

Investigating Emergent Contaminants

--Pharmaceutical impacts and possible solutions--

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Abstract

Studies in many countries have demonstrated the presence and in some cases negative effects of pharmaceutical products at trace levels in surface and groundwater. The major inputs of pharmaceuticals come from households and hospitals, due to excretion and improper disposal of unwanted or expired medications. Even though the environmental impact of pharmaceuticals in the environment at trace levels has not been clearly determined preventative action should be taken in the face of uncertainty.

The purpose of this paper is to analyze the current disposal practices of unused/unwanted or expired pharmaceutical products, their studied environmental impacts, and some possible solutions. A survey of local hospitals and nursing homes was conducted to determine direct pharmaceutical inputs. This paper examines some of the actions that could be taken to decrease the amount of pharmaceuticals that are released into the environment.

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Introduction

Developed to promote human health and wellbeing, certain pharmaceuticals and personal care products (PPCPs) have made their way into our nation's waters and are starting to attract negative attention. Pharmaceutical residues from humans and animals, personal care products, and their metabolites are continually introduced to the aquatic environment as complex mixtures. They can enter the water from discharge of treated domestic wastewater, treated industrial wastewater, commercial feeding operations, and surface application of manure.¹ The discovery of a variety of pharmaceuticals in surface, ground, and drinking waters around the country is raising concerns about the potentially adverse environmental consequences of these contaminants. There is increasing concern that the PPCPs detected in our nation's waters could cause adverse environmental effects, including, but not limited to; endocrine disruption in aquatic life and (or) increased antibiotic resistance.

A study by the United States Geological Survey (USGS) published in 2002 brought this issue into the limelight. A sampling of 139 streams across 30 states found that 80 percent had measurable concentrations of prescription and nonprescription drugs, steroids, reproductive hormones, and their by-products.² This and other studies detecting PPCPs in surface, ground, and drinking waters across the country are raising concerns about public safety and the potentially adverse environmental consequences of these contaminants.

The presence of these compounds in surface waters is an emerging issue in environmental science. The USGS broadly defines emerging contaminants as "any synthetic or naturally occurring chemical or any microorganism that is not commonly

monitored in the environment but has the potential to enter the environment and cause known or suspected adverse ecological and (or) human health effects.”³ Some of the pharmaceuticals in question are not new but our ability to look for and measure them is ever increasing. It has only been in the past few years that continually improving chemical analysis methodologies have lowered the limits of detection to allow researchers to identify these compounds and their metabolites at very low levels, in the parts-per-billion (ppb) and parts-per-trillion (ppt) range.

PPCPs consist of a incredibly expansive, diverse collection of thousands of chemical substances, including prescription and over-the-counter (OTC) therapeutic drugs, perfumes, cosmetics, sun-screen agents, diagnostic agents, and many others. This broad collection of substances refers, in general, to any product intended to be consumed or applied externally by individuals for personal health or cosmetic reasons. All PPCPs have the potential to be excreted, disposed of, or washed into sewage systems and from there discharged to aquatic or terrestrial environments.

The steady increase in the use of potent pharmaceuticals, driven by both drug development and our aging population, is creating a corresponding increase in the amount of pharmaceutical waste generated. While many of these PPCPs are present at very low levels they are continually released into the environment. Others remain in the environment because they are resistant to breakdown. Continual, multi-generational exposure of aquatic life in the environment to multiple PPCPs has unknown consequences. Laboratory studies have demonstrated that various pharmaceuticals can elicit responses in aquatic organisms at relatively low levels.^{4,5} Human exposure also has unknown consequences, but even if there are no current risks, there may be problems

derived from the perception of risk. Pharmaceuticals are designed to induce specific biological effects at specific targets for a limited period of time. The continuous, wide spread, long-term exposure of PPCPs to the environment, although at low concentrations, may result in gradual almost undetectable changes.

The two largest sources of pharmaceuticals entering the sewer systems are believed to be from hospitals and households; including both human excretion and drain disposal of pharmaceuticals. Most often unused or expired medications are either flushed down the toilet or thrown in the garbage where they pose a threat to the environment. If flushed, pharmaceuticals may pass through treatment facilities and end up in surface and groundwater. If landfilled, they have the potential to leach from the landfill into groundwater. Alternately, without a safe and effective method for disposal, prescription drugs may be left indefinitely in medicine cabinets where they pose a threat of potential prescription drug misuse or abuse.

Currently, municipal sewage treatment plants are not engineered specifically for PPCP removal as most were built before PPCP became part of the equation. Removal efficiencies from treatment plants vary from chemical to chemical and among individual sewage treatment facilities. Sewage treatment plants are designed to reduce nitrates, phosphates, dissolved organic carbon, and pathogens, which have been the major pollutants of concern in domestic waste. Some PPCPs are not affected by sewage treatment processes, others may be degraded, and still others may be converted to “daughter” compounds.

Further steps need to be taken to understand the potential risk and if necessary to help protect our environment and human health. To determine the best policy from

which to proceed, this paper examines in detail the disposal of pharmaceuticals and their daughter compounds to establish their presence, effects, and major inputs to the aquatic environment. That will be followed by an overview of the current research initiatives, pharmaceutical take back programs, and regulatory challenges in the United States and abroad.

The next part of the paper focuses on waste and drinking water treatment of pharmaceuticals, current options and influent and effluent sample measurements. Finally, policy recommendations and possible future steps will be provided with conclusions. This paper will focus primarily on human pharmaceutical inputs, excluding for the most part the inputs from personal care products, industrial and commercial manufacturing waste, animal husbandry products, and runoff which are beyond the scope of this paper.

Section 1 - Background

1. Pharmaceuticals as Pollutants

During the last three decades, the impact of chemical pollution has focused almost exclusively on the conventional “priority” pollutants (e.g. pesticides); however this is just one piece of the larger puzzle.⁶ The occurrence of pharmaceutical products in the environment has gained attention since the 1980s; however their occurrence has become more widely evident since the 1990s because of the continual improvement in chemical analysis methodologies.⁷ Not only are pharmaceuticals in the environment of special interest with respect to the original compounds introduced, but also because of the differences in their occurrence, their fate, and their effects on target organisms or on non-target organisms in the environment.

Pharmaceuticals are intended to help cure disease and to make people feel better, but the consistent increase in potency and number of prescriptions used, driven by both drug development and our aging population, is creating a corresponding increase in the amount of pharmaceutical waste generated. These drugs that are improving health outcomes and quality of life, replacing surgery and other invasive treatments, and quickening recovery for patients who receive these treatments are making their way into our nation’s waters as pollutants.

With the population of the United States increasing at the rate of one person every 10 seconds and with the average individual filling over 10 prescriptions per year,⁸ pharmaceutical waste is a growing concern. Massachusetts only holds roughly 2%⁹ of the population, but per capita fills over 12 prescriptions per year. According to the

Kaiser Family Foundation's *Prescription Drug Trends*¹⁰ report, from 1993 to 2003, the number of prescriptions purchased nationwide increased 70 percent (from 2 billion to 3.4 billion), compared to a U.S. population growth of only 13 percent.

1.1. Pharmaceutical Inputs

Pharmaceutical products refer to a group of chemicals used for the diagnosis, treatment, or prevention of health conditions. They are usually classified as either over the counter (OTC) or prescription-only medications (POM) then further classified according to their therapeutic purpose.¹¹ Pharmaceuticals and their by-products enter the environment as pollutants in a variety of ways, including: discharge from wastewater treatment plants or private septic systems, leaching from landfills, agricultural runoff, and from local hospitals.

Pharmaceuticals do not usually persist in the environment but continuous inputs have the potential to keep concentrations relatively constant, even if at very low levels. Medications, when administered to the individual can have beneficial results, but once the active ingredients enter the environment as an unknown interacting cocktail of different compounds they can produce unwanted effects.

Pharmaceuticals initially enter wastewater treatment plants from two key sources (Figure 1): the active pharmaceutical compounds and their metabolites are excreted from the body; and from the disposal of unused or expired medications down the toilet or drain. If disposed of in household waste, compounds end up on landfill sites where they may enter the landfill leachate.

The MWRA provides wholesale water and sewer services to 2.5 million people and more than 5,500 large industrial users in 61 metropolitan Boston communities.¹² Within those large industrial users, 9 are pharmaceutical industries, 62 hospitals and 10 long term care facilities that all have the potential to contribute elevated, concentrated doses of pharmaceuticals to their wastewater which will be discussed further in the survey section of this paper.

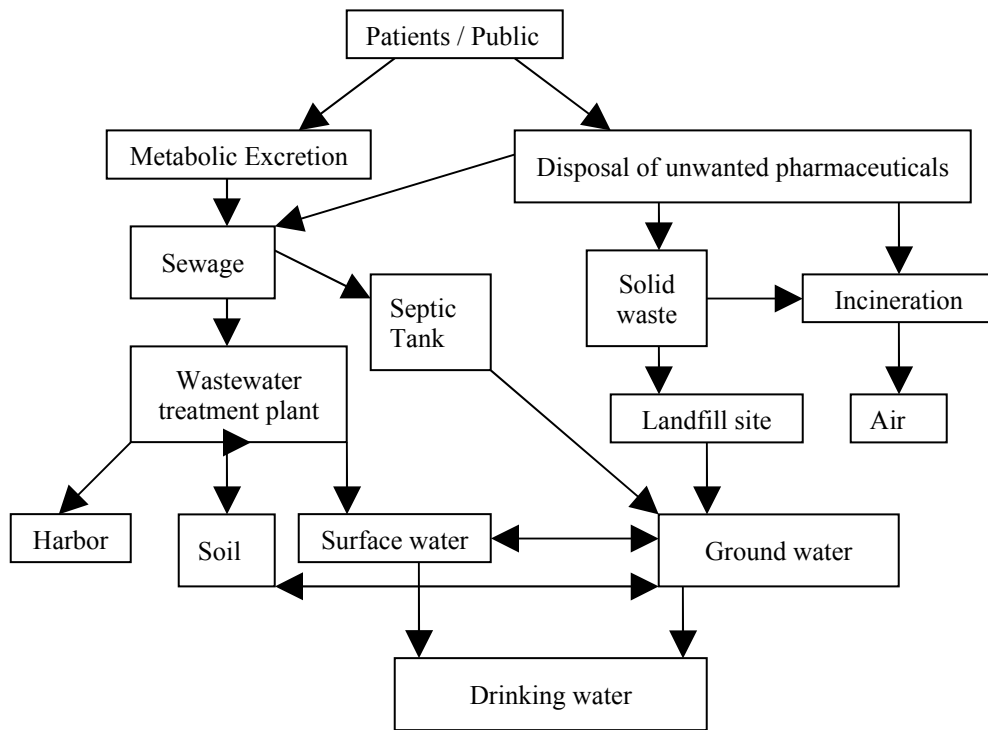


Figure 1: Possible routes of exposure to environment from medications.¹³

1.2. Human Excretion vs. Drain Disposal

Many pharmaceuticals are biotransformed once they enter the body. Excretion rates of active pharmaceuticals in humans can vary anywhere from 0 to 100% of the active compounds. Some compounds are almost completely metabolized before they are excreted, while others are only moderately or poorly metabolized and others yet again, such as contrast media, are excreted completely intact. The individual's diet, age, gender, metabolism, and various additional factors may play a role in the amount of metabolites produced. These metabolites may also be active compounds in and of themselves.

It is nearly impossible to determine the general ratio of pharmaceutical inputs from human excretion vs. the direct flushing of expired medication. This calculation is complicated by the vast number of active pharmaceutical compounds present, possible by-products produced through metabolism and waste water treatments, potential synergistic interactions, and incomplete drug disposal method data.

Table 1 attempts to illustrate the complexity of this issue by displaying the average human excretion rates of the top drugs prescribed in 2005. Each pharmaceutical is different, particularly in terms of how they behave in the human body. Virtually every drug has a different metabolic process, excretion rate, and cascade of bio-active metabolites that can complicate the picture. The list in Table 1 is driven by market share and does not take into account OTC drugs which may be sold in significant amounts.

Many pharmaceuticals, even some on this list have the same active ingredient(s) and their contributions are combined in the waste stream. It is then difficult to distinguish the individual contributions from each medication to determine which compounds have the greatest impact.

Table 1: Human excretion rates of top drugs of 2005 by number of prescriptions dispensed.¹⁴

R a n k	Drug Name	Active ingredients	Primary Use	% Parent compound excreted
1	Paxil®	Paroxetine hydrochloride	Antidepressant	< 3%
2	Lexapro®	Escitalopram oxalate	Antidepressant	8%
3	Hydrocodone	Hydrocodone, acetaminophen	Narcotic Analgesic	Very small amount
4	Xanax®	Alprazolam	Anxiety disorders	No data available
5	Ultram®	Tramadol	Analgesic	30%
6	Vicodin®	Hydrocodone, acetaminophen	Opioid Analgesic	Very small amount
7	Lyrica®	Pregabalin	Anti-seizure	90%
8	Oxycodone	Oxycodone hydrochloride	Opioid Analgesic	19%
9	Prinivil®	Lisinopril	Hypertension treatment	75%
10	Cymbalta®	Duloxetine hydrochloride	Antidepressant	< 1%
11	Lipitor®	Atorvastatin calcium	Cholesterol	< 2%
12	Percocet®	Oxycodone, acetaminophen	Opioid Analgesic	8-12%
13	Zoloft®	Sertraline hydrochloride	Antidepressant	14%
14	Metformin	Metformin hydrochloride	Type 2 diabetes	90%
15	Effexor	Venlafaxine hydrochloride	Antidepressant	34%

1.3. Occurrence and Distribution

Pharmaceuticals in the environment, initially hormones, first came into view in the 1970's.¹⁵ Since then scientists seem to be finding pharmaceutical compounds nearly wherever and whenever they take a close enough look. It was not until recently that researchers developed methodologies to detect these chemicals present at very low concentrations, well below therapeutic doses. The ubiquity of active pharmaceutical compounds, and the fact they are constantly and increasingly introduced to the environment as pollutants are significant to their occurrence and distribution.

The nationwide USGS study published in 2002 found the most frequently detected compounds in surface waters were “coprostanol (fecal steroid), cholesterol (plant and animal steroid), N,N-diethyltoluamide (insect repellent), caffeine (stimulant), triclosan (antimicrobial disinfectant), tri(2-chloroethyl)phosphate (fire retardant), and 4-nonylphenol (nonionic detergent metabolite).”¹⁶ Seven¹⁷ of the 139 total sites sampled in this study were in Massachusetts and of the ten most frequently detected compounds six were measured at concentrations below the national average at these sites (see Table 2 below).

The selection of sampling sites was biased towards streams susceptible to contamination, as in dense urban areas. The high overall frequency of detection for organic wastewater contaminants, in over 80% of the streams studied was likely influenced by the design of this study which focused on susceptible streams. Table 2 displays the concentrations of the most abundant contaminants as a national average compared to the streams sampled in Massachusetts. This list gives some insight into

what is likely to be detectable in the MWRA system, not necessarily what is present or even biologically active. Simply because you can test for something does not make it relevant and if a compound was not detected it does not mean it is not present or significant.

Table 2. Compound Concentration Comparison (Original data from USGS study)

Compound Name	Primary Use	Max (µg/L)	Median (µg/L)	MA Rivers max (µg/L)¹⁸	MA Rivers median (µg/L)
Coprostanol	Steroid	150 ¹⁹	0.088	4.09 (6)	0.19
Cholesterol	Steroid	60 ⁴	0.83	5.22 (4)	1.03
N,N-diethyltoluamide	Insect repellent	1.1	0.06	0.1 (4)	0.07
Caffeine	Stimulant	5.7	0.1	1.6 (6)	0.13
Triclosan	Antimicrobial disinfectant	2.3	0.14	0.16 (4)	0.09
tri(2-chloroethyl) phosphate	Fire retardant	0.54	0.1	0.07 (4)	0.05
4-nonylphenol ²⁰	Detergent metabolite	40	0.8	1 ²¹ (7)	0.5
Ibuprofen	Anti-inflammatory	1.0	0.2	0.45 (4)	0.018
Acetaminophen	Antipyretic	10	0.11	0.94 (6)	0.009
Trimethoprim	Antibiotic	0.30	0.013	0.014 (all)	0.014

1.4. Impacts and Effects

There is limited documentation regarding the direct cause and effect relationships of pharmaceuticals in the environment. The major concerns to date have been the promotion of pathogen resistance to antibiotics and disruption of endocrine systems, but many other active pharmaceutical compounds make their way into the water and have unknown consequences. To date, most of the research of pharmaceuticals as pollutants has been focused on aquatic environments.

The possible effects of these substances on aquatic life are currently not well understood. Potential adverse aquatic effects in field populations are usually predicted from laboratory acute and chronic toxicity data in species such as algae, crustaceans, and fish.²² These tests generally look at one organism's response to one particular chemical, but in the environment organisms are simultaneously exposed to a host of different chemicals over multiple generations making the extrapolation from the laboratory to the field exceedingly difficult.

Current research suggests endocrine disrupting chemicals (EDC), mainly synthetic steroids and other hormones, can lead to changes in sex ratios in fish and other aquatic organisms, "feminization" of male fish, production of vitellogenin (an egg yolk precursor protein) by male fish, and other changes that may affect reproduction or overall health.^{23,24,25} Concentrations at which these effects were observed were lower than concentrations detected in some surface waters sampled by the USGS.²⁶ Aquatic environments are a major concern because organisms in this environment are subject to continual low-dose exposure.²⁷

With respect to pathogen resistance, the World Health Organization (WHO) warns that increasing drug resistance could significantly reduce our ability to cure illness and stop epidemics. Curable diseases, varying from sore throats to tuberculosis and malaria, may become incurable as our once-effective medicines become increasingly ineffective.²⁸ Possible antibiotic resistance developing as a result of active pharmaceutical compounds present in wastewater will not be covered any further in this paper due to limited conclusive research and space constraints.

For humans, consumption of potable water that may contain trace amounts of various pharmaceuticals has been identified as one of the primary potential routes of exposure.²⁹ While some pharmaceuticals have been measured in drinking water,^{30,31} a number of scientists believe that pharmaceuticals at the low levels detected do not pose an appreciable risk to human health.³² Sensitive populations, particularly pregnant woman and children, are believed to be more susceptible to any negative effects, but studies have not shown any impacts on human health as of yet. The exposures found thus far are well below therapeutic levels for human consumption.

Because of the trace concentrations of these drugs, it would take a significant period of time, consuming approximately a gallon of water a day, to achieve a single therapeutic dose of most chemicals: consuming the equivalent of one tablet of Valium or Ritalin would take 3.5 years; a capsule of Benadryl 14.5 years; and one tablet of Children's Tylenol 58 years.³³ However, the potential effects from continuous low dose chronic exposure to active pharmaceutical compounds in humans are not clearly understood.

2.1. Boston Harbor and the Clean Water Act

Boston Harbor, known for its unique historical, cultural, and recreational significance, is the largest seaport in Massachusetts as well as being one of the principle ports on the east coast of the United States. The Harbor has come a long way since once being considered to be the dirtiest in the nation³⁴, where tons of raw sewage were dumped into the outgoing tide everyday. Though Metropolitan Boston's sewer system was one of the best in the country 100 years ago, decades of neglect and lack of technological advances brought it to the brink of disaster in the early 1980s.³⁵

Massive discharges of only partially treated, or often raw sewage was being deposited daily into Boston Harbor on the outgoing tide. However, when the water level rose during high tides the system created a cesspool effect in the harbor leaving its residues on the shoreline. This persistent discharge resulted in serious deterioration of the aesthetic, commercial, and recreational qualities of Boston Harbor.

Growing public awareness and impetus to reduce and regulate water pollution led to the enactment of the Clean Water Act (CWA) which originated from the expanded and reorganized Federal Water Pollution Control Act (FWPCA) of 1948. The CWA remains the principal law governing pollution of the nation's surface waters. The purpose of the CWA, as amended, is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251.

Three separate lawsuits³⁶ filed in the early 1980s against the Metropolitan District Commission (MDC) for violation of the CWA began the cleanup initiative. The MDC was providing wholesale water and sewer services to 60 eastern Massachusetts

communities.³⁷ They treated 350 million gallons per day of wastewater and 50 tons of dry sludge all of which was dumped into Boston Harbor.³⁸

In 1984, Governor Michael Dukakis proposed a bill that would form a new, independent water and sewer authority in Massachusetts, named the Massachusetts Water Resource Authority (MWRA). The MWRA is a semiautonomous public authority established by an act of the Legislature in 1984 designated to assume responsibility for the MDC's sewage department, and thereby also assuming liability as the main defendant in the legal case³⁹. Redevelopment of wastewater treatment systems for Boston Harbor and surrounding areas began in 1985 by the MWRA.

The litigation forced a fledgling organization, the MWRA, into the construction of a new primary and secondary wastewater treatment center at Deer Island, a facility at Fore River Shipyard in Quincy to process sewage sludge, a tunnel from Nut Island to Deer Island, a 9.5 mile outfall tunnel to discharge treated effluent offshore in Massachusetts Bay, and a Combined Sewer Overflow Program. Federal District Judge A. David Mazzone presided over the first 20 years of litigation to make the harbor cleanup one of the largest public works projects ever undertaken in New England.

The Boston Harbor cleanup was the largest court-ordered compliance action in the history of the CWA. The project emerged from a unique set of historical, legal, economic, and political circumstances to become a success. The successful Boston Harbor cleanup was completed under budget and was essentially completed on schedule, but even today the harbor faces certain pollution issues.

The CWA was enacted to eliminate contamination of our Nation's surface and groundwater's', but PPCPs could be slipping through the cracks since most are not currently regulated as pollutants through the CWA.

2.2. Safe Drinking Water Act

Regulated pollutants comprise a small subset of the wide range of chemical stressors to which organisms can be exposed to on a continual basis. In the United States, regulation of contaminants in drinking water began in 1962, with the Public Health Service Standards. These regulations included several compounds now known to be endocrine disruptors, such as arsenic, cadmium, and some phenols.

Presently there are no PPCPs on the current Contaminant Candidate List⁴⁰ (CCL) as published in the SDWA originally passed by Congress in 1974 and amended in 1986 and 1996, leaving them unregulated in surface or drinking waters.⁴¹ The SDWA is designed to protect public health by regulating the nation's public drinking water supply and it requires the EPA to set maximum levels for contaminants in water delivered to users of public water systems.

To be regulated under the SDWA the EPA must find that a chemical: may have an effect on the health of persons, and that there is a likelihood of its occurrence in drinking water at levels of public health concern, and that there must be a meaningful opportunity for public health risk reduction through regulation.⁴² A program is in place within the EPA to consider unregulated contaminants called the Unregulated

Contaminant Monitoring Rule (UCMR) which collects data on a list of substances to decide if they need to be regulated.

Regulation of pharmaceuticals through the SDWA is not likely in the near future because of the largely unknown long-term health effects on humans of trace amounts that remain well below therapeutic doses. This does not take into account the cumulative effect of multiple drugs of similar type, each of which may be found at very low concentrations in the environment. The SWDA requires the use of best publicly available, peer reviewed science on which to base their decisions and the research is not presently available.

3. Disposal of Unwanted Pharmaceuticals

Consumer pharmaceutical wastes are created from prescription drugs for a variety of reasons; a change in prescription, patient's health improves before finishing treatment, patient death, and patient non-compliance. OTC medicines are often sold in bulk and may contain more than is needed before the expiration date or the consumer may switch brands or prescriptions. Many of these expired or unwanted medications are disposed of in the trash or down the drain.

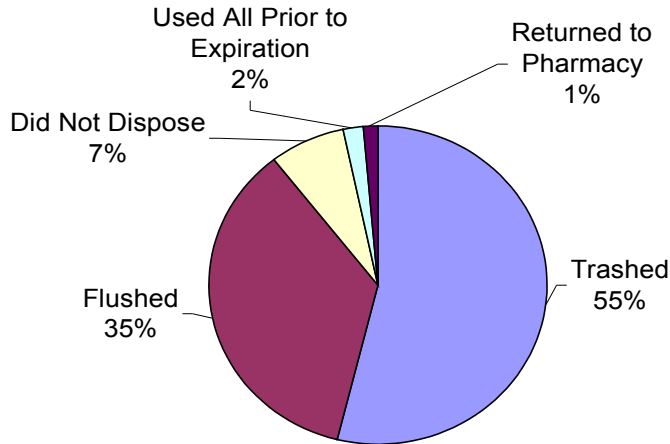
With few exceptions, countries do not have clear and consistent guidelines on how to properly dispose of unwanted pharmaceuticals, especially when it comes to the general public. In February 2007, the White House Office of National Drug Control Policy released the Federal regulations on the Proper Disposal of Prescription Drugs.⁴³ These general recommendations suggest unused pharmaceuticals be mixed with coffee

grounds or kitty litter, placed in an impermeable bag, and thrown out in the trash. They also recommend certain drugs be flushed down the toilet.⁴⁴ Coming in last on their list, they suggest taking unused medications to a community pharmaceutical take-back program.

Incineration is now regarded as the best disposal option for expired or unwanted medications, but it is not a commonly available option for the general public. A 1996 report⁴⁵ on how expired medications are being disposed of found that 1.4% of residents returned medications to a pharmacy, 54% disposed of medications in the garbage, 35.4% flushed medications down the toilet or sink, 7.2% did not dispose of medications, and 2% related they used all medication before expiration (See Figure 2 below).

Studies have reported that approximately one third of the total volume of pharmaceuticals sold in Germany and about 25% of that sold in Austria are disposed of with household waste or down the drain.⁴⁶ This significant contribution from private individuals turns the focus from industry to the activities, actions, and behavior of consumers on their surrounding environment. Some consider flushing unwanted medications down the toilet preferable to throwing medications in the trash where children or illicit drug users might get a hold of them, but flushing in particular may be more closely associated with causing environmental damage. By recommending the medications be crushed, combined with another substance, and placed in the trash reduces the poisoning risk but it has the potential to enter the water through land fill leaching. Even pharmaceuticals captured in leachate at lined landfills are typically transported to wastewater treatment plants, where some pass through untreated.

Figure 2: Household Expired Medication Disposal Methods



3.1. Prescription Drug Abuse and Poisoning

Prescription and OTC drugs can be safe and helpful to people when used in the right way, but many can also be abused and remain a serious public health concern. Medications account for the most common poison exposure category in the United States. They can cause addiction, increased blood pressure and heart rate, seizures, organ damage, and even death. The massive number of medications available presents a substantial accidental poisoning risk if they are not properly stored or disposed. Unsecured disposal to the garbage or using improper facilities increases the risk of drug abuse or poisoning.

The Massachusetts Department of Public Health is part of a Prescription Drug Monitoring Program for the prescribing and dispensing of Schedule II drugs to reduce

substance abuse and raise general awareness of the issue. The goals of the program are manifold, spanning education, abuse prevention, and law enforcement support. It used to be that rebellious children raided parents' liquor cabinets, now they are raiding parents' medicine cabinets for drugs.

3.2. Hospital Survey Summary

In hospitals and nursing homes, pharmaceutical waste is generally discarded down the drain or land filled, except chemotherapy agents, which are often sent to a regulated medical waste incinerator. Pharmacies and drug providers usually send unused or expired pharmaceuticals back to the manufacturer, in other cases they use a reverse distribution company which disposes of the products that are non-returnable.

A confidential telephone survey was conducted over the course of four days in June 2007 (June 6, 7, 11, 12). The purpose of the survey was to attempt to determine how expired or unwanted medications were disposed of in the MWRA sewer system by hospitals and nursing homes, to see what if anything was going into the wastewater. A copy of the survey is provided in the appendix.

During the survey 10 nursing homes and 62 hospitals that lie within the MWRA service area were contacted, 61% responded. At most of the facilities the respondent was the environmental facilities manager, but at some of the sites the nursing staff answered the survey. A detailed message was left if the contact person was out of the office. Most of the interviews lasted 5-10 minutes though some went longer. It should be noted that there were discrepancies between answers given by the environmental manager and the nursing staff even if both were contacted at the same hospital. The nurses that were

working the floor were more likely to say that non-RCRA regulated pharmaceuticals are disposed of down the drain.

A summary of the non-RCRA regulated expired or unwanted pharmaceutical disposal protocols for the 44 respondents (4 nursing homes and 40 hospitals) is provided in Table 3. (RCRA waste is discussed in the regulatory challenges section of this paper.) The unknown portion is comprised of managers that were uncertain of disposal methods that vary from the hospital floor to the pharmacy and protocols that were unclear or not frequently followed.

The survey identified that all chemotherapy and other RCRA regulated wastes were being disposed primarily through hazardous waste vendors, although some went to biohazard waste containers for incineration. A few hospitals sent non-chemotherapy wastes to reverse distributors or DEA-licensed vendors for distribution. Otherwise, most drug wastes went into the sewer system, garbage and biohazard waste containers. The hospitals and nursing homes surveyed within the greater Boston area had about as many different combinations of disposal as the number of drugs themselves.

Table 3: Hospital and Nursing Home within the MWRA service area survey summary
(Source: Author’s survey)

General Disposal Method of non-RCRA regulated pharmaceuticals	Percent of Hospitals or Nursing Home that responded accordingly
Complete hazardous waste disposal of all (no drain)	11%
Reverse-distribution or trash for all (no drain)	7%
Only controlled substances down drain, non-controlled in trash	48%
All pharmaceutical wastes down drain	14%
Unknown/Undefined protocol	20%

Non-regulated liquids and DEA controlled substances were the most common substances being disposed of down the drain. Lacking sufficient monetary resources, understanding of proper disposal options, and (or) time many institutions dispose of unused or expired medications down the drain. Besides, many of them identified the disposal of pharmaceuticals down the drain as the best way to comply with DEA regulations for controlled substances.

According to the CWA’s General Pretreatment Regulations, drain disposal of 15kg (33lbs) or more of U-listed and characteristic wastes and any amount of P-listed⁴⁷ waste in a calendar month requires notification to the local POTW, the state environmental protection agency, and the regional EPA waste management division director.⁴⁸ Many drugs of concern to the EPA and the Center for Disease Control and Prevention (CDC), including hormones, antibiotics, antidepressants, antihypertensives, and other potent drugs, are not caught by the current hazardous waste regulations because they are often present at extremely low doses.

The RCRA hazardous waste regulations have not been substantially updated since their inception in 1976 and as a result have not kept pace with drug development. As our understanding of the impact of waste pharmaceuticals on aquatic species, antibiotic resistance, and perhaps even directly on human health grows, it is possible we shall see even more drugs requiring management either as RCRA hazardous waste or through incineration as a best management policy rather than being disposed of down the drain or sent to a landfill.

Section 2 – Take Back Programs

4. Pharmaceutical Take Back Measures

Improper management of unwanted or expired residential pharmaceuticals poses hazards to both human health and the environment. Some medicines may enter the environment from human excretion, but others enter the environment from the direct disposal of unused or expired products through the waste water stream that could have been disposed of in a more responsible way.

Take back programs provide the legal framework and the logistic resources required to allow health care facilities, patients, and the general public to return unused or expired pharmaceuticals so that they can either be reused or disposed of safely in incineration facilities. Over two dozen different initiatives across the country are either studying the problem or implementing ways to solve it, including take back initiatives at pharmacies or other collection points.

One non-regulatory complication that should be noted is the fundamental conflict between the need to protect public safety and the need to minimize aquatic exposure. Most individuals in possession of unused or expired medications require a clear, convenient, and local take back program. If this is not a program is not in place the medications will likely end up in down the drain to reduce potential poisoning or prescription drug abuse regardless of the environmental consequences.

Although comprehensive data are not currently available, the quantity of pharmaceutical compounds potentially released into the environment through direct drain disposal is suspected to be small compared with that released into the environment from

excretion through patient use. Despite these disposal estimates, take back programs appear to be more cost effective method to reduce source inputs rather than further wastewater treatment to reduce the concentration in effluent.

4.1. Massachusetts Pharmaceutical Take Back Options

According to the Massachusetts Organization for Addiction Recovery (MOAR) website, Massachusetts ranks among the top 5% of states for drug and alcohol use among adults and youth. The abuse of prescription drugs now stands only second (as a group) behind marijuana on the list of commonly abused drugs.⁴⁹ This information prompted the formation of the Massachusetts OxyContin[®] and Other Drug Abuse Commission in 2004 by the Massachusetts' Legislature to investigate the effects of the abuse of prescription medications and illicit drugs on people of all ages in the Commonwealth. In 2006 the Massachusetts OxyContin[®] and Other Drug Abuse Commission recommended that a statewide disposal or take back program be implemented for unused and expired medications.

Massachusetts House listed docket #3855 for 2007 was written in response to concerns regarding the abuse of unused and expired medications and would establish a pilot program, implemented by the DPH, to develop a take back and disposal program. Similar legislation is also under review for the establishment and operation of a drug repository program in the state which would collect and redistribute drugs in their original, sealed, and tamper evident unit dose packaging.

There are currently 33 recycling facilities listed at Earth911.org (See appendix C) in Massachusetts that accept non-controlled pharmaceutical waste. Nine of these

facilities are located within the MWRA service area. Most of the centers offer free collection to town residents and the collection times are limited. Only one center, Clean Harbors Environmental Services, Inc., offers services to all Massachusetts residents, but they charge a fee per pound (\$2.50). It is not clear how the pharmaceuticals are disposed of once they are collected.

4.2. United States Take Back Programs (Not entirely inclusive)

A number of take back programs are analyzed in the following section. These particular programs were either chosen due to their wealth of available information or due to the innovative measures implemented. Each program is different because they serve specific local communities that have different needs, prescription base, supporting agencies, and available funding.

Many take back programs are community based and most are unable to collect controlled substances due to the limitations imposed by the Controlled Substances Act (CSA). One of the most innovative and least expensive programs comes out of La Crosse, Wisconsin where they deputized local waste management officials to handle controlled substances along with all other unwanted or expired pharmaceuticals during regular business hours.

The Product Stewardship Institute has recently taken on a project to compile a comprehensive list describing all of the take back initiatives conducted across the United States. This report was not available before the completion of this paper but more information about the Product Stewardship Institute, located in Boston, Massachusetts, can be found at their web site.⁵⁰

California

On May 31st, 2007 a bill passed through the Senate in California (SB 966, Simitian), requiring every retailer of pharmaceutical drugs to have in place a system for the acceptance and collection of pharmaceutical drugs for proper disposal. The bill now goes to the assembly.

Los Angeles County – Take back programs are in place at household hazardous waste facilities. They will not accept controlled substances due to restrictions by the CSA.

City of Palo Alto – Hosts take back programs at senior centers for all non-controlled substances.

Connecticut

The Connecticut Department of Environmental Protection is currently looking into the possibility of incineration as a means of disposal for collected pharmaceutical waste. They do not have a collection program in place, but they are research ways to implement one.

Iowa

In Iowa legislation was passed (Senate File 579) and signed by the Governor Chester Culver in May, 2007. The Act directs the state to spend \$225,000 on a one year pilot project to collect pharmaceuticals through a take back programs across the state for

disposal by incineration. This bill was enacted to develop pharmaceutical disposal techniques that exclude disposal in a landfill or to a wastewater treatment facility.

Indiana

Collection sites are made available once a year through a cooperative effort of local agencies and Walgreens. Controlled medications are currently accepted year-round at a number of local police stations.

Maine⁵¹

The State of Maine is the first state in the United State to pass legislation for the management of unused or expired pharmaceuticals. In 2003, Maine passed Public Law 2003, Chapter 679 which created the Unused Pharmaceutical Disposal Program with the purpose to ensure the safe, effective, and proper disposal of unused or expired prescriptions. The program was initially delayed due to lack of funding.

The University of Maine Center on Aging, in cooperation with the Maine Benzodiazepine Study Group, was awarded \$150,000 from the Environmental Protection Agency (EPA) in April 2007. This grant will be used to implement and evaluate a mail-back plan to remove unused over-the-counter and prescription medications. The pilot program will also test the effectiveness of an educational campaign about hazards to life, health, and the environment presented by improper storage and disposal of unused medications.

Due to the rural nature of this particular region in Maine a mail back program was selected and they are hoping to make over six thousand mailers available to the public

through participating pharmacies in four counties, Aroostook, Penobscot, Kennebec, and Cumberland. It is estimated the pilot project will remove 1.5 tons of unwanted medications from circulation.

Missouri⁵²

Area Resources for Community and Human Services (ARCHS), a St. Louis based community partnership was awarded over \$150,000 from the EPA to have community grocery stores serve as the collection sites for unwanted medications over an 18 month period. The St. Louis College of Pharmacy will be involved in the collection and inventory of the unused or expired medication.

Northeast Recycling Council (NERC)

The NERC received an EPA grant in 2006 to develop and implement pilot collection programs for unwanted prescription drugs at three levels; retail-based, senior center, and household hazardous waste programs. The programs will be evaluated for solid waste diversion data, participant demographics, costs, lessons learned, and recommendations for change or replication.

Oregon⁵³

The Drug Take Back program in Oregon is still in the stake holder development phase. They have a series of options laid out and some potential funding available, but are waiting to see if California or Washington obtain an exemption from the DEA for a mail back program of controlled substances before moving forward. The Drug Take

Back program has chosen to avoid conducting community take back programs as they are costly to run, primarily with the cost of the pharmacists, and require round the clock law enforcement. Once a take back program is defined funding options and donations will be pursued.

SMARxT DISPOSAL

The U.S. Fish and Wildlife Service and the American Pharmacists Association are working cooperatively to build consumer awareness of the hazards posed by the improper disposal of unwanted or expired medications. The initiative will begin with a pilot program in selected U.S. markets in late 2007 and expanded in 2008 providing educational brochures, websites, and promotional events.

Washington – Clark County

The Clark County Public Works – Recycling and Solid Waste Program administers the program and addresses residents' needs to dispose of both controlled and uncontrolled pharmaceuticals. Residents can take their controlled substances to four different law enforcement locations throughout the area. Each location has a drop off container similar to a postal box. The controlled substances are sealed in a plastic bag and placed into a locker until the sheriff's property officers pick them up and transport them to an incinerator for witnessed disposal. Currently the sheriff does not charge for the disposal costs. Information about funding was not available.

Residents have the option of dropping off non-controlled pharmaceuticals to one of 25 participating pharmacies⁵⁴, household hazardous waste collection events, or the

Central Transfer Station. The pharmacies either ship the pharmaceuticals via FedEx to the Household Hazardous Waste vendor (Philip Service Corp) or has the vendor pick it up. In addition to the general public, veterinarians, medical examiners, and school districts use the program.

Washington – PH:ARM

Washington's PH:ARM pilot program is a stakeholder venture with over 39 participants that include local governments, state agencies, non-profits, private industry, and many other interested parties. The goal of the project is to make disposal as easy as it is to buy the product, and to keep drugs out of the environment. They hope to make it convenient to collect a large volume of pharmaceuticals, and to keep it sustainable and inexpensive to run. The program will eventually be under the operational control of the Washington State Board of Pharmacy. Currently, the program only accepts non-controlled substances. The program team is asking the Drug Enforcement Administration to waive the requirement that only police officers can accept returned, controlled medications.

The program consists of a secured metal drop box located within participating pharmacies where consumers can dispose their non-controlled pharmaceuticals. The containers, which cost about \$600 each, are locked, tamper proof and require two keys for access. Inside a 5-gallon plastic pail is visible through a window. When full, the pail is removed, sealed, and shipped back to a pharmaceutical wholesaler's warehouse. From the warehouse, a vendor ships the medication to an incinerator. A written chain of control documents the drugs movements and provides accountability.

The proposed fully implemented program would consist of 1,301 pharmacies, 900 nursing homes, and 1,361 small animal veterinary clinics; all of which would take in an estimated 91,000 pounds of unwanted drugs annually. Once installed, the estimated cost of the full program is about \$400,000 annually, or \$4.40 per pound of unwanted drugs. The pilot PH:ARM program, slated to run 2006 through 2008, is funded with the support of the Russell Family Foundation, the Public Information and Education fund of the Puget Sound Action Team, Snohomish County Solid Waste Management Division, Seattle Public Utilities, Group Health Cooperative, and the Bartell Drug company. Proposed financing for a state-wide system is expected to come from a stewardship model with financing from pharmaceutical manufacturers.

Wisconsin – La Crosse⁵⁵

Starting June 1st, 2007 the La Crosse County Household Hazardous Waste Facility will accept unwanted or expired medications for disposal. The program will accept controlled and non-controlled medications during regular business hours year round. The medications will be dumped into a 55-gallon drum containing a solvent and ipecac, which dissolves the pills and provides a measure of security.

In Wisconsin pharmaceuticals are exempt from hazardous waste which allows this facility to dissolve the pills without falling under hazardous waste treatment regulations. The filled drums will then be taken to a DEA approved hazardous waste incinerator in St. Louis, the closest one to Wisconsin. During the first few days of the collection over fifty-five pounds of unwanted or expired medications were collected with little or no advertising of the new program. To be in compliance with the DEA, some members of

the household hazardous waste staff were deputized by the local sheriff to permit the collection and handling of controlled substances.

The program is free to all La Crosse County residents, but a charge of 3 dollars per pound will be enforced for all non-residents, pharmacies, and nursing homes. The funding for this program is provided through the La Crosse waste management budget and per pound charges to the local pharmacies and nursing homes. This program provides a permanent solution to a growing problem.

Wisconsin - Milwaukee

In 2006 Milwaukee-based Capital Returns Inc. created enough energy to power more than 220 homes for a year by incinerating 6.5 million pounds of pills and other pharmaceuticals sent by pharmacies and drug manufacturers around the country.⁵⁶ The drugs travel to an incineration plant in Indianapolis run by Covanta Energy, which sells the stream energy to a local utility.

The company is hoping that individual consumers, not just large corporations, will soon have the opportunity to participate in this program, converting unused and expired medication into energy. Federal approval for such a program may take years.

Additional programs throughout the state consisting of one day collections have been initiated in Brown and Milwaukee counties and the city of Marshfield, which have brought in up to 400 pounds of medications each time.

4.3. International Take Back Programs (Not entirely inclusive)

International take back programs are analyzed in the following section. These particular programs were examined because of the wealth of information available on the World Wide Web. Other international programs may be in place, but little or no information was available.

Canada – Ottawa Take it Back Program

The Take it Back Program has been offered in the City of Ottawa since 1997 for the proper disposal of certain household wastes including unused or expired medications. Pharmacies are encouraged to take back medication that they sell and to ensure they are recycled or disposed of properly. It is estimated over 3,950 kg of expired medication has been collected.⁵⁷ This program deals with many other types of household items that should not go into the garbage or down the drain.

Canada -- British Columbia Medications Return Program

The British Columbia Medications Return Program (MRP) was voluntarily established by the pharmaceutical industry in November of 1996. It allows consumers to return, at no charge, their residual medications to most pharmacies in the province. In the 2005 calendar year the MRP collected 39,710 pounds⁵⁸ of pharmaceutical waste. The program does not currently require separation of controlled pharmaceuticals from non-controlled. The program had 844 participating pharmacies located in 131 cities where residents returned unused and expired medications.

The pharmacist removes the medication from its packaging, except liquids, and the medication is stored in a container behind the counter. When the containers were filled the pharmacy calls the disposal vendor to arrange collection and transport to a secure warehouse. The containers are cataloged and held at the warehouse until a load is adequate for trucking to the disposal site, where it is incinerated.

During 2005 1,430 containers were collected; and an average of 1.7 containers from each pharmacy at a total annual cost of \$210,290.20 (US Dollar)⁵⁹ in 2005. The MRP is completely funded by the participating pharmaceutical brand owners through the Post-Consumer Pharmaceutical Stewardship Association.

Australia

In July 1998, the Commonwealth Department of Health and Family Services established and funded a program known as the Return Unwanted Medicines (RUM) Project which established a system for the collection and destruction of unwanted and expired medications. Local Pharmacies collect the pharmaceuticals in certain approved, lined, and sealed containers that are visible but out of reach of the public. Pharmacists are required to record the substances as they are returned and are not paid for their services.

A wholesaler serving the pharmacy collects the full containers to be quarantined and palletized before collection by an appointed waste disposal company who incinerates them. The RUM Project is funded by the Australian government at the cost of about \$737,000 per year. They are working on the concept of “Extended Producer Responsibility”. 5000 pharmacies participated and collected 501,000 pounds in 2005.

European Union

In the European Union over 11 nations have initiated take back programs. Local pharmacies will accept unwanted pharmaceuticals. The funding is split between the pharmaceutical industry and municipalities.

Sweden

The Stockholm County Council promotes medications that are not harmful to the environment and works to influence the pharmaceutical industry to take into account environmental issues in the long-term. One aspect of this work is the assessment and classification of pharmaceuticals according to their impact on the environment. The Swedish Association of the Pharmaceutical Industry conducted an environmental risk assessment, beginning in 2005 to this end. Over the next five years all medications marketed in Sweden will have been assessed for environmental risk.⁶⁰

Consumers are encouraged to take environmental impact into account when comparing medications that are equally safe and suitable for the purpose. They are to return unused medications to the pharmacy. Physicians are asked to review and regularly assess the patient's total consumption of medication in order to reduce waste. They are trying to pass new legislation to improve the movement of medicinal products for collection.

4.4. Reverse Distribution

Drug manufacturers, in an effort to encourage pharmacies or medical centers to purchase their new medications, may offer to buy back certain drugs the pharmacy or medical center is not able to sell or use. The returns industry (or reverse distribution) was created to facilitate the return of unwanted or expired medications to the manufacturer for credit. The unwanted or expired medication remains a product until the decision is made to dispose of it, therefore the pharmacy or medical distributor can potentially return them and receive credit for them without the product being considered hazardous waste.⁶¹ Licensed reverse distributors are permitted by the DEA to handle and dispose of controlled pharmaceuticals to be sure that all controlled substances are accounted for from their creation until their consumption or destruction.

The general public does not traditionally have access to a reverse distributor for the disposal of their unwanted or expired medications and many of the services are too expensive for smaller facilities. A reverse distribution scheme for a pharmaceutical take back program executed at a local pharmacy appears ideal, but pharmacists are unable to accept controlled substances for return and are often unwilling to bother with setting up a non-controlled pharmaceutical return program due to high costs.

5. Regulatory Challenges to the Implementation of a Take Back Program

There are a number of regulatory challenges to the implementation of a take back program; the main issue is the Controlled Substance Act (CSA). It may be possible to obtain DEA exemption/waiver to accept and possess controlled substances for the sole

purpose of safe destruction under the CSA. California and Washington are currently pursuing this option to expand their local pharmaceutical take back programs. Collection in British Columbia and other regions not limited by the CSA or similar legislation⁶² so it is difficult to compare take back programs. Other regulatory issues are discussed further in the following section.

5.1. Controlled Substances Act

Prescription medications in the United States fall under two categories; controlled and uncontrolled. Owing to their abuse potential, controlled medications are regulated by the U.S. Drug Enforcement Agency (DEA), which enforces the Controlled Substances Act (CSA)⁶³ to ensure they are used for their intended purposes. The CSA falls under Chapter 94C of Massachusetts General Laws and includes substances listed under Schedule I - V⁶⁴.

21 CFR § 1301.11(a), § 802(11), and § 841(a) prohibit the transfer of dispensed, controlled substances from the patient to any other entity registered with the DEA to handle or manage controlled substances. Controlled substances may constitute between 5% and 15% of the items collected in a take back program. Common controlled substances that are prescribed include⁶⁵: Xanax®, OxyContin®, Demerol, Ritalin, Abien, Valium®, and Vicodin®.

The goal of the CSA is to ensure there is a closed distribution system so a controlled substance is at all times under legal control of a person registered, or specifically exempted⁶⁶ by the DEA, until it reaches the ultimate user or until it is destroyed. The regulations require law enforcement officers to take possession of any

controlled substances collected and to maintain possession of them at all times, including witnessing their destruction. The DEA regulations do not allow a law enforcement officer to transfer custody of collected household controlled substances to a waste management contractor, even if the contractor is DEA registered for managing controlled substances that have not been dispensed to patients. Therefore, once a prescription is filled, only the person to whom it was prescribed can legally be in possession of the drug. Non-controlled substances are essentially all those not listed in Title 21.

5.2. Resource Conservation and Recovery Act⁶⁷

Resource Conservation and Recovery Act (RCRA) was enacted in 1976 to regulate the transportation, treatment, and disposal of hazardous waste. With the exception of hospitals there are few RCRA barriers to a pharmaceutical take back program. Some pharmaceutical wastes are classified as hazardous wastes, others are medical waste, and still others are non-hazardous wastes. Which category a discarded pharmaceutical falls into depends on its chemical, physical, and toxicological properties and who generates the waste.

Pharmaceuticals collected in local take back programs would be considered “household waste” which is exempt⁶⁸ under the RCRA as ownership of the pharmaceutical would remain with the consumer. Businesses that generate more than 100kg per month of RCRA regulated hazardous waste must manage it as hazardous waste. Therefore the collection site should not take official possession of the pharmaceuticals, but only provide collection points for disposal. The same applies for

long term care facilities, as they are not in official possession of their resident's pharmaceuticals.

5.3. Mailing of Controlled Substances

According to the United States Postal Service (USPS) Domestic Mail Manual, controlled substances may be mailed only if the distribution of the controlled substances is lawful under the federal CSA⁶⁹. The CSA does not prohibit the lawful owner of a prescription medication from mailing them to a law enforcement agency for destruction, and 21 CFR Sec 1307.21 allows any person in possession of controlled substances to transfer the drug to a person authorized to possess the drug, such as law enforcement. The USPS and CSA regulations manage the way controlled substances can be packaged and mailed. The controlled substances must be mailed in the original container, with the label intact, in a secure envelope or packaging that does not indicate the parcel contains controlled substances.

5.4. Health Insurance Portability and Accountability Act (HIPAA)

The HIPAA administered by the U.S. Department of Health and Human Services (DHHS) sets national standards to protect the privacy of personal health information. These standards require that prescription drugs labels be managed to prevent release of personal medical information. The primary requirements are to protect personal information so that it cannot be viewed by others, and to ensure that labels will be destroyed prior to or during prescription drug containers disposal. The HIPAA is mainly

directed towards medical care providers, such as pharmacies, but it also includes entities that collect waste from pharmacies if they are defined as business associates and may include organizations conducting take back programs.

Section 3 – Waste and Drinking Water Treatment

6. Waste and Drinking Water Treatment of Pharmaceuticals

Pharmaceuticals primarily enter wastewater treatment plants from households through excretion or improper disposal, but also through inputs from hospitals and industry sewers. Existing wastewater treatment processes are optimized to reduce human waste which is primarily biological in origin, not pharmaceutical waste. Currently the major pollutants of concern in domestic waste solids are nitrates, phosphates, dissolved organic carbon, and pathogens. Treatment facilities do not traditionally monitor or measure organic microcontaminants such as pharmaceutical residues.

Influent and effluent waters can be tested for active pharmaceutical compounds, but there are many complications. It has only been in the past few years that continually improving chemical analysis methodologies have lowered the limits of detection to allow researchers to identify these compounds and their metabolites at very low levels, particularly in a mixed waste stream matrix. Consequently, extensive extraction, cleanup, and sophisticated instrumentation are usually required to analyze these complex compounds and mixtures. Because of these advanced methodologies required, samples can only be sent to a limited set of laboratories and can often be very expensive to process.

Due to the complexity of the tests and the low concentrations present, not detecting active pharmaceutical compounds in the wastewater effluent does not necessarily mean that the water is clean and in these precise tests you only find what you are looking for. With the vast array of possible chemicals that could be present and

possible interfering compounds, narrowing the range of what is to be tested for is challenging. The overall understanding of pharmaceutical removal during treatment is limited because “the analyses for these compounds are rare, and when detected, they are present at fluctuating concentrations near analytical method detection limits.”⁷⁰ Most of our knowledge about the removal of these compounds is derived from the laboratory.

Wastewater discharged to sewage treatment plants is subject to various levels of treatment depending on the setup of the facility, before being discharged to receiving waters. Pharmaceutical compounds in wastewater display a broad range of removal efficiencies by waste and water treatment technologies⁷¹. Some pharmaceuticals are not degraded completely and travel through water treatment facilities with only minor reductions in concentrations, while other are transformed into new compounds and still other compounds may be completely degraded in the treatment process.

Other factors, besides biological treatment, affecting removal of substances from the waste stream include weather related incidents such as wet-weather overflow or the opposite, low inflow during dry conditions, which leads to higher concentrations due to a low volume of water. As a result, some portions can be directly released into the environment via wastewater effluent due to vary levels of treatment and may have adverse ecotoxicological effects.

6.1. MWRA Current Waste and Drinking Water Treatment

Around 215 million gallons of drinking water are supplied and around 350 million gallons of sewage are treated every day by the MWRA, serving 61 communities

collectively.⁷² This staggering statistic helps to keep in mind the volume of water that is treated daily by MWRA facilities.

Wastewater Treatment

The MWRA provides primary and secondary treatment for most of the wastewater in the greater Boston area. Initially the sewage from 43 metropolitan Boston communities, rainy-weather street runoff from certain communities, and infiltration from below ground leaks in pipes is transported to several headworks facilities where large objects, such as logs and bricks, are screened out.⁷³ Then any mud and sand are allowed to settle out in a grit chamber. From there the sewage flows to primary settling tanks where up to 60% of the solids, but very few toxic chemicals, in the waste stream settle out as a mixture of sludge and water.⁷⁴

Oxygen and activated sludge is first added in the secondary treatment phase to speed up the growth of micro-organisms which consume the wastes and then settle out. During this process around 80-90% of human waste and other solids have been removed, along with a significant portion of toxic chemicals. Before the treated wastewater is discharged into Massachusetts Bay through a 9.5 mile outfall tunnel it is treated with chlorine as a disinfectant, and then dechlorinated.

The residual sludge left over from primary and secondary treatment is processed further in large egg-shaped sludge digesters. In the digesters the sludge is mixed and heated to reduce its volume and kill disease-causing bacteria. The remainder is transported by barge to a palletizing plant in Quincy, Massachusetts where it is dewatered, heat-dried, and converted to a pellet fertilizer for use in agriculture, forestry,

and land reclamation.⁷⁵ It should be noted that some active pharmaceutical compounds may adhere to the sludge particles and could be left untreated during this process, this is discussed further in the wastewater treatment options section.

Active pharmaceutical compounds are not the only potential toxic compounds dealt with in the wastewater industry. Careless households and industries introduce toxic products down the drain including motor oil, pesticides, paints, solvents, and cleaners to dispose of them even when other options are available.

Drinking Water Treatment

The MWRA also provides drinking water to 50 communities serving about 2.2 million Massachusetts residents. This water is piped from well protected, naturally filled reservoirs, Quabbin Reservoir and the Wachusett Reservoir, in western Massachusetts after a significant storage time.

After collection, the reservoir water is first disinfected with ozone gas bubbles, and then chloramines are added to protect the water from potential contamination as it is carried through the pipelines. Later sodium bicarbonate is added to raise the pH to reduce the chances that metal particles from home plumbing could dissolve into tap water and finally fluoride is added for healthy teeth.⁷⁶

This reservoir water is considered to be of very high quality and passes all state and federal regulations, but has the minute possibility of active pharmaceutical compound contamination from the few home septic systems present within the remote, protected watershed. Considering the USGS study which found pharmaceutical compounds in

most of the higher risk surface waters they sampled it would not be an entirely unrealistic supposition.

6.2. Possible Waste and Drinking Water Treatment Options

Profound knowledge of the degradation, transport, and fate of pharmaceuticals is important to evaluate the elimination processes in wastewater treatment plants and to assess environmental and health risks. Furthermore, degradation of pharmaceuticals and their metabolites in the environment are related to the efficiency of wastewater and drinking water treatment technologies.

Wastewater Treatment

It is not entirely clear what happens to pharmaceuticals during sewage treatment. Some active pharmaceutical compounds may be sorbed to particulate matter and removed as sludge, chlorinated during the disinfection process or destroyed (oxidized) during the disinfection process. Others still may be degraded due to other wastewater treatment processes or may pass through the entire system to the environment unchanged. With the wide variety of treatment techniques, environmental variables, and array of active pharmaceutical compounds the final fate of these medications are difficult to predict or develop sampling techniques.

Table 4: Average Effectiveness of Various Treatment Methods for Pharmaceutical Removal.⁷⁷

Operation or Treatment Method	Average Effectiveness at Removing Pharmaceuticals
Ozonation / advanced oxidation process	Excellent – Good
Coagulation / flocculation	Poor
Chlorine / Chlorine dioxide	Poor
Activated Carbon (AC)	Excellent
Ultraviolet irradiation (UV)	Good
Softening / metal oxides	Poor
Nanofiltration and reverse osmosis	Excellent
Ultrafiltration and microfiltration	Good
powdered activated carbon	Good

POSEIDON was a European Union project formed to assess technologies for PPCP removal and their results were published in June 2005. In their study they determined that biological degradation and sorption onto sludge are the main mechanisms for PPCP removal during municipal wastewater treatment and some are significantly degraded during anaerobic sludge digestion. An important highlight of the ozonation was the effective oxidation/degradation of three major endocrine disruptors (17 α -ethinylestradiol, 17 β -estradiol and estrone), which probably lose most of their estrogenic potency.

Furthermore, it can be predicted that the potential for the formation of resistant bacterial strains is lowered significantly because antibiotics were no longer detected in the ozonated wastewater. “Acidic drugs such as diclofenac, bezafibrate, and ibuprofen that are removed easily during wastewater treatment are subject to additional removal during post treatment steps like polishing lagoon, gravel filter or infiltration pond. On the other hand, neutral substances such as diazepam and carbamazepine that hardly show any

removal during wastewater treatment remain stable during post treatment steps as well as in the groundwater.”⁷⁸

Research regarding the degradation of pharmaceuticals (and other specific chemicals) in wastewater treatment is just emerging. Thousands and thousands of unique compounds could potentially be present, including possible interactions and transformations. Promising wastewater treatment options for the degradation of active pharmaceutical compounds were only touched on in this section and the majority of the research is ongoing.

Drinking Water Treatment

The MWRA treats its drinking water with an advanced process using ozone gas bubbles and chloramines for disinfection and preservation. Ozonation has been shown to be very effective at removing active pharmaceutical compounds.⁷⁹ While the ozone or other drinking water treatment may be effective at removing the parent compound, the breakdown products should be considered.

Ozone is a pretty aggressive oxidizer and may take the parent compound to other breakdown products. It is possible these breakdown products could be more toxic than their original parent compounds. More research is needed to determine how these treatment processes affect the final breakdown product.

MWRA drinking water comes directly from a preserved reservoir, so these active pharmaceutical compounds may not even be present. In other communities the distance from “toilet to tap” is much, much smaller and these compounds may be present at higher concentrations.

6.3. Implications for Wastewater Treatment and Water Suppliers

Testing is necessary to know if and what particular active pharmaceutical compounds are present in any particular waste or drinking water region. However, testing for pharmaceuticals in waste and drinking water is expensive and challenging due to many variables; demographics, treatment and sampling technology, hydrology, season, and a vast array of compounds present with possible metabolites. There are thousands of distinct chemical entities with numerous, and increasing, therapeutic classes and end uses that have the potential for high biological activity.

Wastewater Issues

Wastewater treatment plants are designed to remove conventional pollutants such as suspended solids and easily biodegradable organic material, not other pollutants such as pharmaceuticals. Wastewater treatment plants then discharge into surface waters, making them the main source of pharmaceuticals to the environment. The negative environmental impacts connected to trace active pharmaceutical compounds in surface waters are being connected back to point source releases from wastewater treatment plants, regardless of how they first entered the waste stream.

Drinking Water Issues

The general public perception of risk is very important and cannot be overestimated in this case. Dr. Christian Daughton of the EPA wrote in a paper recently that comprehensive chemical analysis of water supplies “is costly, extraordinarily time-consuming, and viewed by risk managers as prompting yet additional onerous and largely unanswerable questions.”⁸⁰ But he maintains it should be done anyway because it is a useful way of maintaining public confidence in the water supply. Since it could be years before actual effects from pharmaceuticals in the environment are clearly known the precautionary approach should apply taking into account public perception.

Some people claim to feel worse or have negative side effects after taking or coming into contact with inert chemicals; the flip side of placebos. This phenomenon is often called the “nocebo” effect and is often defined as the real, adverse physiological reactions people sometimes develop when they learn they have been exposed to something, even if there is no evidence it may be harmful. In fact, the idea that there are unwanted chemicals in the water supply could provoke public anxiety, regardless of their real power to harm.

7. MWRA Influent and Effluent Wastewater Samples

The MWRA has initiated a preliminary sampling program to determine the potential presence, transport, and ultimate fate of active pharmaceutical compounds (and other selected chemicals) within their service area. This testing will help determine the scope of the problem by determining; how effective current treatment is with respect to

the degradation of pharmaceuticals, to see which compounds are present, and in what concentrations.

All municipal sewage, regardless of location, will contain trace amount of pharmaceuticals. The issue is not unique to any particular municipal area. Each geographic area will differ only with respect to the types, quantities, and relative abundance of individual pharmaceutical compounds. These remaining questions will hopefully be answered with thorough wastewater testing.

7.1. Methods

The MWRA laboratory conducted a limited amount of wastewater sampling at Deer Island Treatment Plant in Winthrop, Massachusetts.⁸¹ Two sets of samples were taken during low flow conditions; one set in August 2007 and the other in September 2007. Each set consists of an influent, primary effluent, secondary effluent, and final effluent sample for a minimum of 8 wastewater samples. Quality control samples consisted of one field blank per sample set and two matrix spike samples for the project performed on an MWRA sample.

Wastewater samples were sent to Montgomery Watson (MWH) Laboratory for analytical processing. The laboratory methods are USGS Method 2 and USGS Method 4. A list of the chemicals to be tested for is provided in Appendix D of this paper. The USGS study published in 2002 used five different methods; the MWRA has chosen two of these methods for analysis.

Section 4 – Results

8. Recommendations

When developing policy for future change there are issues that are unforeseen and those that are unforeseeable. Even though the impact of pharmaceuticals in the environment at trace levels has not been clearly determined, there are many pollution prevention measures that could be implemented in a precautionary way. These measures follow the hierarchy of: minimize/reduce, reuse/recycle, and finally proper disposal. Several potential approaches to this issue are possible: relying on government regulation, implementing proper disposal methods, rethinking and redesigning sewage treatment, and/or developing more environmentally friendly pharmaceuticals.

I believe best approach to reduce trace contamination of pharmaceuticals in the environment and the drinking water is to substantially reduce the quantities entering raw sewage at the source. Any measures at the source will facilitate the removal in the treatment process afterwards. Source measures include, but are not limited to; proper disposal of unwanted or expired medications, prescription control, ecologically friendly pharmaceuticals, product stewardship, and urine separation.

Initiating a local take back program, despite its regulatory challenges, appears to be the best way of reducing pharmaceutical impacts to the environment. A take back program would not only increase consumer awareness, but it would simplest approach to decrease direct inputs. These source measures should be undertaken in conjunction with research to better understand the various long-term impacts of trace pharmaceuticals as pollutants in the environment.

The old adage used to recommend “an apple a day” now our society is moving towards “a pill a day”. We ingest a regular dose of caffeine, ibuprofen for aches, daily multivitamins, antacids, birth control, and they are only a few on a whole list of regularly consumed supplements and medications.

8.1. Regulatory

Biological systems can suffer exposure to countless chemical stressors, only a small number of which are regulated. The pharmaceutical industry produces thousands of compounds each with a unique chemical make-up and purpose, but none are regulated because their present environmental concentrations fall far below the usual measurement limits. New regulations should take into account the possible negative effects stemming from chronic low dose exposure, where the concentrations are well below the average therapeutic levels.

As of April 2006, nearly 28 million organic and inorganic substances had been documented.⁸² This only includes the known universe of chemicals not the unimaginable universe of potential chemicals. Of these nearly 28 million known chemicals, nearly 10 million were commercially available, representing a 60% increase over the prior 3-year period.⁸³ Of these, fewer than a quarter of a million (240,000) were inventoried or regulated by numerous government bodies worldwide, representing less than 0.9% of the known universe of chemicals.⁸⁴ That leaves an immense amount of chemicals unregulated.

Regulations to monitor, in depth, the disposal of unwanted or unused pharmaceuticals on the industry level could be brought about through clarifying,

reconsidering, and expanding the current RCRA Hazardous Waste regulations. This could eliminate drain disposal of medications in local hospitals and nursing homes and encourage proper disposal. RCRA regulations monitor large and small waste generators, but changes to the CSA has more relevance for individual consumers looking for proper disposal methods.

The CSA stands in the way of developing a comprehensive community take back program that includes controlled substances. The DEA and other regulatory officials should consider allowing pharmacists to render controlled substances unusable simply by mixing them with rubbing alcohol or another solvent, thereby eliminating the legal problems with collecting controlled substances without an officer of the law present.

Eliminating permit requirement for collection would allow the collection of pharmaceuticals at locations without hazardous waste collection facilities permits. Implement product stewardship requirements. Cradle-to-Cradle management of potentially hazardous products like pharmaceuticals has been suggested.⁸⁵ There are many possible approaches to implementing a product stewardship management strategy for residential pharmaceuticals. For example, it might be possible to modify the reverse distribution system to accommodate management of residential pharmaceutical waste. Product stewardship approaches are relatively new in the United States and it is likely that substantial effort would be required to develop a plan that would be generally acceptable to most affected parties.

8.2. Individuals

As consumers the most important recommendation is to never flush unwanted or expired medications down a toilet or drain, especially if you use a septic system. First, find out if any pharmacies in your community will take back medications, or if a take back program exists in your community. If these are not options encourage your provider and/or community officials to implement such a program.

If no other disposal options exist, alter the medications in some way and place them in the trash. They should be sealed to prevent seepage, making sure all identifying information has been removed and that something should be added to the medication to make it unusable. Products similar to kitty litter, coffee grounds, or powdered spice should be added to liquid medications, glue or water to pills, or a small amount of disinfectant to any medication to make them unusable.

We need to be part of the change we seek. Margaret Mead once stated “Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it’s the only thing that ever has.” Individuals must work to educate themselves, family members, friends, and coworkers about this emerging environmental issue.

Ask your doctor for medications with low environmental impact or for low prescription amounts and refill options and commit to health prevention strategies to reduce your reliance on medications whenever possible.

Individual consumers, collectively, input the greatest amount of pharmaceuticals to the waste stream and need to be in command of source control. This can be done through prescription control, proper disposal of unwanted or expired medications, and convincing local regulatory officials that this is an issue of concern.

8.3. Pharmacists and Health Care Providers

It is important for facilities to educate consumers about the importance of proper disposal of pharmaceutical waste at a take-back site or event, and never down the toilet. This could be done by promoting product stewardship and implementing in-house take back programs to demonstrate awareness and community support. While collection of unwanted or expired medications at pharmacies will require certain regulatory and management issues, its convenience for consumers means it would probably be an effective waste pharmaceutical collection method.

Physicians should not prescribe more medications than can be used; if in doubt, repeating the prescription is preferable or prescribe starter packs and refill packs whenever available. All health care providers should review and regularly reassess the patient's total consumption of medication in order to reduce excess waste and duplication. A closer look should be taken to see if a non-pharmaceutical option is viable for the patient. This could be a challenging issue in regards to insurance companies' patient co-pay and rules that favor longer prescription periods.

It should be the goal of every institution to always take cost-effectiveness and environmental impact into account when comparing medications that are equally safe and suitable for the purpose. They need to initiate proactive efforts to eliminate pharmaceutical disposal into wastewater and promote waste minimization. Providers should follow Europe's lead listing pharmaceuticals by their environmental impacts and persistence. When medical efficacy, safety, and price are comparable the drug posing the lowest environmental risk should be prescribed.⁸⁶

8.4. Public Agencies

Coordinate with and support other organizations seeking to improve the disposal of pharmaceutical waste. Local public agencies should work together to establish a pilot program to work out the anticipated cost, the expected waste to be collected, and the regulatory and management issues prior to widespread initiation of a collection program. This would also work to obtain sufficient information to support legislative action that would simplify permitting requirements for a permanent program.

Human Health

Public agencies involved in developing policies concerning human health need to develop an outreach campaign and communicate a common, widely publicized, message to the public. While drugs are widely marketed, information available to consumers about the management of unwanted or expired pharmaceuticals is limited, disjointed, and often conflicting. Recommendations for sewer disposal of unwanted or expired pharmaceuticals remain common, despite the threat to water quality. The public's perception of risk is very important and work need to be done to educate the individual to ensure consistent cooperation.

It is important to involve the local media in any consumer awareness program. Most of the newspaper articles and media clips concerning the issue of trace pharmaceuticals in water have had more of an alarmist spin. A concerted effort should be made to circulate the current research effort, the possible solutions, and how individual consumers can help.

Environmental Protection

Environmental agencies need to work together to protect aquatic organisms from the known effects from pharmaceuticals as ecological pollutants. Direct cause and effect relationships have yet to be drawn from the public health perspective, but extensive research has been conducted documenting the environmental impacts. By focusing on the particular active pharmaceutical compounds that are present within a region work could progress to protect sensitive species.

Waste and Drinking Water Providers

Waste and drinking water treatment facilities should strive to understand environmental impacts of existing treatment technologies and work to advance new ones. Regular sampling should be implemented to monitor the occurrence and fate of active pharmaceutical compounds, with both influent and effluent. Sampling should be conducted periodically to examine trends, to contrast seasonal changes, and to monitor treatment capabilities. This research will be useful to understand the scope of the problem for a particular demographic and geographic area. It will also be useful to help weigh the public's perception of risk vs. the real hazard present.

Wastewater treatment facilities should also work with the public, hospitals, nursing homes, and industry to reduce the amount of pharmaceuticals entering the waste stream through direct disposal. They should also monitor the amount of pharmaceuticals and other potentially harmful compounds in treated biosolids that are used as fertilizer.

8.5. Research

More research is necessary to get a handle on this emerging issue. The paramount public concern should be more closely examined: Does the occurrence of trace levels of multiple pharmaceuticals in source waters pose risks to human health, especially for at-risk subpopulations?⁸⁷ This would include possible antibiotic resistance or endocrine disruption.

As mentioned in previous sections water treatment options should be researched, but this should be done on a national level. This reduction has led to programs, particularly in arid regions, such as the water re-use “toilet-to-tap” program, facilitating public acceptance of water recycling/reuse programs and research into its viability.

We need to develop technologies for source separation of wastes (via toilet re-engineering). Most pharmaceuticals are excreted through urine⁸⁸, so separation of wastes for alternative treatment could be a viable wastewater treatment method. This future advancement might be more applicable to large hospitals and nursing homes where patients have a disproportionately higher medication intake than the rest of the general population.

Researchers need to establish safe land uses for biosolids, which are thought to contain higher levels of pharmaceuticals and other chemical compounds. It is thought that active pharmaceutical compounds tend to be sorbed to particulate matter and disposed of sludge. This research should also determine if active pharmaceutical compounds are degraded by heat drying.

Finally, work should be done to develop a monitoring system for detecting pharmaceuticals as well as changes in status and trends of existing pollutants in wastewater. Some work has been done to use caffeine as an indicator of pharmaceutical presence in the water, but it is still under development. The challenges to this and similar research has been discussed in a previous section.

Conclusion

A discussion of pharmaceuticals (and personal care products) in the environment and their future implications is very complex, involving many different aspects of chemistry, toxicology, ecology, medical science, public policy and perception, and consumer behavior. Their exact environmental impact and effect is not clear at this time and it seems likely that the issue would not be resolved in the near future due to the fact that the science and technology required to fully assess this risk is still in the early stages of development.

However, if we follow the advice of the precautionary principle which implies that “when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically”. There are a number of proactive source reduction measures that could be taken to decrease the amount of active pharmaceutical compounds that are introduced to the aquatic environment, mainly due to the actions of the general public.

When developing policy for future change there are often issues that are unforeseeable, but then there those that were just unforeseen. We are already witnessing the ecological impacts from pharmaceuticals as pollutants in the environment. It is time for a policy change to eliminate or diminish these impacts.

It is difficult to allocate resources in the face of uncertainty. Low cost measures should be taken first and those would probably not include infrastructure investments at waste and drinking water facilities. Minimizing the disposal pathways through take back programs could be more effective and less costly than extensive wastewater treatment facility modifications or other remediation steps.

For most of us, we have been trained to dispose of unused or expired medications by flushing them down the drain. This practice evolved from our desire to keep potentially dangerous drugs out of the hands of others, especially children. However, recent research is showing that this may be the least environmentally friendly method of disposal. The best available disposal practice may vary depending on the county you live in or the wastewater agency that serves your region.

There are thousands of pharmaceuticals on the market and they each exert specific pharmacological effects that may lead to particular effects not readily explained by simple relationships. While toxicology experiments can measure the combined effects on individuals (mainly aquatic organisms), it is difficult to measure the extent of these effects on populations in the field.

We now understand that exposure from environmental sources at therapeutic doses is not the concern for public health. It is the chronic low dose cocktail of active pharmaceutical compounds that we are exposed to, especially for sensitive populations.

But the exposure to non-target organisms that suffer continual exposure could be significant.

Municipal wastewater has potentially been contaminated with pharmaceuticals since their implementation and subtle effects such as feminization of fish have already been found in the receiving waters of wastewater treatment plants. Due to the widespread occurrence of pharmaceuticals in rivers and groundwater, contamination of drinking water is known in some cases albeit at very low levels. The potential human health risks associated with minute levels of pharmaceuticals in water is still being determined and the general public's perception of this risk is sometimes more important than the risk itself.

More research is needed to increase our knowledge and understanding of the fate of drugs in surface waters, their products of degradation, the complexity issues brought about by possible chemical interactions, and the role of environmental monitoring. We must recognize the importance of communicating scientific data, which has a role in informing a broader audience of the environmental safety of medicines. This will require collaborations among industry, scientists, academia, regulators, physicians, and the public. The continuing development of new medications, the escalating prescription of drugs, and population increases will only serve to amplify the occurrence of pharmaceuticals in the environment.

Appendix A

Acronyms

ARCHS – Area Resources for Community and Human Services
CCL – Contaminant Candidate List
CDC – Center for Disease Control
CLF – Conservation Law Foundation
CFR – Code of Federal Regulations
CSA – Controlled Substances Act
CWA – Clean Water Act
DEA – United States Drug Enforcement Agency
DEP – Massachusetts Department of Environmental Protection
DHHS – Department of Health and Human Services
DPH – Massachusetts Department of Public Health
EDC – endocrine disrupting chemicals
EPA – United States Environmental Protection Agency
FDA – Food and Drug Administration
FWPCA – Federal Water Pollution Control Act
HIPAA – Health Insurance Portability and Accountability Act
MDC – Metropolitan District Commission
MWH – Montgomery Watson Laboratory
MOAR – Massachusetts Organization for Addiction Recovery
MRP – Medications Return Program
MSD – Metropolitan Sewerage District
MWRA – Massachusetts Water Resources Authority
NERC – Northeast Recycling Council
OTC – over the counter
POM – prescription-only medications
POTW – Public owned treatment works
PPB – parts per billion
PPCP - pharmaceuticals and personal care products
PPT – parts per trillion
RUM – Return Unwanted Medications program
RCRA - Resource Conservation and Recovery Act
SDWA – Safe Drinking Water Act
UCMR – Unregulated Contaminant Monitoring Rule
USGS – United States Geological Survey
USPS – United States Postal Service
WHO – World Health Organization

Appendix B

Hospital / Nursing Home Survey

- 1.) How does _____ currently dispose of any unwanted or expired medication?

If Take Back Program is in Place-

- 2.) When was this program initiated?
- 3.) Does this program apply to controlled and uncontrolled substances?
- 4.) What are the most common medicines disposed of? How many lbs on average are collected?
- 5.) What is the fate of the collected pharmaceuticals?
- 6.) How effective is the take back program?
- 7.) How is the program funded?

If No Take Back Program is in Place-

- 2.) Do you have a daily or weekly estimate of pharmaceutical waste?
- 3.) What are the most common medicines disposed of?
- 4.) In your opinion, would your hospital be interested in volunteering for a pharmaceutical take back program?
- 5.) What challenges would you anticipate in such a program?

Appendix C

Collection Sites in Massachusetts (As of 06-25-07 on Earth911.org)

Minuteman Household Hazardous Waste Facility Program Information

No Pharmaceuticals?
Arlinton, MA 02474
781-316-3108

Clean Harbors Environmental Services, Inc.

Each Saturday between 8 am to noon from April to October 31st.
1 Hill Avenue
Braintree, MA 02184
781-380-7100

Town of Stoneham Household Hazardous Waste Day Information

Stoneham, MA 02180
781-438-0760

Town of Weymouth HHW Collection Site

Monday to Friday 8am to 5pm
120 Winter Street
Weymouth, MA 02188
508-785-8318

Town of Reading HHW Collection Event

May 19, 2007
75 Newcrossing Road
Reading, MA 01867
781-942-9077

Wellesley Recycling & Disposal Facility HHW Drop-off Site

May 6th
169 Great Plain Avenue
Wellesley, MA 02482
781-235-7600

Town of Lynnfield Public Works HHW Program Information

Lynnfield, MA 01940
781-334-3143

Norwood HHW Program Information

Norwood, MA 02062
781-255-9988

Middleton Transfer Station HHW Program Information
Middleton, MA 01949
978-777-0407

City of Brockton HHW Program Information
Brockton, MA 02301
508-580-7135

Scituate HHW Program Information
280 The Driftway
Scituate, MA 02066
781-545-8725

Framingham HHW Program Information
No Pharmaceuticals?
Framingham, MA 01701
508-532-6005

Sudbury Transfer Station HHW Program Information
Tues, Thurs, and Sat 8-3pm
Sudbury, MA 01776
978-443-8891

Town of East Bridgewater HHW Program Information
Thatcher Street
East Bridgewater, MA 02333
508-378-1653

Town of Chelmsford HHW Collection Information
Saturday 9-1pm
50 Billerica Road
Chelmsford, MA 01824
978-250-5203

Kingston Transfer Station HHW Drop-off Site
Kingston, MA 02364
781-585-0510

BFI/Allied Waste
Late April
1080 Airport Road
Fall River, MA 02720
508-676-1091

Massachusetts Military Reservation HHW Program Information

Buzzards Bay, MA 02532
800-319-2783
Please call 508-759-0651 for additional information

Fairhaven Recycle Center HHW Program Information

5 Arsene Street
Fairhaven, MA 02719
508-979-4022

City of New Bedford HHW Collection Program Information

2x's a year
New Bedford, MA 02740
508-763-5924

Town of Dartmouth Transfer Station HHW Program Information

2x's year
South Dartmouth, MA 02748
508-763-5924

City of Sturbridge Recycling Center HHW Program Information

3rd Sat of each month 10-2pm
Breakneck Road
Sturbridge, MA 01566
508-347-2504

Upper Cape Cod HHW Collection Event

No Pharmaceuticals?
Sat 9-1pm
500 Old Barnstable Road
Mashpee, MA 02649
800-319-2783

Massachusetts Military Reservation HHW Program Information

Falmouth, MA 02540
800-319-2783
Please call 508-548-7611 extension 254 for additional information.

Monson's Board of Health HHW Program Information

Monson, MA 01057
413-267-4100

Chatham Transfer Station HHW Drop-off Site

97 Sam Ryder Road
Chatham, MA 02633
508-945-5155

Belchertown Department of Public Works HHW Program Information

No Pharmaceuticals?
290 Jackson Street
Belchertown, MA 01007
413-323-0415

Town of Wilbraham HHW Program Information

Wilbraham, MA 01095
413-596-2814

Town of Longmeadow HHW Program Information

Longmeadow, MA 01106
413-565-4153

Town of Greenfield Department of Public Works HHW Drop-off Site

Cumberland Road
Greenfield, MA 01301
413-772-1528

Town of Southampton HHW Drop-Off Site

Moosebrook Road
Southampton, MA 01073
413-527-3666

City of Westfield HHW Program Information

Westfield, MA 01085
413-572-6206

Town of Egremont Transfer Station HHW Program Information

171 Egremont Plain Road
South Egremont, MA 01258
413-528-0182

Appendix D

Montgomery Watson (MWH) LABS -- PPCP METHODS

Proposed Testing

USGS Method 4

2,6-di-tert-butylphenol 10 ng/L
4-Methylphenol 25 ng/L
4-Nonyl Phenol 25 ng/L
Alpha Chlordane 10 ng/L
Bisphenol A (BPA) 25 ng/L
Caffeine 25 ng/L
Carbaryl 50 ng/L
Chlorpyrifos 25 ng/L
DEET 25 ng/L
Diazinon 25 ng/L
Dieldrin 25 ng/L
Methyl Parathion 25 ng/L
Phenol 100 ng/L
TDCPP 25 ng/L
Triclosan 50 ng/L
Triphenylphosphate 25 ng/L
Tris (2-butoxyethyl) phosphate 100 ng/L
Tris (2-chloroethyl) phosphate 25 ng/L

USGS Method 2

Acetaminophen 1 ng/L ES +
Caffeine 1 ng/L ES +
Carbamazepine 1 ng/L ES +
Estradiol, 17B 1 ng/L ES +
Fluoxetine 1 ng/L ES +
Gemfibrozil 1 ng/L ES -
Ibuprofen 1 ng/L ES -
Iopromide 5 ng/L ES -
Progesterone 1 ng/L ES +
Sulfamethoxazole 1 ng/L ES +
Testosterone 1 ng/L ES +
Triclosan 5 ng/L ES -
Trimethoprim 1 ng/L ES +

NOTE: tris(1,3-dichloro-2-propyl) phosphate (TDCPP), is a flame retardant.

Not Offered

Amoxicillin	Methadone
Azithromycin	Morphine
Ciprofloxacin	Nonylphenol polyethoxylate
Cotinine	Octylphenol
Estrone	Octylphenol polyethoxylate acid
Estradiol, Ethinyl	Salicylic acid
Lipitor	

Endnotes:

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- ⁶ Daughton, C.G. and Ternes, T.A. 1999. Pharmaceutical and Personal Care Products in the Environment: Agents of Subtle Change. *Environmental Health Perspectives*, **107**, (6): 907 - 938 [available: <http://epa.gov/nerlesdl/chemistry/ppcp/images/errata.pdf>]
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- ⁸ Data calculated by Kaiser Foundation based on Vector One™: National from Verispan, L.L.C.: Special Data Request, 2005; U.S. Census Bureau, Annual Population Estimate.
- ⁹ Estimate from the U.S. Census Bureau 2006 population data set. [Available: www.census.gov]
- ¹⁰ Kaiser Family Foundation, Prescription Drug Trends, October 2004
- ¹¹ E.g. antibiotics, analgesics, anti-inflammatory drugs, antihistaminic agents, ect.
- ¹² Massachusetts Water Resource Authority general information [Available: <http://www.mwra.com/02org/html/whatis.htm>] (Last Visited June 28, 2007)
- ¹³ Gualtero, S. 2005. Pollution Prevention Measures for Unwanted Pharmaceuticals. Columbia University web site. [Available: www.seas.columbia.edu/earth/wtert/sofos/Gualtero_IETerm_.pdf] (Last Visited June 26, 2007)
- ¹⁴ Top Drug Prescription Sales for 2005 (latest year available) [Available: www.rxlist.com] (Last Visited June 12, 2007) Percent excreted obtain either from www.rxlist.com or taken from patient product inserts. The percent excreted most often equals percent found in urine though may include percent in feces, usually in less than 24 hours. All numbers are approximate.
- ¹⁵ Tabak, H.H. and Bunch, R.L. 1970. Steroid hormones as water pollutants. In: *Developments in Industrial Microbiology*, Washington, pp 367-376
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- ¹⁷ Site 1- Merrimack River below the Concord River, Site 2- Charles River above the Watertown Dam, Site 3- Laundry Brook at Watertown, Site 4- Faneuil Brook at Brighton, Site 5- Muddy River at Brookline, Site 6- Stony Brook at Boston, and Site 7- Charles River at Boston Science Museum.
- ¹⁸ River number corresponding to highest value is designated within parentheses.

- ¹⁹ Concentration estimated – value greater than highest point on calibration curve.
- ²⁰ Concentrations estimated – reference standard prepared from a technical mixture.
- ²¹ Estimated value
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- ³⁰ Stackelberg PE, Furlong ET, Meyer MT, Zaugg SD, Henderson AK, and Reissman DB. 2004. Persistence of Pharmaceutical Compounds and Other Organic Wastewater Contaminants in a Conventional Drinking-Water-Treatment Plant. *Science of the Total Environment*. **329**: 99 – 113.
- ³¹ Jones, O. A.; Lester, J. N.; Voulvoulis, N. 2005. Pharmaceuticals: A Threat To Drinking Water? *Trends Biotechnol.* **23**: 163 – 167.
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³⁸ Massachusetts Water Resource Authority, The State of Boston Harbor Report-03/04 [Available: <http://www.mwra.com/harbor/html/2002-09.htm>] (Last visited 4/25/07)

³⁹ The MDC was plagued with financial and operational problems that most agreed would bar it from effectively making improvements to the MSS necessary to clean up Boston Harbor, thus necessitating the creation of a new authority to oversee the cleanup and operate the MSS.

Boston Braces For Harbor Clean-up; Bonding clout gives new agency power to fund clean-up effort, ENGINEERING NEWS-RECORD, February 21, 1985.

⁴⁰ U.S. EPA Drinking Water Contaminant Candidate List and Regulatory Determinations. [Available: <http://www.epa.gov/safewater/ccl/index.html>] (Last Visited June 27, 2007)

⁴¹ No PPCPs are on the CCL to be considered for regulation over the next several years

⁴² U.S. EPA Safe Drinking Water Act – Understanding the Safe Drinking Water Act [Available: <http://www.epa.gov/safewater/sdwa/30th/factsheets/understand.html>] (Last Visited August 2, 2007)

⁴³ 4

White House Office of National Drug Control Policy [Available: http://www.whitehousedrugpolicy.gov/drugfact/factsht/proper_disposal.html]

⁴⁴ 4

A list of drugs the FDA advises should be flushed down the toilet can be found at the above web address. These guidelines are in place to avoid the diversion of drugs for illegal purposes.

⁴⁵ Kuspis DA, Krenzilok EP. 1996. What happens to expired medications? A survey of community medication disposal. *Veterinary and Human Toxicology*. **38**: 48 - 49.

⁴⁶ Krummerer, Klaus. Pharmaceuticals in the Environment: Sources, Fate, Effects, and Risks. Springer. 2nd edition. 2004

⁴⁷ U-listed and P-listed wastes are generally pure chemicals, but presumably have been converted to waste somehow and now must be disposed. Some are on containers as residue or have been used as solvents. P-listed wastes are generally more toxic than u-listed wastes.

⁴⁸ 4

Clean Water Act's General Pretreatment Regulations for existing and new sources of pollution. [Available: www.access.gpo.gov/nara/cfr/waisidx_02/40cfr403_02.html] (Last Visited June 27, 2007)

⁴⁹ 4

Rannazzisi, Joseph T. "Status of the Efforts of the FDA and DEA in regulating Schedule II Prescription Painkillers, Specifically OxyContin and Other Opioid Analgesics." DEA Congressional Testimony. Government Subcommittee on Regulatory Affairs. Boston, MA: September 13, 2006.

⁵⁰ Product Stewardship Institute - More information available: [<http://www.productstewardship.us/displaycommon.cfm?an=1&subarticlenbr=181>]

⁵¹ 5

Information gathered from personal correspondence with Dr. Stevan Gressitt. More information available: [<http://www.epa.gov/aging/grants/winners/umca.htm>]

⁵² Information gathered from personal correspondence with Michael Nelson. More information available: [<http://www.epa.gov/aging/grants/winners/archs.htm>]

⁵³ Information gathered from personal correspondence with Monica Hubbard.

⁵⁴ 5

List of participating pharmacies. [Available: <http://www.co.clark.wa.us/recycle/Publications/PartPharmacy.pdf>] (Last Visited June 11, 2007)

⁵⁵ Information gathered from personal correspondence with Jeff Gloyd and Dean Loeffler.

[Available: www.co.la-crosse.wi.us/SolidWaste/HHM/] (Last Visited July 11, 2007)

⁵⁶ Pharmaceutical disposal companies turn unwanted drugs into power. July 26, 2007. *The Examiner*. [Available: http://www.examiner.com/a-848146~Pharmaceutical_disposal_companies_turn_unwanted_drugs_into_power.html]

⁵⁷ 5

Ottawa – Take it Back! Program Information [Available: <http://app01.ottawa.ca/takeitback/Background.do?lang=en>] (Last Visited June 12, 2007)

⁵⁸ 5

Post-Consumer Residual Stewardship Program- Medications Return Program 2005 Annual Report. Submitted on April 30th, 2006. [Available: <http://www.env.gov.bc.ca/epd/epdpa/ips/meds/pdf/ar2005.pdf>.] (Last Visited June 12, 2007).

Number converted from 18,012 kg

⁵⁹ 5

Exchange rate of 0.9346 on May 31, 2007 from 225.000 Canadian dollar. Which equates to a cost of \$4.81 per pound.

⁶⁰ Results posted at < http://www.janusinfo.se/imcms/servlet/GetDoc?meta_id=7238 >

⁶¹ 21 CFR Parts 1300, 1301, 1304, 1305, and 1307. The Definition and Registration of Reverse Distributors from the Department of Justice

⁶² 6

The Single Convention on Narcotic Drugs is an international treaty against illicit manufacture and trafficking of narcotic drugs, which is the basis behind the CSA in the US and the Misuse of Drugs Act of 1971 in the United Kingdom.

⁶³ 6

21 U.S.C. § 801, Pub. L. No. 91-513, 84 Stat.1236 (Oct. 27, 1970) Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 It is the legal basis by which the “manufacture, importation, possession, and distribution of certain drugs are regulated by the federal government.”

⁶⁴ Title 21, Code of Federal Regulations (CFR), Sections 1308.11-1308.15 Schedule VI shall include all prescription drugs not included in the previous schedules and are considered non-controlled. [Available: www.mass.gov/legis/laws/mgl/gl-94c-toc.htm]

⁶⁵ A list of controlled substances in alphabetical order is provided at:

[<http://www.deadiversion.usdoj.gov/schedules/alpha/alphabetical.htm>]

⁶⁶ 21 CFR § 1301.24 exempts law enforcement.

⁶⁷ **Infectious Waste Disposal and Transport** - Waste sharps are presumed to be infectious, but not hazardous, waste in Massachusetts. Sharps include, but are not limited to, medical equipment such as hypodermic needles, syringes with needles attached, and lancets, which may cause punctures or cuts. They are regulated under Massachusetts Department of Public Health (DPH) regulations (State Sanitary Code Title VIII, 105 CMR 480.00) and Massachusetts Department of Environmental Protection (DEP) regulations (310 CMR 19.000). Infectious sharps must be segregated from other wastes and collected in labeled, leak proof, rigid, puncture-resistant, shatterproof containers to be incinerated or ground-up according to state approval.

⁶⁸ 6

The three generator status' under RCRA and Conditionally Exempt, Small Quantity Generator, and Large Quantity Generator.

⁶⁹ Found under The United States Postal Service Domestic Mail Manual Section 483.2 “The Mailability of Controlled Substances”

⁷⁰ Snyder, S.A., Westerhoff, P., Yoon, Y., and Sedlak, D.L. 2003. Pharmaceuticals, Personal Care Products, and Endocrine Disruptors in Water: Implications for the Water Industry. *Environmental Engineering Science*. **20**, (5): 449 – 469

- ⁷¹ Daughton, C.G. 2003. Cradle to Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health – Rationale for and Avenues toward a Green Pharmacy. *Environmental Health Perspectives*. **111**, (5): 757 – 774
- ⁷² Massachusetts Water Resource Authority. Essential Statistics. [Available: <http://www.mwra.com/02org/html/whatis.htm>]
- ⁷³ Massachusetts Water Resource Authority, How the Sewer System Works. [Available: <http://www.mwra.com/03sewer/html/sewhow.htm>] (Last visited 7/18/07)
This grit material is then taken to a landfill for environmentally safe disposal.
- ⁷⁴ Massachusetts Water Resource Authority, How the Sewer System Works. [Available: <http://www.mwra.com/03sewer/html/sewhow.htm>] (Last visited 7/18/07)
- ⁷⁵ Massachusetts Water Resource Authority. How the Water System Works. [Available: <http://www.mwra.com/04water/html/watsys.htm>] (Last visited 7/18/07)
- ⁷⁶ Massachusetts Water Resource Authority. How the Water System Works. [Available: <http://www.mwra.com/04water/html/watsys.htm>] (Last visited 7/18/07)
- ⁷⁷Table derived from - POSEIDON – Assessment of Technologies for the Removal of Pharmaceuticals and Personal Care Products in Sewage and Drinking Water Facilities to Improve the Indirect Potable Water Reuse. 2004. Dr Thomas Ternes Project Coordinator. [Available: www.eu-poseidon.com]
- ⁷⁸ POSEIDON – Assessment of Technologies for the Removal of Pharmaceuticals and Personal Care Products in Sewage and Drinking Water Facilities to Improve the Indirect Potable Water Reuse. 2004. Dr Thomas Ternes Project Coordinator. [Available: www.eu-poseidon.com]
- ⁷⁹ POSEIDON – Assessment of Technologies for the Removal of Pharmaceuticals and Personal Care Products in Sewage and Drinking Water Facilities to Improve the Indirect Potable Water Reuse. 2004. Dr Thomas Ternes Project Coordinator. [Available: www.eu-poseidon.com]
- ⁸⁰ Daughton, C.G. 2005. “Emerging” Chemicals as Pollutants in the Environment: a 21st Century Perspective. *Renewable Resources Journal* **23**, (4): 6 – 23
- ⁸¹ Laboratory Officials = Mike Delaney, Director of Laboratory Services and Steve Rhode, Laboratory Manager at the Central Laboratory on Deer Island. Information on specific methods gathered from personal correspondence.
- ⁸² Information from the American Chemical Society’s Chemical Service in their CAS Registry.
- ⁸³U.S. Environmental Protection Agency. [Available: www.epa.gov/nerlesd1/chemistry/pharma/critical.htm]
- ⁸⁴ U.S. Environmental Protection Agency. [Available: www.epa.gov/nerlesd1/chemistry/pharma/critical.htm]
- ⁸⁵ Daughton, C.G. 2003. Cradle to Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health – Rationale for and Avenues toward a Green Pharmacy. *Environmental Health Perspectives*. **111**, (5): 757 – 774
- ⁸⁶ Swedish Association of the Pharmaceutical Industry - environmental risk assessment. Results posted at < http://www.janusinfo.se/imcms/servlet/GetDoc?meta_id=7238 >
- ⁸⁷ Daughton, C.G. “PPCPs in the Environment: Future Research – Beginning with the End Always in Mind,” In *Pharmaceuticals in the Environment*, Kümmerer K (Ed.), 2nd edition, Springer, 2004, Chapter 33, pp.463 - 495
- ⁸⁸ Larsen, T.A., Peters, I., Alder, A., Eggen, R., Maurer, M., and Muncke, J. Re-engineering the Toilet for Sustainable Wastewater Management. *Environmental Science and Technology* **35**, (9): 192 – 197

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MWRA

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