Pharmaceuticals in Wastewater Streams: Disposal Practices and Policy Options in Santa Barbara

A 2007 Group Project Proposal

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Abstract

The release of pharmaceuticals into the environment is becoming an important environmental issue. Trace amounts of pharmaceuticals have been detected in wastewater effluents and surface waters, and the pharmaceuticals have the potential to negatively impact organisms residing in receiving water bodies and surrounding areas. There are many potential sources of pharmaceuticals, but one of the least regulated groups is the average consumer. End-users dispose of drugs by flushing them down household plumbing or putting them in the trash. Excretion of unmetabolized drugs and metabolites may also be a significant, uncontrolled source of pharmaceuticals.

The goals of this project are: 1) to synthesize the state of knowledge concerning the presence and effects of pharmaceuticals in the environment; 2) to characterize the extent of this problem in the Santa Barbara community; and 3) to propose and evaluate policies or programs that will help mitigate the release of pharmaceuticals into the environment. One of the potential programs that will be examined is a drug recycling program, which would enable unused pharmaceuticals from health care facilities to be collected and redistributed to low-income members of the community.

Research will be conducted using current scientific literature and available information on other communities’ programs and policies. In addition, original data will be collected through institutional and community surveys. The end product of this project will be a report outlining feasible policies and programs for Santa Barbara. This report will include information on costs, potential roadblocks, guidance documents, and possibly draft legislation.
Project Objectives

The release of pharmaceuticals into the environment is emerging as an important environmental issue. Researchers have found trace amounts of pharmaceuticals in wastewater effluents and surface waters, as well as negative impacts on organisms residing in receiving water bodies and surrounding areas. The purpose of this project is to understand the extent of this problem, both in the Santa Barbara community and at a broader level, and to recommend programs and policy solutions that will mitigate the release of pharmaceuticals into the environment. These recommendations will be made following an evaluation of behavior, as well as economic, political, and administrative barriers and opportunities. Specifically, the project will:

I. Synthesize the state of knowledge and identify information gaps concerning the presence and effects of pharmaceuticals in the environment, as well as current practices and policy responses relating to their release.

II. Determine household behavior and institutional practices within the Santa Barbara community relating to the release of pharmaceuticals into the environment.

III. Assess the potential benefits and feasibility of policy solutions, including, but not limited to, a drug recycling program, to mitigate pharmaceutical release.

Significance

The scientific literature strongly suggests that the uncontrolled release of unused and unmetabolized pharmaceuticals in the environment is detrimental to aquatic life and thus to ecosystems, particularly downstream of wastewater treatment facilities. Despite the newness of the problem and the limits of available data, early discussion of possible solutions should not be avoided. Scientific research does not always provide answers in a timely or accurate manner (Jordon 1998); consequently, measures to mitigate potential impacts should be researched as a necessary precaution before more detrimental effects are discovered. Any practices that could be implemented to reduce drug delivery to waste disposal systems would potentially benefit the environment and human health.

Because chemicals can impact broad geographic areas as they migrate from their point of release, the project will have local as well as regional significance. The project may also result in substantial savings from the reduced disposal and subsequent reuse of costly pharmaceuticals. A collection and recycling program could help divert a small portion of this waste into a program benefiting persons without medical insurance, for instance.

It is important to remember that although scientific literature suggests pharmaceuticals are ubiquitous in the environment (Dove 2006), we are choosing to focus on Santa Barbara because of our close proximity to it. However, solutions proposed and implemented here will act as a model for similar solutions to be developed elsewhere. Although the primary data gathered from telephone and in-person surveys will be specific to Santa Barbara, the process of assessing and analyzing the pharmaceutical waste issue will be applicable to other regions. Our final report will provide a much-needed template that will guide other counties pursuing information and solutions. The package will include a comprehensive review of scientific literature, a complete case study of behavior assessment
and analysis, and an evaluation of several actions that could be implemented to mitigate the release of pharmaceuticals to wastewater.

**Background information**

Pharmaceutical and medicine manufacturing is one of the fastest growing industries in the United States, generating $196.7 billion in retail pharmacy drug sales in 2005 (IMS 2005), up from $108 billion in 1999 (U.S. Census 2001). Regardless of future economic uncertainties, the market for pharmaceutical products is expected to remain strong (BLS 2005), especially considering the increasing average age of the population and continuing technological advances (Daughton and Ternes 1999). Recent innovations in analytical methods (Ternes et al. 2004) are showing that this burgeoning industry is a cause for concern, as pharmaceuticals and their metabolites have been established as nearly ubiquitous environmental pollutants in surface and ground waters (Dove 2006).

The term “pseudopersistent” has been used to describe the continual introduction of pharmaceuticals into the environment, and little is known about the human or ecological hazards possible from multiple, cumulative exposure to these substances (Daughton 2002). From published occurrence data, it seems probable that most, if not all, urban wastewater is contaminated with pharmaceutical compounds, differing only in the type and abundance of the substances present (Daughton 2003). The existence of drugs in surface waters, groundwater, and even marine systems has also been confirmed (Jones et al. 2002). In a study of over 95 organic chemicals in U.S. streams and rivers, the presence of multiple organic pollutants was found to be relatively common, with a median of seven and as many as 38 compounds being found in a given water sample (Kolpin et al. 2002). More data on metabolites as well as parent compounds are needed in order to understand fully the fate and transport of individual pollutants in the hydrological cycle and during wastewater treatment (Jones et al. 2002), as the degradation products of pharmaceuticals may also be toxic (Isidori et al. 2005; Bedner and MacCrehan 2006).

**Risks posed by pharmaceuticals**

Pharmaceuticals are biologically active molecules and will likely affect the normal processes of aquatic and soil organisms in the environment. For example, fluoxetine, a common antidepressant, affects neuronal and hormonal function by inhibiting the re-uptake of serotonin in humans. Lower vertebrates and invertebrates also use serotonin as a neurotransmitter; fluoxetine has the potential to alter appetite, immune system function, and reproduction in these organisms (Brooks et al. 2003; Fent et al. 2006).

Some research indicates that pharmaceuticals are already affecting aquatic organisms. For example, Jobling et al. (2003) showed a higher incidence of male feminization for fish living in water bodies receiving wastewater effluent. They attribute the increased intersex nature of the fish to the presence of estrogenic compounds in the water. Another documented environmental effect of pharmaceuticals is increased antibiotic resistance in wastewater discharge from hospitals (Kummerer and Henninger 2003). A number of researchers are trying to quantify the risks created by various pharmaceuticals based on the following factors: target organisms, environmental conditions, and physicochemical properties of pharmaceuticals (Hernando et al. 2006; Sanderson et al. 2004a).
Routes of entry and regulations
Introduction of pharmaceuticals and their byproducts to the aquatic environment may occur at any stage in their lifecycle. Pollution created at different stages along the lifecycle is regulated by different government agencies with different agendas, and in some cases, it is not regulated at all. The stages of the lifecycle include: 1) research and development (such as at university laboratories); 2) manufacturing and production by pharmaceutical companies; 3) wholesale distribution; 4) delivery or prescription in hospitals, medical offices, hospices, nursing homes and clinics; 5) retail sale in pharmacies and drug stores; 6) reverse distribution; and 7) consumer use, excretion, and disposal of drugs.

Disposal is one of the most important areas in any study of the introduction of pharmaceuticals to the environment and encompasses many activities that may not be obvious routes of introduction. In the United States there are two types of medications where regulation is in place for drug disposal. The first is controlled substances, where disposal by pharmacies is carefully regulated by the U.S. Drug Enforcement Agency. The DEA accepts incineration or flushing into the wastewater as viable means of destruction for controlled substances (DEA 2003). The agency does not have specific guidelines regulating disposal at the level of the end-user or patient.

The second type of regulated medications is those considered hazardous under the Resource and Conservation Recovery Act and the Code of Federal Regulations (40 CFR Part 261). There are two ways a pharmaceutical can be considered hazardous waste: as a listed waste or as a characteristic waste. Hazardous waste management involves specific management practices, including permits, special transportation manifests, and specific bans against land disposal without treatment (Musson and Townsend 1998). Hospitals, pharmacies, and reverse distributors are required to follow specific guidelines regarding the destruction of drugs that are deemed hazardous waste. At least one study has shown, however, that most of these institutions are either unaware of their RCRA obligations or choose to ignore them (Oliver and Chapman 2003). These guidelines do not apply to the actions of consumers.

End-user disposal of pharmaceuticals is the least regulated route of entry into the environment. Disposal methods are apparently driven by personal preference and include dumping down the drain and throwing into the trash. Kuspis and Krenzelok (1996) surveyed 500 patients and found that 1.4 percent returned medications to a pharmacy, 54 percent disposed of medications in the trash, 35.4 percent flushed drugs down the toilet or sink, 7.2 percent did not dispose of medications, and 2 percent stated they used all medication prior to expiration.

In addition to direct disposal to wastewater, excretion is another important means of entry of pharmaceuticals and bioactive metabolites to the waste stream. Many drugs are not fully metabolized in the body and so may be excreted to the sewer system. Medicinal compounds are generally excreted after being partially or completely converted to water-soluble metabolites (Daughton 2003), but a significant amount of the original substance may also be excreted unchanged (Hirsch 1999).

Incineration at any level of the lifecycle may introduce pharmaceuticals and bioactive byproducts into the aquatic environment through atmospheric wetfall, dryfall, and washout. Pharmaceuticals may also enter the environment through landfill leachate, tissue decomposition in cemeteries (which are considered a special landfill class), or through withdrawn body fluids discharged directly into municipal sewage systems during embalming (Daughton 2003b).
There are no government standards regarding accepted levels of pharmaceuticals in drinking water or in effluent released into streams or lakes. Water and sewage agencies are not required to look for them, and most do not (Cone 2006). The FDA only requires that pharmaceutical companies perform an environmental assessment of a new product if their anticipated production of the drug is more than 40,000 kg/year, ignoring the possibility of inputs from multiple companies that might all be making the same drug (Thacker 2005). When environmental assessments are conducted, concentration data is extrapolated over the entire United States, ignoring such factors as geographic variability in disposal or any possible interactions (Daughton 2003a). However, the EPA is researching and monitoring pharmaceuticals in waterways and studying the potential risks involved for the trace amounts found (Miller 2005). The agency is likely to add some pharmaceuticals to a new candidates list, which could initiate monitoring of water (Cone 2006).

Current mitigation practices
Despite the lack of regulation at the federal level, some states have recently been working on their own to develop plans to mitigate pharmaceutical release. The two most prominent courses of action are: setting guidelines for drug disposal or allowing implementation of drug recycling programs for hospitals, nursing homes, and pharmacies. Although several successful examples of both types of programs can be found, barriers preventing full acceptance still exist, such as cost, liability, and legislative issues. Twenty-six states including California have implemented drug-recycling programs (Benson 2005). In 2005, Senate Bill 798, sponsored by Sen. Joe Simitian, authorized counties to collect unused prescription drugs from nursing homes, wholesalers, and manufacturers and redistribute them to persons in need of financial assistance (Health and Safety Code Division 116, Section 150200-150207). The medication cannot be a controlled substance and cannot have been in the possession of a patient or any individual member of the public. The confidentiality of the patient to whom the medicine was originally prescribed must be maintained, and only unexpired, unopened drugs in tamper-proof packaging will be accepted. The bill also protects certain persons and entities accepting, disposing, and dispensing pharmaceuticals against liability.

Approach
The project will research current scientific literature, as well as existing policy and program responses. In addition, institutional and household surveys will be conducted to collect original data on disposal practices and the volume and types of drugs being disposed of in the Santa Barbara community. Based on an analysis of this data, the group will identify and evaluate an array of options to mitigate the release of pharmaceuticals into the environment and make recommendations.

I. Review scientific literature and existing policies and programs to determine:
   - The volume and types of pharmaceuticals manufactured, prescribed, and dispensed
   - Potential sources of pharmaceuticals in the environment
   - The presence of pharmaceuticals in the environment
   - The risks that pharmaceuticals in the environment pose to organisms and ecosystems
   - Regulations in place that govern the management and disposal of pharmaceuticals
   - Case studies of programs and policies that mitigate the release of pharmaceuticals into the environment
II. Data collection

Household Survey
This project will conduct a telephone survey of a minimum of 500 randomly selected households in the Santa Barbara County to determine behavior relating to pharmaceutical use and disposal. This survey will consist of closed-ended, categorical questions that are amenable to statistical analysis. We will make use of the UCSB Social Science Survey Center for consultation. Depending on funding, we will hire the center to complete the survey, hire and train UCSB undergraduates to complete the survey and/or conduct the survey ourselves. We will also submit three to nine questions to UCSB’s annual Central Coast Survey, the results of which will be available in February 2007.

Institutional Survey
The project team will also survey 50 to 75 randomly selected pharmacies, nursing homes, hospitals, and hospices in Santa Barbara County either by telephone or in person. This survey will consist of both categorical and open-ended questions.

The household and institutional surveys will address:
- Quantities and types of drugs used in Santa Barbara County
- Actual use and disposal practices by consumers
- Management and disposal practices of pharmacies, hospitals, nursing homes, hazardous waste facilities, etc.
- Pharmaceutical disposal advice given by pharmacies to consumers
- Volume of unopened pharmaceuticals that would qualify for a recycling program
- Community perception of the issue, as well as willingness to support policy or participate in a program solution

Other data collection
Wastewater treatment facilities are not required to test for the presence of pharmaceuticals in the water, and no such tests have been completed in Santa Barbara. Though it is beyond the scope of this project to complete comprehensive water testing, pending funding, we will commission water sample testing.

Currently, the County advises Santa Barbara residents to dispose of unwanted medications by taking them to a pharmacy or hazardous waste facility. We will interview hazardous waste facility personnel to determine if they encourage use of the facility for this purpose, the volume and types of pharmaceuticals they collect, attitudes toward pharmaceutical collection, and management obstacles.

III. Analysis and recommendations

Based on the information collected, we will identify and assess the costs, benefits, and feasibility of various policy solutions to mitigate the release of pharmaceuticals into the environment. Possible solutions include a drug recycling program, a drug collection program, education and outreach, legislation, change in regulation or enforcement practices, and guidance documents for pharmaceutical management and disposal. This analysis will be useful beyond Santa Barbara, but upon its conclusion, we will recommend a specific course of action for the county. The proposed solution will create a more integrated approach to the management and disposal of pharmaceuticals.
among consumers, dispensers, and reverse distributors. We will take into consideration the response of stakeholders to proposed solutions.

**Deliverables**

In this research project, the results from interviews and surveys will be available as both electronic files and in hard copy. A thorough statistical analysis of data from the community survey (principle component or other multivariate analysis) will be presented in the form of graphs and/or tables. An analysis of the costs and benefits of future policy solutions and pilot programs will be conducted. Recommendations for policy solutions and programs based on our analytical results will be proposed to mitigate the release of pharmaceuticals into the environment in Santa Barbara. A final report, presentation, and project brief that summarizes results will be given at the conclusion of the project in spring 2007.

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**Stakeholders**

Interested parties include the County of Santa Barbara, City of Santa Barbara, consumers, pharmacies, clinics, manufacturers, nursing homes, hospices, hospitals, hazardous waste facilities, and wastewater treatment facilities.
Appendix I: References


California Health and Safety Code Section 150200-150207.


Daughton, C.G. “Cradle-to-cradle stewardship of drugs for minimizing their environmental disposition while promoting human health. I. Rationale for and Avenues toward a Green Pharmacy” Environmental Health Perspectives 111.5 (2003a): 757-774.

Daughton, C.G. “Cradle-to-cradle stewardship of drugs for minimizing their environmental disposition while promoting human health. II. Drug disposal, waste reduction, and future directions.” Environmental Health Perspectives 111.5 (2003b): 775-785.


Appendix II: Project timeline

Spring 2006
- Background information gathering
- Proposal writing
- Web site construction
- Survey preparation

Fall 2006
- Conduct interviews and survey
- Data analysis
- Write Draft Report

Winter 2007
- Determine management recommendations based on results from survey
- Project Defense presentations
- Draft of final report due to faculty advisor
- Submit information for group project presentation program
- Final Report
- Project Brief

Spring 2007
- Project poster
- Public presentation of Final Report

Below is a general timeline for the project. A project management file will be developed to ensure all tasks are completed in a timely manner.

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Appendix III: Budget

A. Expenditures

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B. Budget justification

The Bren School has allocated $1,300 toward the successful completion of this project. This total is divided among two main categories: $200 toward printing and the residual to be used for all other expenses. The $200 printing allotment has already been split among group members; an additional $20 has been placed in each printing account. Of the remaining $1,100, it was recommended that $250 be set aside for the printing of the final poster and other expenses associated with the final presentation. A substantial percentage of our budget has been allocated to “methodology costs.” This general category includes all expenses associated with the tasks outlined in the “methodology” section of the proposal. These expenditures will be regularly reviewed to ensure we keep within our spending limit. The last section, “miscellaneous,” will act as a buffer, catching all unplanned expenses; this category will also be regularly evaluated. This budget is subject to change; it is the job of the financial manager to track expenditures and reallocate funds among categories as needed, as well as notify the other team members of any changes.