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 Crosse[55]

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 Colombia 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 providence. In the 2005 calendar year the MRP collected 39,710 pounds[58] 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 legislation[62] 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 - V[64].

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 include[65]: 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 exempted[66] 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 Act[67]

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 exempt[68] 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 CSA[69]. 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 technologies[71]. 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 Treatement

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 (17α-ethinylestradiol, 17β-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 diclodenac, 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 there 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 relationship 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 lead 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 urine[88], 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 disproportionably 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 wide-spread 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 publics 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
Azithromycin
Ciprofloxacin
Cotinine
Estrone
Estradiol, Ethinyl
Lipitor
Methadone
Morphine
Nonylphenol polyethoxylate
Octylphenol
Octylphenol polyethoxylate acid
Salicylic acid

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

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[63] 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] 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"

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[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)
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