WASTE MANAGEMENT

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August 10, 2010

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Materials Management and Local Assistance Program
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Via Email: Burke.Lucy@CalRecycle.ca.gov

Subject: Comments on Pharmaceutical Drug Waste Collection Programs in California

Dear Mr. Lucy:

Thank you for the opportunity to provide written comments to you regarding the subject matter following the recent CalRecycle Workshop held in Sacramento on July 20, 2010.

The purpose of this letter is to articulate WM's position on safe disposal of unused or expired consumer drugs. WM offers three secure and environmentally protective options for household pharmaceutical disposal: destruction by medical waste incineration, destruction by waste-to-energy, and secure disposal in a Subtitle D Municipal Solid Waste (MSW) landfill. This letter describes each option and summarizes:

- Environmental protection and security safeguards offered by each disposal option,
- Regulatory requirements for disposal of household pharmaceuticals, and
- Ultimate goals for development of safe collection and disposal programs for unused consumer medications.

Regulation of Controlled Substances Hampers Development of Drug Take-Back Programs

Waste Management (WM) is working with stakeholders to develop safe, convenient and low-cost take-back programs to offer separate collection and disposal of consumers' unused medications. Unfortunately, federal requirements for the handling of controlled substances that prohibit consumer return of unused "controlled" drugs except to law enforcement officials, hampers the development of these programs. This has resulted in the need for a sheriff or other law enforcement officer to be present at consumer take-back events. It also requires the presence of a pharmacist to accurately identify and segregate the controlled substances, and creates barriers to the collection of all pharmaceuticals in permanent kiosks or through mail-back envelopes or containers. Attached is a

copy of recent correspondence to WM Healthcare Solutions dated June 22, 2010 from the U.S. Department of Justice regarding take-back programs that may receive any amount of a controlled substance. These requirements impose a substantial barrier to establish convenient and low-cost pharmaceutical take-back programs.

Federal Guidelines Recommend Discarding Unused Drugs in Household Trash

Historical disposal of drugs consisted of flushing them into the wastewater treatment system in toilets or drains. However, recommended disposal practices have shifted in light of the measurement of many pharmaceutical compounds in waste water system effluent and receiving water bodies. [1]

In February 2007, the White House Office of National Drug Policy and the federal Food and Drug Administration issued guidelines for the proper disposal of pharmaceuticals. These guidelines recommend:

- Taking advantage of community pharmaceutical take-back programs for central collection and disposal;
- Dispose of unused or expired drugs by mixing them with an undesirable substance, such as coffee grounds or kitty litter and putting pharmaceuticals in impermeable, nondescript containers and throwing them in household trash; and
- Flushing unused drugs down the toilet ONLY if the label or patient information instructs doing so (about a dozen prescription drugs carry these instructions).

A number of states (e.g., Florida, Tennessee, Michigan, Massachusetts, and New Jersey) have echoed federal guidelines in encouraging consumers to avoid accidental poisonings and drug diversion by disposing of their unused medications in household trash.[2] The Pharmaceutical Research and Manufacturers of America (PhRMA), along with the U.S. Fish and Wildlife Service and American Pharmacists Association have also endorsed these guidelines. Environmental groups, concerned that landfill disposal of unused drugs may also result in pharmaceutical compounds escaping to the environment, have called for alternative disposal methods. Several states are considering product stewardship legislation that would require pharmaceutical manufacturers to fund and/or operate various forms of consumer drug take-back and disposal programs, although none has enacted legislation.[3] To date, WM is not aware of any state considering banning household pharmaceuticals from municipal landfill disposal.

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[1] Endocrine Disrupting and Pharmaceutical Compounds in Municipal Landfill Leachate, Innovative Waste Consulting Services, LLC, October 25, 2007
[2] Ibid.
[3] Consumer Rx Take-Back Programs: Challenges & Solutions, presentation by C. Smith, WM Healthcare Solutions, January 2010

The Regulation of Pharmaceutical Waste

Unused pharmaceuticals discarded by households are considered solid waste under Subtitle D of the federal Resource Conservation and Recovery Act (RCRA) and are predominantly regulated at the state and local levels. Although approximately five percent of prescription drugs are designated as hazardous waste under Subtitle C of RCRA when discarded, the federal regulations exempt household generated hazardous waste from Subtitle C regulation. This federal exclusion continues through the central collection and disposal of household-generated pharmaceuticals by take-back programs.

States are authorized to more stringently regulate hazardous wastes should they choose to do so.[4] Some states have taken the position that consumer-generated pharmaceuticals that meet the definition of a hazardous waste, when collected at a central location come back into RCRA Subtitle C regulation. This position requires that drugs either be segregated at the collection event or that all collected pharmaceuticals must be disposed at a RCRA-permitted hazardous waste treatment, storage and disposal facility. Given that the cost for such disposal is five to ten times higher than similar destruction in a regulated medical waste incinerator or waste-to-energy facility, this process adds unnecessary cost to the disposal of the drugs collected by take-back programs or events.[5]

California's regulation of pharmaceutical waste is extremely complex and these wastes may be regulated as a hazardous waste, a medical waste, or a solid waste under California law.

Pharmaceuticals that are Regulated as RCRA Hazardous Waste in California

In California, the Department of Toxic Substances Control (DTSC) is the agency authorized to regulate pharmaceutical wastes to the extent they are regulated as hazardous waste under the federal Resource Conservation and Recovery Act (RCRA). California's hazardous waste laws govern the management of waste pharmaceuticals that meet the federal definition of hazardous waste found in Title 40 Code of Federal Regulation (40CFR) 261.3. However, pharmaceutical wastes produced households and certain small, non-household generators, known as Conditionally Exempt Small Quantity Generators (CESQGs), are not regulated as hazardous waste under RCRA.

Pharmaceuticals that are Regulated as Medical Waste in California

Some wastes that are not regulated under RCRA – such as wastes that contain zinc and wastes produced by generators who are exempt from RCRA (such as Conditionally Exempt Small Quantity Generators) – are nevertheless identified as hazardous waste in California. Besides the chemical and physical properties mentioned above, a number of additional factors can cause a waste to exhibit the

[4] RCRA and Pharmaceutical Waste Management: A Brief Federal Overview, presentation by L. Lauer, U.S. EPA, Office of Resource Conservation and Recovery, to Product Stewardship Institute, January 2010

[5] WM Comments to EPA on Proposed Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, EPA-HQ-RCRA-2007-0932, March 4, 2009

characteristic of toxicity under California standards. If the waste contains a substance listed in the California Code of Regulations Sections 66261.24(a)(1) and 66261.24(a)(2) at a concentration above the specified limit, the waste would be identified as a hazardous waste in California. In addition, a waste that is toxic when inhaled, or that is fatal to certain types of fish in laboratory tests, is considered a hazardous waste in California.

Pharmaceutical wastes that meet California's definition of hazardous waste but not RCRA's definition, as well as pharmaceutical wastes generated by people who are not regulated under RCRA, are subject to the Medical Waste Management Act (Division 104, Part 14 California Health and Safety Code). (However, pharmaceutical waste produced by a household is not regulated as hazardous waste or medical waste.) Wastes that are not subject to regulation as a hazardous waste or medical waste (e.g., household pharmaceutical wastes) would be subject to regulation as solid waste under the Integrated Waste Management Act.

Whether or not a specific generator or activity is regulated under RCRA or the Medical Waste Management Act or as a solid waste may depend on a number of complicated factors. Clearly, in order to encourage the safe and secure collection and management of pharmaceutical waste, compliance with California's complex array of waste regulations must be clarified and facilitated.

Very Small Amounts of Consumer Pharmaceuticals Are Destined for Disposal in MSW Landfills

In the absence of organized consumer pharmaceutical take-back programs, unused drugs will likely be discarded in household trash for ultimate disposal in Subtitle D-regulated municipal solid waste (MSW) landfills or where available, combusted and destroyed in MSW waste-to-energy (WTE) plants. Only very limited data exist on the mass of pharmaceutical waste that is disposed of in landfills. In 2007, Musson and Townsend conservatively estimated (high end) the **possible amount of consumer pharmaceuticals disposed in landfills in the U.S. at between 1,259 to 7,555 tons per year.**[6] Their estimates were based on the number of prescriptions issued, the fraction of medications that are typically unused, the fraction of unused medications typically disposed, and other factors accounting for over-the-counter drugs, hospital disposal practices, and nursing home practices.[7] **To put this tiny amount in perspective,** a joint study by BioCycle and Columbia University, "The State of Garbage in America," estimated that **266,412,964 tons per year of MSW were landfilled in 2006, and 28,394,109 tons per year were combusted in WTE plants.**[8]

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[6] Musson, S. and Townsend, T., An Evaluation of the Mass of Pharmaceutical Waste in Municipal Solid Waste, submitted to Environmental Science and Technology, August 2007.

[7] Endocrine Disrupting and Pharmaceutical Compounds in Municipal Landfill Leachate, Innovative Waste Consulting Services, LLC, October25, 2007

[8] The State of Garbage in America, 16th Nationwide Survey of MSW Management in the U.S., BioCycle and the Earth Engineering Center, Columbia University, *BioCycle*; December 2008

Musson and Townsend also analyzed the waste composition of incoming waste loads in Orange County, Florida, sorting over 6,200 pounds of waste into 22 samples. The results indicated that the concentration of pharmaceuticals was approximately 8 parts per million on a mass basis.[9]

The Contribution of Landfilled Pharmaceutical Compounds to Surface Waters is Extremely Low

The pharmaceutical industry among others has studied the environmental fate of unused medications disposed in household trash and sent to MSW landfills. Tischler and Kocurek prepared a report in 2006 for the Pharmaceutical Research and Manufacturers of America (PhRMA) estimating the potential for release of 23 active pharmaceutical ingredients (APIs) to surface waters through disposal in Subtitle D MSW landfills. The potential landfill releases were compared to the releases occurring from patient use and excretion to wastewater treatment systems. Despite several conservative estimates designed to over-predict the occurrence and release of APIs in landfill leachate, Tischler and Kocurek found that the average contribution of landfill leachate to the total load of APIs in surface water ranged from 0.21% to 0.78%. [10] **In other words, only a fraction of one percent of all APIs discharged to surface waters was predicted to originate from drugs disposed in MSW landfills.**

WM is concerned that the CalRecycle Background Paper prepared for July 20, 2010 Workshop does not appear to have a balanced discussion of this issue. The Background Paper cites an unpublished report from the State of Maine suggesting that landfill leachate might be a source of pharmaceuticals in the environment. In addition, there was a comment made by a CalRecycle at the workshop that appeared to substantiate that CalRecycle is under the impression that landfill leachate may be a significant source of pharmaceutical contamination in the environment.

According to information provided by the State of Maine regarding their unpublished landfill leachate report, their preliminary conclusion is that a variety of pharmaceuticals were detected at very low concentrations with filtered results but that the actual concentrations may be much higher. The State of Maine's apparently contends that because the laboratory filtered the samples before analysis, the reported concentrations underestimate the total mass of Pharmaceutical and Personal Care Products (PPCPs) leached from landfills. WM does not believe this position is justified. The filtering process removes particulates, typically > 5 or 10 microns and generally does not "filter" dissolved soluble compounds.

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[9] Endocrine Disrupting and Pharmaceutical Compounds in Municipal Landfill Leachate, Innovative Waste Consulting Services, LLC, October25, 2007

[10] Tischler/Kocurek, Potential Releases of Unused Medicines in subtitle D landfill Leachate, report prepared for PhRMA, 2006

However, the real underlying issue with the Maine "report" is that with very low reported sensitivity of the instruments and methods used, matrix interference from other constituents in the sampled leachate likely makes the reported PPCPs values in the leachate quantitatively unreliable with a high degree of false positive results.

The State of Maine reported their results as quantifiable at *parts per trillion* (ng/L) levels. The validity of the results from spiked samples in distilled water would be questionable but when the results are reported from a matrix that commonly provides interference with analytical methods (high organic and inorganic matrix) the reliability of such results are highly suspect.

The Oregon Association of Clean Water Agencies conducted a literature review of the fate of pharmaceutical compounds in landfill leachate. The author of the review, Dr. Nason, noted that a 2004 study by Schneider *et al.* also reported that the contribution of landfill leachate to the total pharmaceutical load at a municipal wastewater treatment plant was small (attached). [11] Nason also compared the theoretical leachate concentrations for ibuprofen from the Tishler/Kocurek study to actual field measurements of ibuprofen in leachate reported from several European studies. The Tischler/Kocurek report predicted ibuprofen concentrations ranging from 43 to 130 milligrams per litre, while actual field measurements ranged from 4 to 21 micrograms per litre. Nason concluded that the estimates made by Tischler/Kocurek were indeed conservative over-predictions of the occurrence of pharmaceutical compounds in surface water. [12]

U.S. EPA Office of Research and Development's National Risk Management Research Laboratory conducted analyses of six pharmaceutical compounds in samples of leachate and/or runoff from twelve subtitle D MSW landfills and an MSW transfer station. The research findings will be published in the Journal of Science of the Total Environment. The EPA project manager said that EPA was unable to develop a methodology to confidently extract and analyze low levels of pharmaceutical compounds in landfill leachate because the high levels of dissolved organic carbon in MSW leachate confound the analytical equipment. EPA found that quantification of pharmaceutical compounds in the very low levels found in landfill leachate is highly uncertain.

A significant number of modern MSW landfills, particularly those operated in more arid climates, recirculate leachate within the landfill to enhance anaerobic digestion of wastes. This practice not only speeds stabilization of waste and enhances gas production for energy recovery, but also minimizes the amount of leachate discharged to onsite or offsite wastewater treatment.

WM requests that CalRecycle revise its position that landfill leachate may be a significant source of pharmaceutical waste in the environment. WM does not believe that the body of evidence simple does not support such a position.

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[11] Nason, J., Literature Review: Occurrence and Fate of Pharmaceutical Compounds in Landfill Leachate, prepared for Oregon Association of Clean Water Agencies, August 2007
[12] Ibid.

EPA Believes that Modern MSW Landfill Liners will Prevent Migration of Disposed Pharmaceuticals to Groundwater

Studies of the environmental fate of pharmaceuticals disposed in landfills have also evaluated releases to groundwater. Nason reported only one documented instance of groundwater contamination occurring from a lined landfill, which had a breach in its composite liner, and noted several studies showing contamination of groundwater underlying older, unlined landfills. Nason concluded that past disposal of pharmaceuticals at unlined, unmonitored landfills could still pose risks of groundwater contamination, but that lined landfills are successful at containing pharmaceutically active compounds. [13] In 2008, authors Tischler et al. reviewed an EPA study (December 2002) of the performance of Subtitle D landfill liner systems in which **EPA concluded that required composite liner systems (required at all active landfills starting in 1991) will substantially prevent leachate migration for the entire period of significant leachate generation for typical landfills.**[14]

EPA, working with a peer review team led by Dr. Rudy Bonaparte, also concluded that the estimated service life of high-density polyethylene (HDPE) membrane liners is about 1,000 years. While 50% degradation of strength properties can occur within approximately 750 years, that burial of the HDPE liner as is the case in landfill applications, can extend the service life by decreasing the availability of oxygen.

Long-term integrity of landfills is further supported by the small number of landfill failures that have occurred during operation, after closure, or following catastrophic events. Several literature reviews of studies conducted on landfills following natural disasters revealed no major structural failures at closed, modern landfills, and no significant impacts caused by catastrophic events (e.g., hurricanes, earthquakes, or wildfires). [15] [16] The few significant problems that occurred at operating landfills were investigated and found to be the result of either a specific operational failure or poor construction. Forensic studies on the performance of landfills during catastrophic events found that the landfills were highly resistant to damage from such events and that environmental protection systems remained intact.

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[13] Nason, J., Literature Review: Occurrence and Fate of Pharmaceutical Compounds in Landfill Leachate, prepared for Oregon Association of Clean Water Agencies, August 2007

[14] Bonaparte R., Koerner R.M., Daniel D.E., December 2002, Assessment and Recommendations for Improving the Performance of Waste Containment Systems, EPA/600/R-02/099, U.S. EPA Office of Research and Development, Cincinnati, OH

[15] Roberts et al., "The EGC Takes on Three Hurricanes in Polk County," MSW Management, March/April 2005

[16] Matasovic, N., Kavazanjian, E., "Cyclic Characterization of Landfill Solid Waste," ASCE Geotech, Geoenvironmental Engineering, 1998

Tischler et al. further concluded that given the EPA and other findings regarding landfill integrity, the likelihood of landfill leachate leaking to groundwater is negligible and estimates of such releases are not practical. [17] Further, based on the negligible contribution of landfill leachate to the presence of pharmaceutical compounds in surface water, Tischler et al. concluded that **encouraging the disposal of unused medications in MSW landfills would decrease surface water discharges of active pharmaceutical ingredients that are caused by flushing unused medications into sewerage systems.** [18]

Unused Consumer Medications can be Safely Destroyed in MSW Waste-to-Energy Facilities

WM operates sixteen waste-to-energy (WTE) plants under its Wheelabrator division, combusting municipal solid waste and generating enough renewable energy to power 700,000 homes per day – although we do not operate any such plants in California. Our WTE plants are permitted to safely destroy non-hazardous pharmaceutical wastes and federally exempt household pharmaceuticals. WM Wheelabrator plants safely and effectively combust pharmaceutical wastes from manufacturers (including pharmaceutical packaged products, raw materials, and waste from production) and have extensive experience both conducting certified destruction of non-hazardous controlled substances for the federal Drug Enforcement Administration, and witnessed burns for manufacturers.

WTE facilities are subject to stringent environmental standards and employ sophisticated air quality control equipment. As a result of the controls employed at these plants, dramatic reductions in emissions have been achieved (reducing dioxin and mercury emissions by 99% and 97% respectively) leading EPA to conclude that waste-to-energy generates electricity with "less environmental impact than almost any other source of electricity."[19] [20]

Consumers in communities served by a waste-to-energy plant can confidently dispose of their unused medications in household trash, which will be safely and effectively destroyed. WTE plants can also serve as a safe disposal destination for consumer drug wastes collected through consumer take-back programs.

WM's Medical Waste Incinerator is a Safe Disposal Destination for Unused Consumer Medications that are Centrally Collected

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[17] Tischler, L.,Buzby, M., Cunningham, V., Finan, D., Parke, N., "Landfill Disposal as an Approach to Reduce Discharges of Medicines from POTWs," Proceedings of the Water Environment Federation, WEFTEC 2008

[18] Ibid.

[19] EPA Memorandum, EPA Office of Air Quality Planning and Standards, Emissions from large and Small MWC Units at MACT Compliance, August 10, 2007

[20] EPA Memorandum, EPA Office of Solid Waste and Emergency Response and Office of Air and Radiation, Recognizing the environmental efforts of MSW waste-to-energy industry, February 14, 2003

In states and communities that have developed take-back programs to collect and destroy unused consumer medications, medical waste incineration (MWI) is a safe and effective disposal option. WM owns and operates a MWI in Chambers County, Texas. Medical waste incinerators are permitted to destroy the biohazardous waste generated by hospitals, clinics, doctors and dentists, and veterinary clinics in the diagnosis and treatment of patients. **Non-hazardous pharmaceutical wastes may also be safely disposed of by MWIs with appropriate state permits.** Medical waste incinerators are stringently regulated under the federal Clean Air Act, which requires sophisticated air quality control equipment to minimize emissions.

Goals of a Comprehensive Consumer Pharmaceutical Take-back Program

As stated previously, WM supports the development of safe, convenient and low-cost take-back programs to offer separate collection and disposal of consumers' unused medications. We are working hard with other stakeholders to make such programs available through our Health Care Solutions offerings. WM believe that the ideal take-back program will have the following characteristics:

1. Convenient
2. Safe (both from a physical and a diversion perspective)
3. Cost-effective
4. Available to the entire population, including the disabled or home-bound
5. Able to provide a sample set of data on unused pharmaceuticals to enable source reduction of unwanted drugs in the future

To achieve these goals, well-designed take-back programs will most likely include:

- **Multiple drug return options**, such as kiosk drop boxes in pharmacies and other convenient locations, mail-back containers, and community events for scheduled drop-off;
- **Use of existing transportation infrastructure**, such as USPS, FedEx, and UPS to provide cost-effective logistics;
- **Flexible disposal options** that are compliant with federal and state regulatory requirements;
- **Disposal** of returned household pharmaceuticals by incineration at a permitted **medical waste incinerator or MSW waste-to-energy facility** will be significantly less costly than disposal at a hazardous waste incinerator;
- **Appropriate state agencies** should be tasked with development of **regulatory criteria for program approval, performance and oversight** to ensure that ultimate disposal is secure and environmentally protective; and
- Return options **compliant with Federal Controlled Substances Act.**

Essential to the development of state take-back programs, Congressional action is needed to amend the Controlled Substances Act to offer more flexibility in the management of controlled substances returned by consumers. Currently, HB 5809, the Safe Drug Disposal Act, would amend the Controlled Substances Act to allow the Drug Enforcement Agency (DEA) to promulgate new regulations governing the safe, convenient and cost effective drug take back programs. Without these statutory and regulatory changes, the only take-back program options available are community events staffed by law enforcement personnel, or kiosk-style collection hosted and managed at law enforcement offices.

In addition, Waste Management, in partnership with other organizations, is developing an innovative take back program, which we would like to discuss with you in the near future.

Waste Management appreciates the opportunity to provide these comments for your consideration. Please contact me if you have any questions regarding this information. Please let me know if you would like copies of any of the references cited in this letter and I will strive to secure them for you.

Sincerely,

Charles A. White, P.E.
Director of Regulatory Affairs/West
CAW:cb

Attachments: 1. 2007 Nason Report, "Literature Review: Occurance and Fate of Pharmaceutical Compounds in Landfill Leachate"
2. June 22 letter to WM Healthcare Solutions from U.S. Department of Justice

cc: Howard Levenson, Deputy Director, CalRecycle, howard.levenson@calrecycle.ca.gov
Brenda Smyth, Division Chief, CalRecycle, brend.smyth@calrecycle.ca.gov
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Literature Review: Occurrence and Fate of Pharmaceutical Compounds in Landfill Leachate

Prepared for

Oregon Association of Clean Water Agencies

by

Jeffrey A. Nason, Ph.D.

August, 2007

Abstract

In light of the recent guidance issued by the White House Office of National Drug Control Policy, directing consumers to dispose of unwanted prescription drugs in household trash, a review of the available research focused on the occurrence and fate of pharmaceutical compounds in landfill leachates and groundwater contaminated by unlined landfills is presented. Research, primarily outside the U.S., has detected and quantified pharmaceutical compounds in landfill leachate and in groundwater down gradient of leaking and unlined landfills at concentrations on the order of ng/L to mg/L. The highest concentrations (> 100 μg/L) have been found in instances where pharmaceutical production waste was disposed of at the site; concentrations on the order of ng/L to μg/L were more typical of municipal solid waste landfills. According to theoretical calculations and a limited amount of field data, the total load of all pharmaceutical compounds to surface water via landfill leachate is predicted to be small (< 1%). However, the likelihood that drugs disposed of in landfills will ultimately end up in surface water is compound specific.

Introduction

In February of 2007, the White House Office of National Drug Control Policy released guidance on the proper disposal of unused or unwanted prescription drugs (ONDCP, 2007). The guidance directs consumers to dispose of the unused drugs in household trash or to take advantage of drug take-back programs, rather than flushing the drugs down the toilet. Although a great deal of research has focused on the fate of pharmaceutical compounds in municipal wastewater (Jones *et al.*, 2005), relatively little is known about the occurrence, transformation and fate of pharmaceutical compounds in landfills. Bellante *et al.* (2003) argue that the small number of studies is a result of the broad variety of pharmaceutical compounds and the relatively small amounts of pharmaceutical compounds present in municipal solid waste. This document is a review of available technical literature regarding the absence or presence of pharmaceuticals in landfill leachate and groundwater below unlined landfills. Previous literature reviews focused on pharmaceuticals in aquatic systems (Heberer, 2002), household drug disposal (Bellante *et al.*, 2003; Bound and Voulvoulis, 2005), household hazardous waste (Slack *et al.*, 2005) and pharmaceuticals in landfill leachate (Metzger, 2004), along with the U.S. EPA's new website focused on pharmaceuticals and personal care products (USEPA, 2007), were extremely useful in identifying the pertinent literature and placing it in the context with the larger problem of pharmaceuticals and personal care products in the environment.

Occurrence of Pharmaceuticals in Landfill Leachate

To date, a limited number of studies have investigated the presence or absence of pharmaceutical compounds in landfill leachate and/or groundwater contaminated by landfill leachate. The work that has been done has focused on a wide variety of prescription and non-prescription drugs and their environmental metabolites. Studies have examined both active and closed landfills and those with and without leachate collection systems. As noted by Metzger (2004), comparisons of concentrations between landfills are impossible due to the varied nature of waste disposed of in municipal solid waste landfills, as well as leachate dilution by rainwater. What the available research does convey, however, is the range of concentrations that have been measured. What

follows is a review of the pertinent literature in this area. A data table summarizing the specifics of each study (drugs, concentrations, landfill characteristics, etc.) is contained in Appendix A.

Eckel *et al.* (1993) re-analyzed gas chromatography/mass spectrometry data from a sample collected in 1984 as part of an earlier study. The sample was collected 300 m down gradient from an unlined Florida landfill that was active in 1968 and 1969, receiving waste from two large naval bases. It is believed that waste from a large hospital located on one of the bases contributed to the waste disposed of at the site. As a result of the analysis, the sedatives pentobarbital and meprobamate and the anticonvulsant phensuximide were identified (but not quantified) in the groundwater. The investigators drilled a new well adjacent to the 1984 sampling location and analyzed the groundwater for pentobarbital. The compound was found at a concentration of 1 μg/L.

Holm *et al.* (1995) sampled groundwater at depths from 5.5 to 10 m down gradient (0-260 m) of an unlined Danish landfill that accepted approximately 85,000 tons of waste from pharmaceutical manufacturing over the course of 13 years prior to the closure of the landfill in 1977. Six sulfonamides (sulfanilic acid, sulfanilamide, sulfaguanidine, sulfadiazine, sulfadimidine, sulfamethizol) and three byproducts of their production (aniline, *o*-chloroaniline, *p*-chloroaniline), one barbiturate (5,5-diallylbarbituric acid), an analgesic (propyphenazone), an intermediate in the production of meprobamate (2-methyl-2-*n*-propyl-1,3-propanediol), and an anti-foaming agent used in pharmaceutical production (tri-(2-methylpropyl)-phosphate) were found in the groundwater; concentrations ranged from less than 1 μg/L to 18 mg/L across the compounds, sampling locations and depths.

Ahel *et al.* (1998) sampled solid waste and underlying soil (1 m) from three different locations within an active unlined landfill in Croatia. Solids were analyzed for several different chemicals. The analgesic propyphenazone was found in the soil at concentrations up to 0.1 mg/kg in the soil and 10 mg/kg in the solid waste itself. Isopropylidene carbohydrate derivatives from the manufacture of Vitamin C were also found at concentrations in excess of 10 mg/kg in the solid waste and up to 1 mg/kg in the

underlying soil. The authors link these concentrations to disposal of pharmaceutical production waste, rather than from disposal of municipal refuse.

In a subsequent study at the same site (Ahel and Jelicic, 2001) the authors also examined the concentrations of pharmaceutical compounds in the landfill leachate and groundwater underlying the landfill. Three phenazone analgesics (propyphenazone, aminopyrine, and antipyrine) were detected in the solid waste, leachate, underlying soil and groundwater. Propyphenazone was found at concentrations up to approximately 50 μg/L in the leachate and in the groundwater, suggesting that the compound is highly mobile and persistent in the environment. Aminopyrine was also present in the leachate (up to 16 μg/L) and the groundwater (up to 36 μg/L). However, concentrations declined rapidly from "hot spots" of the compound within the landfill. Antipyrine was found in the leachate at trace levels (< 50 ng/L).

Paxeus (2000) quantified approximately 200 organic compounds from three landfills in Sweden. Landfill A, active since the mid 1970's, received mixed waste (incineration, wet screenings from a wastewater treatment plant, industrial) that did not appear to include household waste. Landfill B, active since 1964, received mixed waste (sewage sludge, industrial, construction, household). Landfill C, closed at the time of the study (operated 1938-1978) received all kinds of waste (household, industrial, chemical, construction, sludges, cadavers, etc.). While not explicitly stated, it appears that these three landfills were equipped with leachate collection systems as yearly leachate production rates were cited. Three antiphlogistics were found in leachate from these landfills. Ibuprofen was found at a concentration of 8 μg/L in leachate collected from landfill A, phenazone was found at concentration of 37 μg/L in leachate collected from landfill C, and isopropylphenazone was found at concentrations of 1.1 μg/L and 49 μg/L from leachate collected at landfill A and landfill C, respectively.

Schwarzbauer *et al.* (2002) took advantage of a breach in the liner of a landfill in Germany, sampling seepage (leachate) and leakage water (collected in a mining system below the landfill, but above the water table) for a wide variety of organic compounds. Two analgesics (ibuprofen and propyphenazone) and the environmental metabolite of a

blood lipid regulator (clofibric acid) were detected in both of the leachate samples and the leakage sample. The concentration of propyphenazone ranged from 110-140 μg/L in the leachate and in the leakage water, again indicating the compound's persistence in the environment. Although detected in the leachate and the leakage water, ibuprofen and clofibric acid concentrations were not quantified.

In a follow-up study at the same site, Heim *et al.* (2004) looked more in depth at the persistence of some organic chemicals in the groundwater surrounding the leaking landfill. Ibuprofen, propyphenazone and clofibric acid were detected in the groundwater (up to 500 m from the edge of the landfill) and in the leakage water collected from the exit of the mine shaft running below the landfill (at a distance of approximately 2 km from the landfill). Propyphenazone was present at concentrations of up to 1.4 μg/L in the groundwater adjacent to the landfill and up to 100 ng/L in the leakage water. Clofibric acid was found at concentrations up to 1.1 μg/L in the groundwater and up to 55 ng/L in the leakage water. Concentrations of ibuprofen in the groundwater were not reported, but the compound was present in all leakage water samples at trace levels (< 5 ng/L). Concentrations in the groundwater and leakage water were 100-1000 times less than the concentrations measured in the leachate (Schwarzbauer *et al.*, 2002), but their presence indicates that the compounds are mobile and persistent in the environment.

Barnes *et al.* (2004) tested for 76 organic wastewater contaminants in groundwater wells down gradient of a closed landfill in Norman, Oklahoma. The unlined landfill was operated from 1920-1985, at which point it was closed, capped with clay and vegetated. During operation, the landfill received residential and commercial waste, along with some hazardous waste. Wells varied from 3 ft to 584 ft away from the landfill. Of the 76 compounds that were analyzed, 21 were antibiotics or metabolites of antibiotics, and 18 were human prescription or non-prescription drugs or metabolites. One antibiotic (lincomycin) and one metabolite of a human non-prescription drug (cotinine) were detected in the wells. Lincomycin was found at concentrations ranging from < 0.05 to 0.1 μg/L and cotinine was found at concentrations ranging from < 0.05 to 0.13 μg/L.

Schneider *et al.* (2004) measured the concentrations of 28 different pharmaceutical compounds in the leachate from two active municipal landfills in Germany that received household waste. While not explicitly stated, the fact that leachate production rates were listed suggests that both landfills were lined. Concentrations of the various compounds ranged from ng/L to μg/L levels, with the highest concentrations being found for several analgesics (*e.g.*, ibuprofen, propyphenazone, and phenazone) and an anticonvulsant (primidone). Details of the chemical concentrations can be found in Appendix A. The distribution and quantity of these compounds in the landfill leachates was compared to the distribution and quantity in municipal wastewater influent. It was found that the distributions were quite different, and that the contribution of the leachate stream to the total load of pharmaceuticals in the influent of the wastewater treatment plant was small.

Foreign Literature

The specifics of two studies published in German were summarized in a literature review in English by Metzger (2004). As reported in that article, Schneider *et al.* (2001) measured the concentrations of several pharmaceutical compounds in two municipal landfills in Germany. Quantified drugs included clofibric acid, diclofenac, ibuprofen, indomethacin, pentoxyfylline and primidone; concentrations ranged from 1 to 20 μg/L. Metzger did not report any details regarding the specifics of the landfills. Concentrations of specific compounds can be found in Appendix A.

Metzger also summarized the work of Breidenich (2003) who investigated the presence of several drugs in the leachate from five active municipal landfills in Germany. Of the twelve pharmaceuticals investigated, large concentrations (5-10 μg/L) of clofibric acid, ibuprofen, carbamazepine, and phenacetin were found in the leachates. It is assumed that some of the landfills were lined as some were equipped with leachate treatment systems. Carbamazepine, clofibric acid, ibuprofen and diclofenac were also detected in groundwater down gradient of a closed landfill at concentrations ranging from 0.19 to 2.1 μg/L. Concentrations for specific compounds can be found in Appendix A.

Fate of Pharmaceuticals in Landfill Leachate

Tischler/Kocurek (2007) prepared a report for the Pharmaceutical Research and Manufacturers of America, estimating the potential for release of 23 active pharmaceutical ingredients (APIs) to surface waters through disposal in Subtitle D municipal solid waste landfills (*i.e.*, those with low-permeability liners and leachate collection and/or treatment systems). Using reported pharmaceutical sales and estimates of the fraction of sold drugs disposed of in landfills (5-15%), municipal solid waste production, leachate production rates, compound specific partitioning coefficients, rates of anaerobic degradation and hydrolysis in landfills, and fractional removal of the APIs in leachate treatment systems (assumed to be equivalent to secondary wastewater treatment) the authors estimated the annual load of each API to surface water. The calculated mass loadings were compared with the loads of APIs released to surface waters through patient use via wastewater treatment plant effluent. Literature estimates of the loss by human metabolism and the degradation during conventional wastewater treatment were used in that calculation.

Not surprisingly, APIs with high sales and low partitioning coefficients had the highest potential release rates in landfill leachate. Despite several conservative estimates (*e.g.*, disposal of drugs free of their packaging, leachate rates based on high average precipitation, and no assumed leachate recirculation or other operation to promote degradation), the average contribution of landfill leachate to the total load of all APIs to surface water was predicted to range from 0.21 to 0.78%. In other words, only a fraction of one percent of all APIs discharged to surface water was predicted to originate from drugs disposed of in municipal solid waste landfills. It should be noted that the predicted contribution of some individual APIs were considerably higher than the aggregate values reported above. Examples of APIs with high relative percentages were albuterol sulfate (3-9%), doxycycline (2-6%), enalaprilat (7-19%), ibuprofen (4-10%), and norfloxacin (9-22%). In these cases, landfill disposal resulted in a higher percentage of the total load because the compounds had low partitioning coefficients and a large fraction of many of these compounds are metabolized, reducing the load to surface water via the patient use pathway.

The theoretical prediction that pharmaceuticals in leachate from municipal solid waste landfills accounts only for a small fraction of the total load of pharmaceuticals to a wastewater treatment plant (assuming that the leachate is disposed of to a sanitary sewer system) has been confirmed in one instance. Although specific percentages were not given, Schneider *et al.* (2004) reported that the contribution of landfill leachate to the total pharmaceutical load at a municipal wastewater treatment plant was small. Further evaluation of the results of the Tischler/Kocurek report can be accomplished by comparing the theoretical leachate concentrations presented in the report with field measurements from the studies cited above. Unfortunately, the only API predicted in the report and measured in the field is ibuprofen. The Tischler/Kocurek report predicts ibuprofen concentrations ranging from 43 to 130 mg/L in landfill leachate while actual field measurements ranged from 4 to 21 μg/L (Paxeus, 2000; Schneider *et al.*, 2001; Breidenich, 2003; Schneider *et al.*, 2004). This comparison is further evidence that the estimates made in the Tischler/Kocurek report are indeed conservative. Nevertheless, active pharmaceutical compounds disposed of via municipal solid waste landfills are expected to contribute to the total load of those compounds to surface waters, if only at a small percentage of the total load including the patient use pathway.

Finally, the Tischler/Kocurek report indicates that the potential for release of pharmaceutical compounds from Subtitle D landfills to the underlying groundwater are negligible, based on the EPA's estimates of liner integrity and estimated lifetime. However, failure of landfill liners have been reported (Schwarzbauer *et al.*, 2002; Heim *et al.*, 2004). Furthermore, the literature cited above has also shown that disposal of pharmaceutical compounds to unlined landfills has occurred in the past and poses a substantial risk to the underlying groundwater.

Discussion

It is clear from the available literature that a variety of pharmaceutical compounds are being detected in the leachate collected in lined landfills and in groundwater contaminated by seepage from unlined landfills. In one instance, groundwater was contaminated by a leaking lined landfill (Schwarzbauer *et al.*, 2002; Heim *et al.*, 2004).

Concentrations of a wide variety of prescription and non-prescription drugs in the leachate and contaminated groundwater have been found to range from less than 1 ng/L to approximately 18 mg/L (see Appendix A). Among the most commonly detected pharmaceuticals were the analgesics ibuprofen (up to 20.7 μg/L in leachate, up to 0.19 μg/L in groundwater) and propyphenazone (up to 120 μg/L in leachate, up to 4 mg/L in groundwater) and clofibric acid, an environmental metabolite of a blood lipid regulator (up to 10 μg/L in leachate, up to 1.3 μg/L in groundwater).

The context for this report is the disposal of unused/unwanted drugs to solid waste landfills. As such, it is important to examine the potential source of the drugs quantified in these studies. In a few of the studies cited above, landfills received large quantities of hospital waste (Eckel *et al.*, 1993) or waste from pharmaceutical production (Holm *et al.*, 1995; Ahel *et al.*, 1998; Ahel and Jelicic, 2001). The highest concentrations (*i.e.*, greater than approximately 100 μg/L) of pharmaceutical compounds found in the groundwater down gradient of these unlined landfills is likely attributable to the large loads of pharmaceutical waste, rather than the disposal of unused/unwanted drugs. However, these studies do demonstrate the mobility and persistence of certain classes of pharmaceutical compounds in landfill, soil and groundwater environments.

In addition to landfills receiving large quantities of pharmaceutical waste, some of the sites were noted to have received sludge from municipal wastewater treatment plants (Paxeus, 2000). It is possible that some of the pharmaceutical compounds present in the leachate originated from that sludge via municipal wastewater treatment, rather than the disposal of unwanted/unused drugs directly to the landfill. Although the earliest detections of pharmaceutical compounds in landfill leachates and contaminated groundwaters were from sites receiving large quantities of pharmaceutical waste, more recent studies, focusing on landfills receiving primarily commercial and household waste have also revealed the presence of pharmaceutical compounds in landfill leachate.

Lined vs. Unlined Landfills

In only one documented instance has groundwater been contaminated by a lined landfill. In that case (Schwarzbauer *et al.*, 2002; Heim *et al.*, 2004), a known leak in the landfill

liner was the source of the subsurface contamination. On the other hand, several unlined landfills have been shown to have contaminated the underlying groundwater with pharmaceutical compounds (Eckel *et al.*, 1993; Holm *et al.*, 1995; Ahel *et al.*, 1998; Ahel and Jelicic, 2001; Breidenich, 2003; Barnes *et al.*, 2004). Although lined landfills are successful at containing pharmaceutically active compounds, those compounds must be treated, either at a dedicated leachate treatment facility, or at a municipal wastewater treatment plant. Any compounds that remain after that treatment are discharged to the environment. The report by Tischler/Kocurek (2007) predicted the partitioning, degradation, and treatment of several pharmaceutical compounds in leachate from lined landfills. That analysis required a great number of assumptions and it is clear that improved understanding of the fate of pharmaceutical compounds in lined landfills and leachate treatment systems is necessary. A current study is underway at the University of Florida (Townshend, 2003), but no results have been published at this time.

Active vs. Closed Landfills

There does not appear to be any correlation between the presence or absence of pharmaceuticals and whether the landfill is active or closed. However, the majority of the closed landfills that were investigated were unlined (Eckel *et al.*, 1993; Holm *et al.*, 1995; Breidenich, 2003; Barnes *et al.*, 2004). In those cases, direct contamination of the groundwater with pharmaceutical compounds was the result. Clearly, disposal of pharmaceuticals to unlined landfills poses a significant risk.

Conclusions

A wide variety of pharmaceutical compounds have been detected in landfill leachate from lined landfills and in groundwater down gradient of unlined landfills. The presence or absence of pharmaceuticals does not appear to be correlated with the operating status of the landfill (active vs. closed). However, a larger number of closed landfills were unlined and therefore posed a greater risk of direct contamination of the groundwater. Neglecting the sites thought to be contaminated with hospital (Eckel *et al.*, 1993) or pharmaceutical production waste (Holm *et al.*, 1995; Ahel *et al.*, 1998; Ahel and Jelicic, 2001), concentrations of pharmaceutical compounds in leachate ranged from less than 10 ng/L to

as high as 120 μg/L. In contaminated groundwater, concentrations ranged from < 1 ng/L to as high as 140 μg/L. Much higher concentrations (up to 18 mg/L) were found in groundwater contaminated by unlined landfills that had received pharmaceutical production waste.

The potential benefits of disposing pharmaceutical compounds to landfills are the partitioning of some pharmaceuticals to organic matter and biological or chemical degradation within the landfill. However, the fraction of the pharmaceutical compounds that end up in the leachate must be removed prior to surface water discharge; some fractions of those compounds can escape treatment and end up in the environment. Theoretical predictions (Tischler/Kocurek, 2007) and field data (Schneider *et al.*, 2004) suggest that drugs disposed of in municipal solid waste landfills contribute only a small fraction (< 1%) of the total load of pharmaceutical compounds discharged to surface water via municipal wastewater treatment plants and landfill leachate treatment systems. However, for individual compounds, this percentage is estimated to be as high as 20%. Although the total load of pharmaceuticals to surface waters is predicted to be small, it is not zero. Furthermore, the likelihood that drugs disposed of in landfills will ultimately end up in surface water is compound specific.

These preliminary studies provide a starting point, but further research is necessary to more completely understand the transformation and ultimate fate of pharmaceutical compounds in landfill leachate. To date, only a few studies have examined the concentrations of pharmaceutical compounds in leachate from lined landfills (Paxeus, 2000; Schneider *et al.*, 2001; Schwarzbauer *et al.*, 2002; Breidenich, 2003; Heim *et al.*, 2004; Schneider *et al.*, 2004) and all of those studies focused on landfills in countries other than the U.S. Additional study in the U.S. is necessary to more fully evaluate the occurrence and fate of pharmaceuticals in landfill leachates and the potential implications of the White House Office of National Drug Control Policy's guidance directing consumers to dispose of unused pharmaceuticals in household trash.

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Appendix A – Summary of Data from Literature Review

Drug Classification	Compound	Concentration (µg/L)[1] Leachate	Groundwater	Liner[2]	Active[3]	Source[4]	Citation[5]	Notes
analgesic, antiphlogistic, anti-inflammatory, antipyretic	aminopyrine	0.06-16	<0.05-36	N	Y	PPW	Ahel and Jelicic (2001)	solid waste (0.005-0.02 mg/kg) soil (0.003-0.007 mg/kg)
	antipyrine	<0.05		N	Y	PPW	Ahel and Jelicic (2001)	
	diclofenac	1.8			Y*		Schneider et al. (2001)	data from Metzger (2004)
			0.26	N*	N		Breidenich (2003)	data from Metzger (2004)
		3.19		Y*	Y	HW	Schneider et al. (2004)	median concentration
		1.183		Y*	Y	HW	Schneider et al. (2004)	median concentration
	dimethylamionphenazone	4.764		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.668		Y*	Y	HW	Schneider et al. (2004)	median concentration
	ibuprofen	8			Y		Paxeus (2000)	no HW at this landfill according to the article
		20.7			Y*		Schneider et al. (2001)	data from Metzger (2004)
		N.Q	N.Q.	Y	Y		Schwarzbauer et al. (2002)	
		9.5			Y		Breidenich (2003)	data from Metzger (2004)
			0.19	N*	N		Breidenich (2003)	data from Metzger (2004)
			N.D.	Y	Y		Heim et al. (2004)	
			<0.005		Y		Heim et al. (2004)	groundwater discharge to surface water
		9.362		Y*	Y	HW	Schneider et al. (2004)	median concentration
		4.894		Y*	Y	HW	Schneider et al. (2004)	median concentration
	indomethacine	1.6			Y*		Schneider et al. (2001)	data from Metzger (2004)
		0.017		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.141		Y*	Y	HW	Schneider et al. (2004)	median concentration
	ketoprofen	0.697		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.438		Y*	Y	HW	Schneider et al. (2004)	median concentration
	naproxen	0.445		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.288		Y*	Y	HW	Schneider et al. (2004)	median concentration
	phenacetin	4.7			Y		Breidenich (2003)	data from Metzger (2004)
	phenazone	37			Y		Paxeus (2000)	
		5.507		Y*	Y	HW	Schneider et al. (2004)	median concentration
		1.761		Y*	Y	HW	Schneider et al. (2004)	median concentration
	piroxicam	0.481		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.931		Y*	Y	HW	Schneider et al. (2004)	median concentration
	propyphenazone		<10-4000	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
				N	Y	PPW	Ahel et al. (1998)	<0.01-0.1 mg/kg (soil); 0.1-10 mg/kg (solid waste)
		1.1			Y		Paxeus (2000)	
		49			N		Paxeus (2000)	
		3.7-60	5-50	N	Y	PPW	Ahel and Jelicic (2001)	solid waste (0.05-22 mg/kg) soil (0.003-2.9 mg/kg)
		110-120	140	Y	Y		Schwarzbauer et al. (2002)	
			<0.001-1.4	Y	Y		Heim et al. (2004)	
			0.002-0.1	Y	Y		Heim et al. (2004)	groundwater discharge to surfacewater
		9.173		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.455		Y*	Y	HW	Schneider et al. (2004)	median concentration
antibiotic	lincomycin		<0.05-0.10	N	N		Barnes et al. (2004)	
	sulfadiazine		<20-1160	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfadimidine		<20-900	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfaguanidine		<20-1600	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfametizole		<20-330	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfanilamide		<20-300	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfanilic acid		<20-10440	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient

Drug Classification	Compound	Concentration (µg/L)[1] Leachate	Groundwater	Liner[2]	Active[3]	Source[4]	Citation[5]	Notes
anticonvulsant, antiepileptic	carbamazepine	5.2			Y		Breidenich (2003)	data from Metzger (2004)
			2.1	N*	N		Breidenich (2003)	data from Metzger (2004)
		1.415		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.202		Y*	Y	HW	Schneider et al. (2004)	median concentration
	phensuximide		N.Q.	N	N	MW	Eckel et al. (1993)	
	primidone	3			Y*		Schneider et al. (2001)	data from Metzger (2004)
		5.011		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.002		Y*	Y	HW	Schneider et al. (2004)	median concentration
	valproic acid	0.205		Y*	Y	HW	Schneider et al. (2004)	median concentration
	valproic acid	0.122		Y*	Y	HW	Schneider et al. (2004)	median concentration
anti-foaming agent	tris(2-methylpropyl) phosphate		<1-80	N	N	PPW	Holm et al. (1995)	used in pharmaceutical productior
antineoplastic	cyclophosphamide	0.192		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.097		Y*	Y	HW	Schneider et al. (2004)	median concentration
	ifosfamide	0.042		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.032		Y*	Y	HW	Schneider et al. (2004)	median concentration
antitussiva	dihydrocodeine	0.101		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.014		Y*	Y	HW	Schneider et al. (2004)	median concentration
barbituate	5,5-diallylbarbituric acid		<10-205	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
beta-blocker	atenolol	0.044		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.034		Y*	Y	HW	Schneider et al. (2004)	median concentration
	metroprolol	0.031		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.024		Y*	Y	HW	Schneider et al. (2004)	median concentration
	propranolol	0.01		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.01		Y*	Y	HW	Schneider et al. (2004)	median concentration
bronchiodilator	clenbuterol	<0.01		Y*	Y	HW	Schneider et al. (2004)	median concentration
		<0.01		Y*	Y	HW	Schneider et al. (2004)	median concentration
byproducts of sulfonamide production	aniline		<10-1100	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	o-chloroaniline		<10-110	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	p-chloroaniline		<10-50	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
hypnotic/sedative	pentobarbital		1	N	N	MW	Eckel et al. (1993)	
intermediate in production of meprobamate	2-methyl-2-n-propyl-1,3-propanediol		<10-18000	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
lipid regulator	clofibric acid (a metabolite)	2.9			Y*		Schneider et al. (2001)	data from Metzger (2004)
		N.Q.	N.Q.	Y	Y		Schwarzbauer et al. (2002)	
		10			Y		Breidenich (2003)	data from Metzger (2004)
			1.3	N*	N		Breidenich (2003)	data from Metzger (2004)
			<0.005-1.1	Y	Y		Heim et al. (2004)	
			<0.005-0.055	Y	Y		Heim et al. (2004)	groundwater discharge to surfacewater
		2.658		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.879		Y*	Y	HW	Schneider et al. (2004)	median concentration
	bezafibrate	1.353		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.773		Y*	Y	HW	Schneider et al. (2004)	median concentration
metabolite of nicotine	cotinine		<0.05-0.13	N	N		Barnes et al. (2004)	
phosphodiesterase inhibitor	pentoxyfylline	2.1			Y*		Schneider et al. (2001)	data from Metzger (2004)

Drug Classification	Compound	Concentration (µg/L)[1]		Liner[2]	Active[3]	Source[4]	Citation[5]	Notes
		Leachate	Groundwater					
production of vitamin C	isopropylidene carbohydrate deriv.			N	Y	PPW	Ahel et al (1998)	<0.1-1 mg/kg (soil) <0.1->10 mg/kg (solid waste)
psychiatric drug	diazepam	0.453		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.192		Y*	Y	HW	Schneider et al. (2004)	median concentration
sedative	meprobamate		N.Q.	N	N	MW	Eckel et al (1993)	
			N.Q.	N	N	PPW	Holm et al (1995)	anecdotal evidence
vasodilator	pentoxifylline	2.875		Y*	Y	HW	Schneider et al. (2004)	median concentration
		1.116		Y*	Y	HW	Schneider et al. (2004)	median concentration
x-ray contrast media	amidotrizoic acid	0.242		Y*	Y	HW	Schneider et al. (2004)	median concentration
	iomeprol	0.092		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.042		Y*	Y	HW	Schneider et al. (2004)	median concentration
	iopamidol	2.485		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.944		Y*	Y	HW	Schneider et al. (2004)	median concentration
	iopromide	0.199		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.236		Y*	Y	HW	Schneider et al. (2004)	median concentration

[1] N.D. = not detected; N.Q. = detected but not quantified.
[2] Y indicates that the landfill was lined, N indicates that the landfill was unlined. Entries with an asterisk were inferred. Blank entries indicate no data.
[3] Y indicates an active landfill; N indicates a closed landfill. Entries with an asterisk were inferred. Blank entries indicate no data.
[4] Column indicates the likely source of the pharmaceutical in the landfill. HW = household waste; MW = medical waste; PPW = pharmaceutical production waste.
[5] When more than one entry from the same reference for the same chemical, values refer to different landfills.

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

JUN 2 2 2010

Mark L. Iske
Vice President of Operations
WM Healthcare Solutions, Inc
1001 Fannin, Suite 4000
Houston, Texas 77002

Dear Mr. Iske:

This correspondence is in response to your letter dated March 29, 2010, to the Drug Enforcement Administration (DEA). Please accept DEA's apology for the delay in responding to your inquiry. In your letter, you stated that WM Healthcare Solutions, Inc. (WMHS) would like to develop a program to help individuals dispose of unwanted pharmaceuticals in a safe and environmentally protective manner. Due to concerns that it would be difficult to exclude controlled substances from the collection process, however, WMHS has not developed such a program. You mentioned that other companies have initiated collection programs that are premised on the idea that if ultimate users are directed not to place controlled substances into collection containers, then the program would fall outside the scope of the Controlled Substances Act (CSA) and its implementing regulations.

Based on the above, you asked if reasonable measures were taken to exclude controlled substances from a household pharmaceutical waste program, could the program assume it would not be subject to requirements of the CSA and its implementing regulations. If a pharmaceutical waste program comes into possession of a controlled substance, even inadvertently, and has no legal authority to possess the substance, the program is in illegal possession of the material and subject to CSA provisions.

The CSA and its implementing regulations establish a closed system of distribution that requires individuals or businesses desiring to handle controlled substances to register with DEA or be exempt from registration. Federal law defines an ultimate user as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household...." 21 U.S.C. § 802(27). The CSA exempts ultimate users from the requirement to register pursuant to 21 U.S.C. § 822(c)(3). Beyond such circumstance, the CSA and its implementing regulations do not contemplate a situation in which an ultimate user would distribute a controlled substance even for disposal. Additionally, the CSA and its implementing regulations do not authorize DEA registrants (i.e., reverse distributors, practitioners, and pharmacies) to take possession of controlled substances that were dispensed to an ultimate user. Such activity would be outside the closed system of distribution established by the CSA and its implementing regulations, and enforced by DEA.

DEA has endorsed the requests of state and local law enforcement agencies to collect unwanted pharmaceutical controlled substances from ultimate users. This allowance has been limited to police departments pursuant to 21 C.F.R. § 1301.24(a)(2) that exempts duly authorized law enforcement officials from registration with DEA while acting in an official capacity. DEA will only give its endorsement of a drug take-back program if a state or local law enforcement agency oversees the collection of all surrendered controlled substances. The controlled substances must be under the care of a law enforcement official at all times, and the state or local law enforcement agency must ensure the destruction of these controlled substances.

For additional information regarding DEA's Diversion Control Program, please visit www.DEAdiversion.usdoj.gov. You may also find on this website copies of the regulations and statutes listed above. If you have any further questions regarding this matter, please contact the Liaison and Policy Section at (202) 307-7297.

Sincerely,

Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control