Northeast Waste Management Officials' Association

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Suzanne Rudzinski, Director
Office of Resource Conservation and Recovery
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 5301P
Washington, DC 20460

Dear Ms. Rudzinski:

On July 25, 2011, the Northeast Waste Management Officials' Association (NEWMOA) sponsored a conference call to discuss RCRA pharmaceutical waste management. During that call, representatives from EPA's Office of Resource Conservation and Recovery reported that EPA is no longer supporting the December 2008 proposal to add pharmaceutical wastes currently regulated under RCRA Subtitle C to the universal waste rule *(Federal Register, Vol. 73, No. 232, Tuesday, December 2, 2008)*. Instead EPA is now considering several new options for RCRA pharmaceutical waste, including a "sector-based" approach (similar to the academic labs rule). EPA expressed an interest in receiving feedback on this issue. The Connecticut, Massachusetts, New Jersey, New York, Rhode Island, and Vermont environmental agencies (the participating NEWMOA members) offer the following comments and suggestions on this topic. The agencies from Maine and New Hampshire intend to comment on EPA's regulatory proposals when they become available.

NEWMOA commends EPA for seeking a new approach to regulation of pharmaceutical wastes. However, following that conference call, staff from several NEWMOA states expressed concern that EPA was "missing the forest for the trees" with respect to the regulation of pharmaceutical waste. Increasing amounts of pharmaceuticals are being prescribed, dispensed, or purchased over the counter, resulting in a growing amount of unused, expired, and /or waste pharmaceuticals requiring proper disposal. Meanwhile, in recent years, pharmaceutical compounds have been detected in drinking water supplies and in landfill leachate. The participating NEWMOA members believe that these issues cannot be adequately addressed through a rule that applies only to the handful of pharmaceutical wastes that are currently RCRA-regulated (according to a 2010 EPA presentation, existing RCRA regulations apply to approximately 5-10 percent of all pharmaceuticals).

We believe that a lengthy rulemaking effort focused on regulating pharmaceutical wastes under RCRA Subtitle C only addresses the "tip of the iceberg" and would do little to enhance environmental protection. As such, EPA's rulemaking deliberations need to take into account that a significant part of the pharmaceuticals in the environment problem is due to "non-RCRA" factors such as:

- the disposal of countless non-RCRA regulated pharmaceuticals in landfills, which may adversely impact the environment;
- the substantial quantity of hazardous pharmaceuticals subject to EPA's household

hazardous waste exclusion; and
- the vast quantity of pharmaceuticals disposed into sewer and septic systems.

In addition, there are numerous examples of pharmaceutical products/materials that, under the current regulatory framework, generate extensive interpretive questions for state and federal officials. Waste nicotine gum, nicotine patches, and "empty" Coumadin bottles are just a few of the materials that are subject to regulation as acutely hazardous waste.

Given these factors, competing federal jurisdictions (e.g., DEA and FDA), state and federal resource constraints, and the likelihood that the volume and complexity of the overall pharmaceutical waste stream will continue to increase as our population ages and new compounds are developed, the participating NEWMOA members believe that EPA should consider an entirely different and streamlined approach to managing most pharmaceutical wastes. We suggest that EPA look at the problem holistically, leverage the resources of all of the relevant federal agencies and, in concert with those agencies develop comprehensive pharmaceutical waste management standards that are in line with the risks associated with pharmaceutical wastes and take resulting costs into account.

While the participating NEWMOA members recognize that certain pharmaceutical wastes should be fully regulated under RCRA Subtitle C (e.g., highly toxic pharmaceuticals, wastes resulting from pharmaceutical manufacturing), we urge EPA and the other relevant federal agencies to develop a direct and uncomplicated approach to ensuring proper management of the remaining pharmaceutical wastes that individually do not warrant full regulation under RCRA. Collectively, however, these mostly unregulated materials may have a greater potential for significant environmental impact than those currently regulated under RCRA. To this end, we strongly suggest that EPA consider managing these waste pharmaceuticals through some kind of extended producer responsibility (EPR) system.

We support the DEA take back programs for residentially-generated pharmaceutical wastes and the use of reverse distribution facilities to collect, handle, and ultimately dispose of the wastes generated by pharmacies, hospitals, and other healthcare facilities. As such, we suggest that this existing reverse distribution system be utilized as an integral part of the infrastructure for implementing an EPR program. In addition, pharmaceutical waste handling and disposal protocols should be developed for residential care facilities, such as assisted living centers and nursing homes.

In conclusion, the portion of the pharmaceutical waste stream that is currently regulated under RCRA Subtitle C is very small compared to the overall universe of waste pharmaceuticals. Given that both state and federal hazardous waste programs are facing significant resource constraints, we believe that we must keep state RCRA programs focused on the most critical hazardous waste management issues. We recommend that EPA's approach should be to re-examine and clarify which waste pharmaceuticals should be subject to full RCRA regulation and then with other federal agencies develop a holistic approach to the safe management of the remaining majority of waste pharmaceuticals outside of the RCRA regulatory system. We believe that federal establishment of streamlined but concise standards for the management of all pharmaceutical wastes would improve environmental protection and public safety.

We appreciate your consideration of the concerns and suggestions outlined in this letter. Please contact Terri Goldberg, NEWMOA at tgoldberg@newmoa.org or (617) 367-8558 x302 to discuss the issues described above and identify some next steps. We look forward to working with you on this important effort.

Sincerely,

Peter Pettit, P.E.
NEWMOA Vice Chair

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