as well as EPA's planned approach, is inadequate to meet RCRA's stated goal of protection of human health and the environment. We believe this is, in large part, due to three reasons:

- identification of new hazardous waste pharmaceuticals under RCRA Subtitle C is cumbersome;
- waste management requirements under RCRA Subtitle C were not designed for the scenarios in which pharmaceutical wastes are most often generated; and
- multiple agencies have regulatory control over various pharmaceutical wastes.

ASTSWMO believes a new approach to pharmaceutical waste management addressing each of these issued is needed.

Identification of New Hazardous Waste Pharmaceuticals is Cumbersome

When RCRA Subtitle C regulations first became effective in 1980, EPA identified approximately 31 pharmaceutical compounds in its P- and U-lists of hazardous wastes, while others became subject to regulation because they exhibited a hazardous characteristic.[2] Since that time, many new pharmaceuticals have been approved by the Food and Drug Administration (FDA)[3] while use of those that were originally listed has decreased. By EPA estimates, only 5-10% of the pharmaceuticals currently being dispensed are regulated as hazardous waste. This means, 90-95% of the pharmaceuticals in use today are not regulated for the purpose of environmental protection, and ASTSWMO believes this will remain unchanged in EPA's newest proposal.

Under current RCRA Subtitle C regulations, to add a new pharmaceutical waste to either the P- or U-list of hazardous wastes, EPA must first perform an extensive evaluation of the material pursuant to 40 CFR 261.11[4] prior to initiating the rulemaking process; a costly, time-consuming, and often unpredictable process. ASTSWMO believes this compound-by-compound approach will never allow EPA to catch up and keep up with the vast number of pharmaceuticals in use today and will be developed in the future. This may be part of the reason EPA has not listed any new pharmaceuticals since 1980. While EPA has not amended its lists of hazardous wastes to include new pharmaceuticals, other federal agencies (namely, the Occupational Safety and Health Administration [OSHA] and the National Institute for Occupational Safety and Health [NIOSH]) have identified many pharmaceuticals they consider "hazardous" and have made subject to special handling requirements. Some of these even meet the current EPA criteria for

2 For example, warfarin, arsenic trioxide, cyclophosphamide, hexachlorophene and many others are listed while those using m-cresol as a preservative or those with high alcohol content may be characteristic.

3 Since 1996, the FDA has approved an average of 30 new drugs per year. This equates to over 500 new drugs since 1996 and, assuming this average was approximately the same since 1980, 900 new drugs since RCRA was implemented.

4 This includes determining whether or not the material exhibits a hazardous characteristic or is toxic, carcinogenic, mutagenic, or teratogenic.

being listed as acutely hazardous.[5] Clearly, a single management standard applicable to all post-manufacturing pharmaceutical wastes would alleviate this issue.

RCRA Subtitle C is not Designed for Pharmaceutical Waste Scenarios

ASTSWMO believes the RCRA Subtitle C regulations are a poor fit for the circumstances under which pharmaceutical wastes are often generated. The hazardous waste regulations were primarily designed for managing relatively large volumes of wastes generated in industrial settings and accumulated in tanks or 55-gallon drums. Pharmaceutical wastes are typically generated in relatively small volumes at multiple locations in one facility. Moreover, pharmaceutical wastes are often handled by personnel, such as nursing staff, who do not have the experience or training necessary to easily differentiate between the small number of pharmaceuticals that must be managed as hazardous waste under RCRA and the much greater number that do not. To further complicate matters, EPA has written a myriad of pharmaceutical waste policy documents that must be considered. A simplified regulatory approach could ensure pharmaceutical wastes are properly managed in both "low volume" settings such as physician offices that deal with a few dozen pharmaceuticals (e.g. injection vials or expired drug samples) and "high volume" settings such as hospitals, retail pharmacies, and prisons that must manage hundreds of different pharmaceuticals.

Cross-Agency Jurisdictional Issues

In addition to the EPA, management standards for pharmaceuticals have also been established by the FDA, the Drug Enforcement Agency (DEA) and, as mentioned previously, OSHA and NIOSH—standards that don't necessarily have environmental protection as a primary goal. For example, DEA regulations for disposal of controlled substances are mainly designed to prevent diversion for unauthorized uses rather than environmental protection. ASTSWMO believes any new regulatory approach must be developed in partnership with these other agencies to ensure standards do not conflict and meet the goals of each agency.

POSITION

Today, pharmaceuticals are ubiquitous throughout society and, as the population continues to age, the quantity of pharmaceuticals being dispensed will likely increase. Since EPA has not added any pharmaceutical compounds to its P- or U-lists of hazardous waste since 1980, it seems apparent the slow, methodical process EPA must use to evaluate individual pharmaceuticals for new hazardous waste listings cannot stay abreast of this quickly-evolving waste stream and may actually be a detriment to doing so. Furthermore, we believe EPA's planned approach to develop flexible, sector-specific regulations to be used in conjunction with the current listing process will not provide adequate environmental protection. To alleviate each of the issues identified, ASTSWMO believes post-manufacturing pharmaceutical waste should be regulated as a category.

5 For example, carmustine, dactinomycin, and oxytocin.

Since the most appropriate treatment technology for destroying pharmaceuticals, high temperature combustion, already exists in many States, ASTSWMO believes this category of waste is extremely well-suited for an alternative (and optional) regulatory approach that would conditionally exclude all pharmaceutical wastes from hazardous waste determinations provided the following criteria are met:

1. accumulation occurs in a manner that is protective of human health and the environment;
2. appropriate security and tracking measures are in place to ensure accumulated pharmaceutical wastes are ultimately destroyed at an authorized disposal site and not diverted to illicit uses; and
3. destruction is accomplished via high-temperature combustion in incinerators equipped with appropriate controls to prevent releases into the environment.[6]

By conditionally excluding post-manufacturing pharmaceutical wastes from hazardous waste determinations, generators who may not otherwise be subject to complex RCRA standards could manage all pharmaceutical wastes under one streamlined and protective system instead of managing a few according to stringent RCRA standards while possibly discarding the remainder in the trash. High-temperature combustion in a RCRA or municipal solid waste incinerator, or other incinerators meeting specified temperature, BTU, and residence time requirements, will assure complete destruction and achieve the current treatment standard applicable to nearly all RCRA-regulated pharmaceutical wastes.[7] Combustion ash would continue to be subject to RCRA regulation if it exhibited a hazardous characteristic. Nothing in this Paper precludes States from regulating the ash as a solid waste. Generators would have the option to either comply with the streamlined standards for all their pharmaceutical wastes or segregate them for management as both RCRA and non-RCRA wastes, as applicable.

Finally, ASTSWMO believes that in addition to addressing the shortfalls of RCRA regulation for pharmaceuticals described above, a carefully-crafted regulatory framework that includes education, producer responsibility, and organized collection events may provide incentives for neighborhood pharmacies, law enforcement agencies and household hazardous waste collection facilities to accept pharmaceutical wastes from households, thus preventing these from being disposed in the trash or down the drain.

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6 ASTSWMO recognizes that pharmaceuticals may frequently be mixed with infectious (i.e. red bag) wastes at many facilities. Provided the red bag waste is combusted according to this standard to destroy both the pharmaceutical and the infectious wastes, such comingling would be acceptable under this concept. Pharmaceutical wastes mixed with red bag wastes and sent for autoclaving would not be excluded. Pharmaceutical wastes or residues still in packaging could also be managed under this standard.

7 The treatment standard for most of the listed pharmaceuticals is high-temperature combustion, so our proposal is consistent with current EPA requirements. EPA's September 26, 2012 memorandum regarding household-exempt pharmaceuticals specifically mentions incineration as the optimal method for disposal.

CONCLUSION

The pharmaceutical waste problem will continue to grow as the United States population ages and new drugs are developed. ASTSWMO believes the current RCRA Subtitle C framework is ill-equipped to address the environmental threat posed by pharmaceutical wastes. While some pharmaceutical wastes, such as off-specification manufacturing wastes, should remain fully regulated under RCRA Subtitle C, a simplified regulatory approach that applies to all post-manufacturing pharmaceutical wastes must be considered to help ensure adequate protection of the environment. The ASTSWMO Board of Directors recommends EPA consider the approach outlined in this Position Paper. ASTSWMO would be happy to assist EPA with the development of regulations to implement such an approach.

Adopted by the ASTSWMO Board of Directors on April 23, 2013, in Billings, MT.

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