Economic and Environmental Impacts of Drug Waste Protocols

Preventable drug waste is a problem in many facilities around the United States. Without addressing this issue, patients will continue to pay for drugs they never receive.

By

Mark Ruddat

Luka Christianson

Janelly Torres

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Report Submitted to:

Abigail Ware

Representative Mary Keefe

Professors Laura Roberts and Michael Elmes

Worcester Polytechnic Institute

Abstract:

Our project goal was to investigate the impact of drug waste protocols in Massachusetts and look into legislation in other states related to this issue. We collected data through interviews with pharmacists, patients, nurses, organizations, and lawmakers. Our findings were: safety protocols, overmedication, and expired medication lead to drug waste. Moreover, dropbox areas/cactus devices can be improved, Pharmacy Benefit Managers exacerbate the burden of drug waste, diversion is an overlooked aspect of drug waste, and legislation regarding drug waste is weak. Based on these findings, we recommend solutions such as deprescribing, public awareness of disposal sites, adjustment of safety protocols, creating an environment for drug reuse companies, and implementing dose banding.

Executive Summary:

Drug waste is a vast and complex problem that affects our country. From hospitals to homes, drug waste stems from multiple sources, such as single-dose vials and prescription drugs. In single-dose vials, waste can arise from the leftover medication produced from administering medicine to a patient. As for prescription drugs, expiration dates and overmedication can produce large amounts of waste. Drug waste also affects the economy as patients pay for medications they never get to use. In addition, the cost of medicine has increased over time, exacerbating the economic burden of drug waste. As for the environment, drug waste ends up in rivers and landfills, which can affect those who drink from rivers polluted by pharmaceuticals. Overall, drug waste has been an issue since the creation of pharmaceuticals to treat diseases, and in the United States, more legislation is needed to solve the problem.

The United States has enacted some precautions to eliminate drug waste, such as Section 90004 of the Infrastructure Investment and Jobs Act, which makes manufacturers pay back Medicare for unused medications. While the money gets back to the government, most patients never see any rebates for the medicine they pay for, which can put them into financial hardship. Massachusetts also has state legislation regarding drug waste, such as (H. 4056), An Act Relative to Substance Use, Treatment, Education, and Prevention which mandates a drug stewardship program. These laws address some of the consequences of drug waste but do not help curb the *creation* of drug waste.

However, some solutions already exist and have been tried around the world. The most relevant one, dose banding, is a method where certain groups of drugs are produced in increments. Then, when a patient falls between those increments, they can be given a vial that closely matches what the patient needs instead of a large vial. This reduces waste as a vial can be

completely utilized by a patient. This practice is already prevalent in the United Kingdom for chemotherapy drugs. Another solution is vial sharing, where a vial can be shared among several patients, reducing the amount of drug waste produced overall.

Our project goal was to gather data on how preventable drug waste affects the community to present to Representative Mary Keefe who serves the 15th Worcester District. To do this, we divided our goal into three objectives: investigate specific stakeholders involved with drug waste, explore legislation aimed at preventing drug waste, and propose recommendations on preventable drug waste.

We interviewed many different stakeholders throughout our project such as patients, doctors, pharmacists, nurses, lawmakers, and representatives from organizations that reduce drug waste. We utilized a semi-structured interview with all stakeholders and recorded all meetings to review them later. We interviewed a patient who had suffered from excess drug waste from prescription drugs. We interviewed multiple doctors with a background in deprescription and diversion. We interviewed pharmacists who had worked on a pharmacy benefit managing board. We interviewed nurses who had worked as family nurse practitioners and who had worked in ICUs. We met with Congressman McGovern, Senator Markey, and observed a pharmacy caucus meeting to determine what lawmakers are currently doing. We met with SIRUM to assess what non-governmental organizations are doing to eliminate drug waste.

During our project, we explored various government websites to see what had been done legislatively. We also looked at individual states to assess what each state was doing to impact drug waste. Finally, we compiled our findings and recommendations into a presentation and report. The presentation was given to various legislators as well as our advisors. We have found

seven findings during our research covering insurance, diversion, the causes of drug waste, and various legislation found.

Finding 1: Safety Protocols Can Lead to Excessive Drug Waste

From interviews with nurses and pharmacists, we found excessive drug waste can occur from safety protocols implemented in hospitals or healthcare facilities. Safety protocols are essential to keep patients healthy but can lead to preventable drug waste. When it comes to solid pharmaceutical waste, this is due to expiration dates and medical personnel not being allowed to dispense any expired medication, even if it is still potent after its expiration date. Medical personnel must also discard any drip bags after 96 hours, even if there is still medication in the bag. There is also no ability to vial share due to cross-contamination, even if the nurses use clean needles.

Finding 2: Dropbox Areas and Cactus Devices can be Improved to Prevent the Impact of Drug Waste

According to the pharmacists and nurses we interviewed, there are two kinds of disposal devices: drop boxes and Cactus Devices. Drop Boxes are typically found at police stations or pharmacies, allowing patients to dispose of unused drugs. Unfortunately, the general population is unaware of these boxes or find accessing them inconvenient. Cactus devices are secured medical devices that capture partially administered or unused controlled substances, rendering them non-retrievable and unusable. Although the cactus does dispose of waste, it does not control the creation of waste. Nurses have also informed us that it is time-consuming and is often overfilled.

Finding 3: A Culture of Overmedication Has Lead to Excessive Drug Waste

Multiple pharmacists informed us that the United States has a culture of overmedication. The more medication prescribed, the more waste will be produced. Often, medicine alone is used to treat diseases instead of other lifestyle alternatives such as exercise and diet. Larger prescription sizes exacerbate this effect and lead to excess drug waste.Frequently, the dose or treatment plan can be changed during the middle of a prescription. If this happens 15 days into a 30-day prescription, half of the medicine is now wasted.

Finding 4: Medication Often Expires Before it Can be Utilized, Leading to Drug Waste.

According to most pharmacists and nurses we interviewed, expiration dates are included with drugs to gauge their potency and not their lethality. The medication may not be dangerous to the patient, but simply not as potent as it was before it expired. The patient we interviewed had discarded thousands of dollars worth of medication simply because it had expired. Expired medicines also create drug waste in hospitals. Nurses have explained that they repeatedly dispose of numerous amounts of pharmaceuticals due to them being expired.

Finding 5: Pharmacy Benefit Managers (PBMs) Affect the Price of Medication and Can Exacerbate the Burden of Drug Waste

Pharmacy Benefit Managers manage formularies and affect a patient's copay. From sitting in on a pharmacy caucus meeting, we learned that PBMs can negatively influence the cost of medication by upwards of ten percent. This is due to their role as a ‘middleman’ between insurance companies and pharmacies. The role of PBMs influences the cost of drugs, exacerbating the financial burden of drug waste.

Finding 6: Diversion is an Overlooked Aspect of Drug Waste

Diversion is when a nurse or doctor takes a controlled substance from a medical facility. This is a consequence of having large amounts of drug waste. For example, when a vial is used,

and some is left in it because a patient does not need it, it allows the nurse or doctor to divert it. Diversion is often overlooked in the medical industry, with reported numbers of diversions being around ten percent of all staff. Administrators can quickly accept low diversion numbers and be unaware of further diversions. By reducing drug waste, we could limit the opportunities to divert medications.

Finding 7: Legislation Regarding Drug Waste is Either Non-existent or Weak.

The only critical piece of federal legislation comes in the form of Section 90004 of the Investment of Infrastructure and Jobs Act, which makes manufacturers refund the Center for Medicare and Medicaid Services for any single-dose drug waste. As for state legislation, we reviewed laws from Texas and New York that mandate a drug disposal system be disclosed to the consumer when a prescription is fulfilled. Unfortunately, Massachusetts does not have a similar law currently.

From these findings, we were able to provide recommendations to legislators on potential solutions. Before considering any of our recommendations, we were sure to consider any variables that may be affected by each solution we recommend. This includes safety, cost, addiction potential, treatment, and insurance.

Recommendation 1: Deprescribing

Deprescribing could effectively reduce drug waste created by overmedication. According to multiple pharmacists, deprescribing could be an effective method as many prescriptions are unnecessary. We would recommend the state pass legislation to develop incentives to prescribe less. This could be in the form of tax refunds or rebates. Furthermore, deprescribing would decrease the size of prescriptions. Pharmacies could offer discounts for these smaller prescriptions.

Recommendation 2: Public Awareness of Disposal Sites

To increase the use of disposal sites, we recommend a public awareness campaign to alert the general public to the availability of disposal sites and their necessity. Legislation could be enacted similar to that of Texas, where instructions are given with each prescription that specifically informs the patient how to properly dispose of the medication.

Recommendation 3: Safety Protocols

Two significant aspects of safety protocols can be reworked: expiration dates for prescription drugs and safety protocols within hospitals. For solid forms of pharmaceuticals and their expiration dates, we recommend legislators look at those expiration dates and consult with pharmacists/doctors to investigate the ability to improve the accuracy of expiration dates and assess that information for potential legislation. As for safety protocols in hospitals, we recommend gathering a task force of doctors and experts to look at existing safety protocols and find a way they can be altered to reduce drug waste while keeping patients safe.

Recommendation 4: Minimizing Drug Waste Creation

Through dose banding, the creation of drug waste could be minimized. Therefore, we recommend passing legislation that mandates all future drugs manufactured or sold in Massachusetts be considered for dose banding under the FDA's dose banding guidance for industry. It would make dose banding more prevalent and create the opportunity for manufacturers to implement a method that reduces drug waste.

Recommendation 5: Creating an Environment for the Donation of Excess Medications

Creating an environment that allows drug reuse companies would help eliminate drug waste and provide low-cost medication to those who need it. Reuse companies would take donated unexpired medication from healthcare facilities, nursing homes, and individuals, then

redistribute them to partner pharmacies. The Massachusetts government would need to work with companies to establish a suitable environment for them to operate successfully. Georgia, Ohio, and Wyoming are examples where medications are being donated and redistributed to people who need them because of cooperative governments. This would reduce the amount of wasted medication and provide low-cost medications to those needing them.

Acknowledgements:

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Authorship:

Chapter	Primary Author	Editor
Introduction: 1st Paragraph	Mark	Janelly
Introduction: Body	Janelly	Mark
Introduction: Conclusion	Luka	Janelly
Background: History	Mark	Luka
Background: Environment	Janelly	Mark
Background: Economics	Mark	Luka
Background: Solutions	Luka	Mark
Background: Legislation	Luka	Mark
Background: Conclusion	Janelly	Luka
Methodology: Introduction	Mark	Janelly
Methodology: Stakeholders	Mark	Janelly
Methodology: Legislation	Luka	Mark
Methodology: Ethics	Mark	Luka
Appendix:	All	All
Finding 1	Janelly	Mark
Finding 2	Janelly	Luka
Finding 3	Janelly	Mark

Finding 4	Mark	Janelly
Finding 5	Mark	Luka
Finding 6	Luka	Janelly
Finding 7	Luka	Mark
Recommendation 1	Mark	Luka
Recommendation 2	Mark	Janelly
Recommendation 3	Janelly	Mark
Recommendation 4	Luka	Mark
Recommendation 5	Luka	Janelly
Conclusion	Mark	Luka

Table 1: An authorship table that conveys each significant paragraph and the primary author and editors.

Acronyms:

API: Active Pharmaceutical Ingredients

CDC: Center for Disease Control

CMS: Center of Medicare and Medicaid Services

CSTD: Closed System Transfer Devices

DVO: Drug Vial Optimization

FDA: Federal Drug Administrators

ICU: Intensive Care Unit

IV: Intravenous

MA: Massachusetts

NH: New Hampshire

NY: New York

PBMs: Pharmacy Benefit Managers

TX: Texas

USP: United States Pharmacopeia

WPI: Worcester Polytechnic Institute

Meet the Team

Luka Christianson - Class of 2024 Mechanical Engineering

I mostly grew up in the suburbs of Houston, Texas, where I had access to a great schooling system and a lot of opportunities in order to work with people. One of the projects I had spearheaded when I was younger was to help improve the Fisher Houses, a home for Veterans to use while undergoing medical procedures. This partially developed my interest in healthcare. Currently, I am a Junior studying Mechanical Engineering with a minor in Arabic studies. I am in the Army ROTC Program and I will commission as a second lieutenant once I graduate. In my free time, I usually build and fix up my computers at home.

Mark Ruddat - Class of 2024 Mechanical Engineering

I am a junior studying mechanical engineering and materials science and engineering. I grew up in West Hartford Connecticut, and have been a local to New England ever since. I have lots of experience in manufacturing from internships as well as my hobby in metal working. I spend lots of my free time tinkering in my shop designing or building new projects or working on my car. I love being outside and hanging out with friends, whether that be relaxing or going on a hike. I am a good team player and have lots of experience working in group projects from other courses I have taken.

Janelly Torres - Class of 2024 Aerospace Engineering

I grew up in New Haven, Connecticut, in a school system that taught me there was life beyond an urban city. I went to schools that were primarily focused on getting you ready for college, at some point college became a must and the idea of it was a primary goal. The course load was rigorous but it pushed me to learn how to be a scholar and gave me an idea of what I wanted to study. I choose to go to WPI where I am studying aerospace engineering currently in my junior year. In my free time I love to hang out with friends and focus on photography as one of my hobbies. I enjoy challenges and work well in groups.

Table of Contents

Chapter 1: Introduction 17-18

Chapter 2: Background 19-24

- History (2.1) 19-22
- Environmental Impacts (2.2) 23-26
- Economic Impacts (2.3) 27-31
- Existing Solutions (2.4) 32-35
- Legislation (2.5) 35-23
- Conclusion (2.6) 24

Chapter 3: Methodology 25-30

- Project Goal 25
- Stakeholders (3.1) 25-27
- Legislation (3.2) 27-28
- Recommendations (3.3) 28
- Obstacles (3.4) 29
- Deliverables (3.5) 30
- Ethical Considerations (3.6) 30

Chapter 4: Findings 31-41

- Finding 1 (4.1) 31
- Finding 2 (4.2) 32-38
- Finding 3 (4.3) 31
- Finding 4 (4.4) 40
- Finding 5 (4.5) 40

- Finding 6 (4.6) 41

Chapter 5: Recommendations 31-41

- Deprescribing (5.1) 31
- Disposal Sites (5.2) 32-38
- Safety Protocols (5.3) 31
- Minimizing Drug Waste Creation (5.4) 40
- Donnation of Medication (5.5) 40

Chapter 6: Conclusion 40

- General Thoughts and Comments (6.1) 40

List of Figures:

Figure 1-1: An ad demonstrating early issues with pharmaceuticals

Figure 1-2: The drug discovery process

Figure 2-1: A demonstration of rivers that have pollution from medical waste

Figure 2-2: Amount of waste in metric tonnes

Figure 3-1: Mean payment of patients who are suffering from cancer

Figure 3-2: Hospitals and care facilities that do not use the JW modifier

Figure 4-1: The use of single-dose vials

Figure 4-2: An example of the use of vial sharing

Figure 5-1: Different agencies and their recommendations on single-dose vials

List of Tables:

Table 1: An authorship table for the significant paragraphs

Table 2: A roadmap for the project for the next term

Chapter 1: Introduction

The effects of drug waste are not limited to one part of the world or even to one country; it is a problem that impacts society. Specifically, drug waste affects hospitals, care facilities, doctors, patients, and many more. Regulations are needed to reduce drug waste to improve the environment and decrease drug costs. This issue has been ongoing in the United States since the development of pharmaceuticals to treat diseases. The US has devised different regulatory groups to reduce the adverse effects of drugs, but the government needs to do more to reduce the waste of drugs effectively. Many options exist to reduce drug waste and positively impact the environment and patients.

Pharmaceutical waste is a significant problem worldwide, impacting the environment and the economy. Consumers commonly waste expensive or unused drugs that end up in the environment. The waste creates a biohazard in waterways, the air, and the general environment (Nelson, 2015). Drug waste also impacts the economy. Patients often pay for drugs that will go unused; this is typical in cancer patients who use weight-based medicines that are delivered in a vial.

Our project researched and investigated the impact of drug waste protocols locally and on a federal level. We interviewed stakeholders such as nurses, doctors, pharmacists, patients, and legislators to achieve this goal. Further, we explored legislation that affects drug waste.

In the next chapter, we present our background research on the economic and environmental impacts of drug waste, existing methods to reduce drug waste and the current state of legislation regulating drug waste. Following the background, we discuss the methods we have chosen to complete our objectives. Following those chapters, we present the findings that

we have made throughout our project. Then, we will provide our recommendations to aid future research and legislation.

Chapter 2: Background

2.1 History:

Drug regulation has been discussed in the USA since the development of pharmaceuticals; often, there is tension between the government, companies, and the American people when developing new regulations. Regulations ensure safety from the start of manufacturing, to the use, and to the disposal of the drug.

A lack of regulations on pharmaceuticals in the United States has often led to severe medical side effects. In the past, this was especially true, as the causal link between adverse effects and the treatments that caused them was unknown (Avorn, 2012).

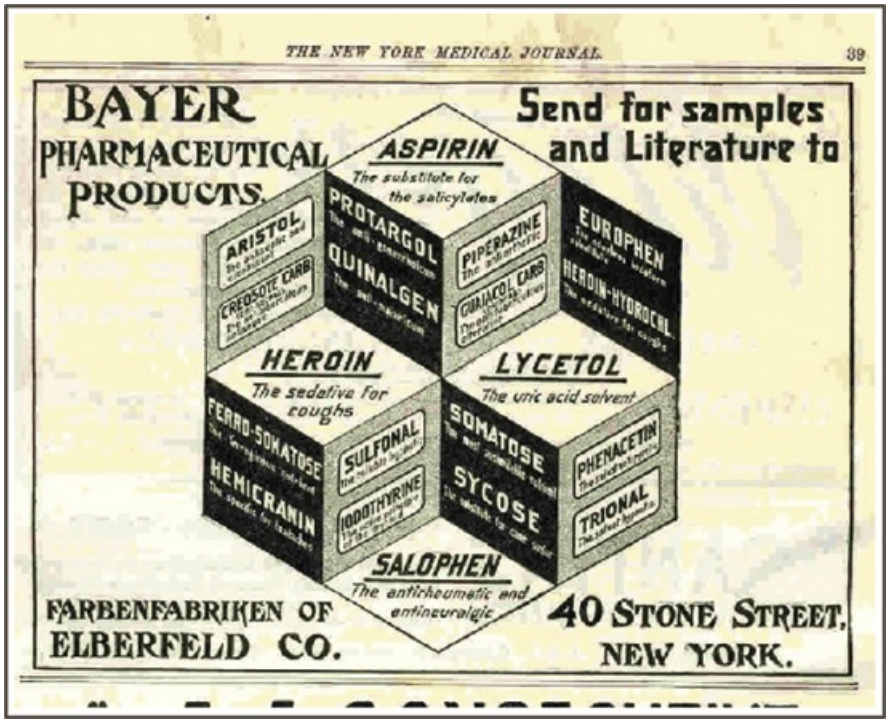


Figure 1-1: The above figure is an early 20th-century advertisement for medicine (Avorn, 2012).

As seen above, Figure 1-1 depicts an advertisement for medicinal treatment. Specifically, heroin is being advertised as a sedative for coughs. While perhaps heroin can help relieve coughs, it is common knowledge that heroin is severely addictive and harmful. This advertisement demonstrates the lack of regulations that influenced the pharmaceutical industry in the past. Unfortunately, the need for continued regulation is seen in the 21st century. For example, a study from 2008 indicates that those who took Aprotinin (a drug utilized during heart surgery) significantly increased the death rate (Avorn, 2012). This study portrays the impact drugs can have on health and indicates the need for regulation to reduce the percentage of adverse side effects. Poorly engineered drugs do not impact only a select few; an increase in death affected 88,000 patients who received Aprotinin (Avorn, 2012). For these reasons, the US government has developed agencies to be a watchdog on the pharmaceutical industry, such as the Food and Drug Administration (FDA).

The FDA is responsible for protecting the public by ensuring the safety of food and drugs. In 1906, the FDA was initially responsible for helping purify drugs (Weill Cornell Medicine, 2011). The FDA protects the health of the US public by identifying drugs, their products, and potential safety issues. Further, in 1938 the Federal Food, Drug, and Cosmetic Act was passed, strengthening the authority of the FDA. With this act, the FDA was granted the ability to mandate the safety of new drugs, authorize inspections of factories, and be allowed to prosecute manufacturers (Weill Cornell Medicine, 2011). Multiple acts have been passed to give the FDA more authority on drugs. In the 21st century, the FDA dramatically influences the cost of medication but does not influence the vial size of the drug approval process (FDA, 2017).

The development of modern drugs is a long process, typically 15 years, and includes discovery, preclinical trials, clinical trials, FDA approval, and post-market surveillance.

Discovery is typically the identification of potential compounds that could treat disease. Clinical trials are tests on living creatures. The preclinical trials test the potential medication on animals to identify which discovered drug has potential. Then, the medication is brought to human clinical trials with approval from the FDA. These trials identify if the drug is safe and effective and determine the *maximum* dosage size. This maximization is the amount of medicine that a patient can handle before the onset of severe negative side effects. (National Academies of Sciences, 2021). These trials seem to maximize dosages that will be sold to the public instead of minimizing dosages. After clinical trials, the drug is sent to the FDA

for approval and will eventually be manufactured and sold into the market.

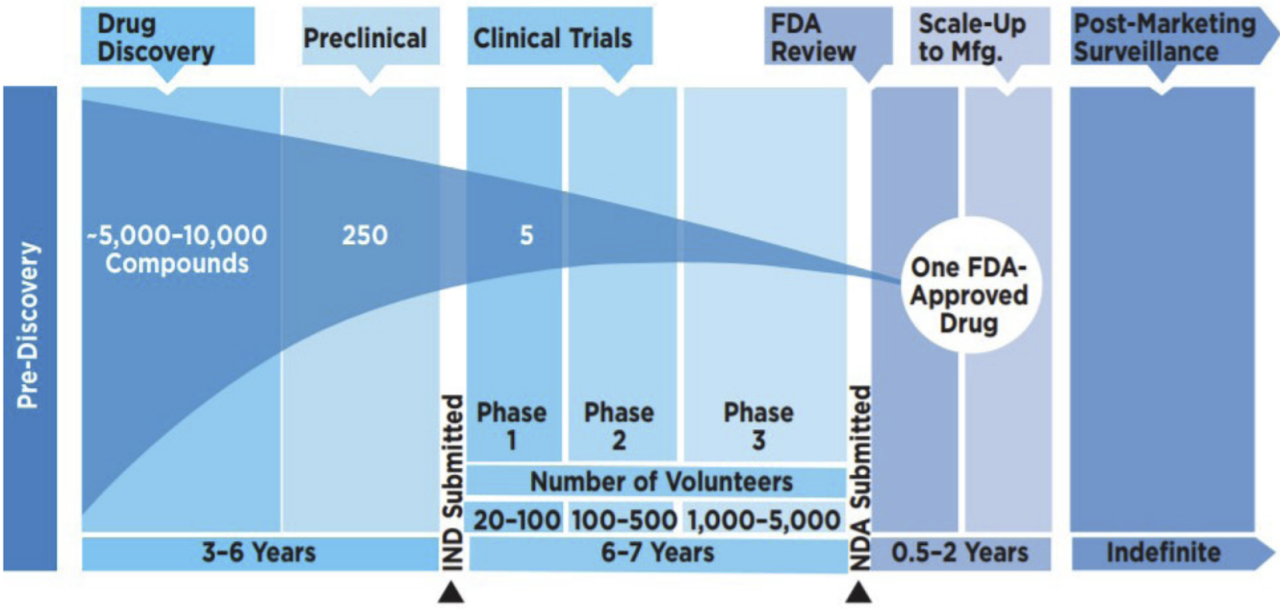


Figure 1-2: The discovery and trial period of new medication in the USA (National Academies of Sciences, 2021).

Determining drug doses is a complex process, as drugs affect individuals differently. Factors include the metabolism, weight, height, and sex of a person (National Academies of Sciences, 2021). Even after the clinical stage, patients being treated may have other uncontrolled variables such as other medication, food intake, or even the environment (Ahmed et al., 2016; Belle & Singh, 2008; Brunton et al., 2017). These variables directly impact the dose size, and because of this, there is a large variability of dose sizes in single-dose vials. Specifically, in cancer treatment, the severity of dosage variability is high. During the clinical trials, the 'maximum tolerated dose' is used. This is the dose right before the onset of life-threatening toxicity (Musuamba et al., 2017). Therefore, some doses are wasted because of the maximization, which has significant environmental and economic impacts. This is due to patients not requiring all of the medicine in a standard dose, often in liquid form.

The amount of wasted pharmaceuticals that come as pills is also significant. Hospitals and healthcare facilities dispose of at least 125 million pounds of pharmaceuticals annually (Nelson, 2015). One example was a Houston community pharmacy where consumers returned approximately 17,000 drugs over a six-month period (Nelson, 2015). A large amount of prescription drug waste is also seen in Alberta, Canada, through a disposal program that collected more than 204 tons of unused drugs in a span of 8 years (Nelson, 2015).

It is essential to understand the historical aspects of pharmaceuticals. Specifically, the drug discovery process allows for the maximization of drug dosages, which leads to further waste. Medicines that are set doses (pills) are often wasted as well. When drugs are improperly discarded, they end up uncontrolled in the environment. This affects those interacting with the environment, such as people drinking contaminated water.

2.2 Environmental Effects:

Understanding the history behind pharmaceutical regulation helps acknowledge drug disposal's environmental effects. With a lack of regulation on pharmaceuticals and methods to properly dispose of them, there is an ongoing issue concerning drug waste. Through the wrongful disposal of pharmaceuticals, the environment is drastically impacted by land and water pollution.

Pharmaceuticals enter the environment and into the water supply through wrongful disposal in a household. When a drug is no longer needed, or past its expiration date, people will discard them in their homes without acknowledging the potential harm pharmaceuticals could have on the environment. Typically pharmaceuticals find their way into the environment when they are improperly discarded down the toilet or sink (Tong, 2010). When drugs are discarded, they can enter the water system or landfills leading to multiple forms of pollution. Studies have shown that active pharmaceutical ingredients (APIs) emitted through wrongful disposal can harm ecosystems and human health (Wilkinson et al., 2022). By drug waste entering waterways, researchers have found that aquatic animals begin to lose natural patterns, and their sexual development and behavior can be abnormally affected (Wilkinson et al., 2022). While fish are constantly being exposed to API's the effect it has is still significant and should act as a warning of its potential harm to humans as well.

The following studies present a global investigation of API pollution in multiple world rivers; research can prove water contamination by showing how pharmaceuticals affect the waterways. The most polluted rivers are in Europe, Africa, and Asia. Countries such as Pakistan, India, and Kenya are in the 90th percentile of cumulative API concentrations. Even places in North America, such as Dallas, Texas, are between the 90th and 80th percentile, with around

10,000 ng/L of cumulative API concentrations (Wilkinson et al., 2022). Some of the least polluted rivers are Norway, Iceland, and even Florida intercoastal, with low API concentrations (Wilkinson et al., 2022).

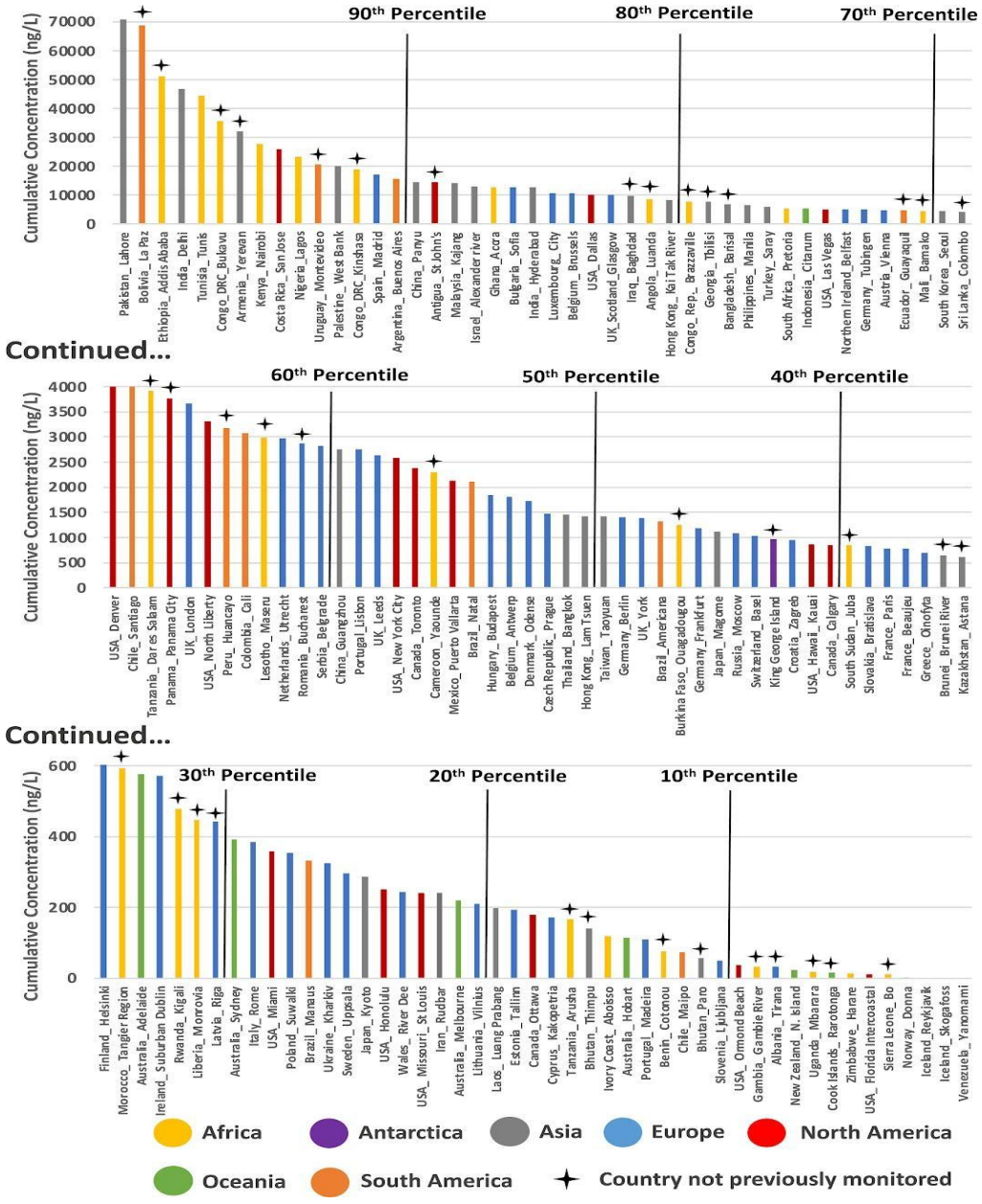


Figure 2-1: Cumulative API concentrations quantified worldwide, percentiles marked by black lines (Wilkinson et al., 2022).

Through this study, it is found that another way pharmaceuticals enter the waterways is through APIs generated by pharmaceutical plants. Most pharmaceutical sites with highly contaminated environments were found in low to middle-income countries. In this case, poor countries are defined by their gross national income, the final income in a year divided by their population, which is about $1,085 or less a year. These highly polluted sites are close to pharmaceutical plants that have received limited previous API monitoring in waterway systems (Wilkinson et al., 2022). A lack of monitoring of APIs causes a build-up of pharmaceutical ingredients and increases the risk of water pollution.

Typically, drugs that are often found in a household are also found in the environment. For example, caffeine and paracetamol are the most common drugs in waterways and have the highest concentration (King, 2022). Caffeine and paracetamol are popular drugs people ingest daily, as caffeine is found in many commodities and continues to be discarded through the trash or sink. Paracetamol is an over-the-counter drug that is used as a common way to treat moderate pain. Even with a lack of tracking APIs, some of the most common drugs found, like caffeine and paracetamol, are prescription drugs such as metformin (diabetes), fexofenadine (antihistamine), and sulfamethoxazole (antimicrobial) (King, 2022). Most of the drugs found in waterways are common drugs, both prescription and non-prescription, that are used every day, that could be limited or disposed of in other ways.

Figure 2-2: The waste, both general and chemically generated by the pharmaceutical company Roche, from 2007 to 2015 (Snyder, 2016).

Further, pharmaceutical companies produce significant amounts of waste; in 2008, as seen in Figure 2-2, there were about 31,295 metric tons of chemical waste which is around the size of 1,970 semi-trucks (Snyder, 2016). It is essential to understand how drug waste impacts the environment. When drugs are wrongfully discarded, they negatively impact the environment. Not only does drug waste cause an environmental impact, but it also impacts the economy. Patients are losing money from not using all of their prescribed pharmaceuticals, and as new forms of medical treatment are discovered, the cost of treatment skyrockets. Drug waste has caused economic impacts just as much as they have environmentally.

2.3 Economic Impact

Advances in medicine, as well as an aging population, have increased the cost of disease treatment. This has severe economic impacts on patients who rely on medication for treatment. For example, between 1995 and 2004, the cost of treating cancer was shown to increase by 75% (Warren, 2008). In the last 20 years, treatment costs have doubled (Tangka, 2013). This drastic increase is affected by pharmaceutical innovations (Warren, 2008). The optimization of treatment leads to a higher treatment cost. The cost of drugs can be influenced by the FDA approval process and clinical trials; an optimized drug will have a longer approval time and be more expensive. Drug costs fluctuate and increase or decrease over time due to external influences. This could be due to government involvement or when a patient's medication shifts.

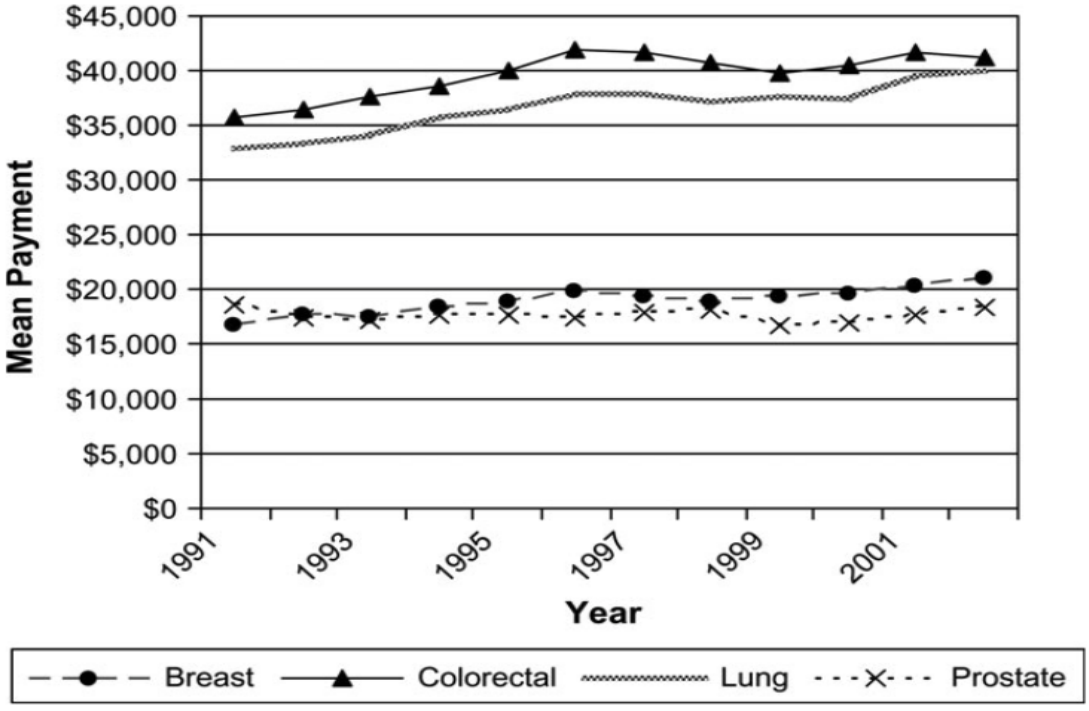
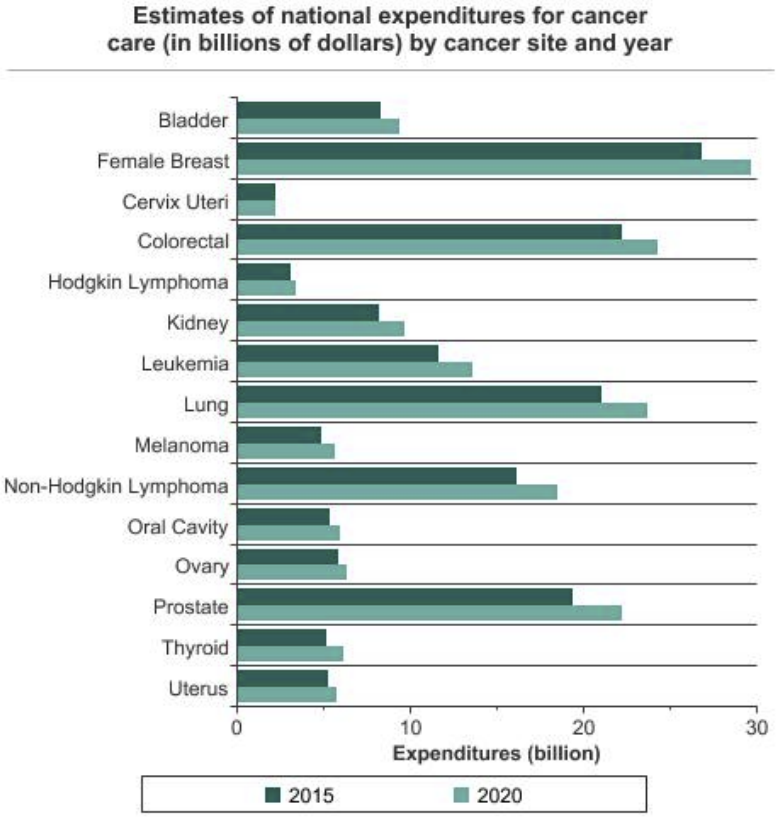


Figure 3-1: The mean Medicare payment of cancer treatment costs over time (Warren, 2008).

Figure 3-1 portrays a steady increase in treatment costs. Population growth and an older generation will likely increase the number of people diagnosed with cancer (Tangka, 2010). Cancer is more prevalent than ever before. In 2005, more than 10 million Americans were diagnosed with cancer (Tangka, 2010).



Source: Mariotto AB, Enewold L, Zhao JX, Zeruto CA, Yabroff KR. Medical Care Costs Associated with Cancer Survivorship in the United States. Cancer Epidemiol Biomarkers Prev. 2020;29(7):1304-12.
Cost estimates expressed in 2020 dollars using the medical care series of the Consumer Price Index for All Urban Consumers (CPI-U).
Total cost for cancer of the cervix uteri are reflected in medical services. Cancer-attributable oral prescription drug costs for cancer of the cervix uteri are not available.

Figure 3-2: Increase in cancer costs at different time periods and multiple

In more recent history, Figure 3-2 demonstrates the significant expenditures for many cancers (National Cancer Institute, 2022). As the demand for specific medicine increases (assuming the supply does not change), the cost will also increase. The increase in cancer treatment costs demonstrates that treatment of disease is expensive, and an aging population will continue to increase the cost of cancer treatment.

There is a severe economic challenge when treating disease. Many weight-based drugs, whose prescription sizes are determined by the patient's weight, are paid for by federal health care, private plans, copayment, and coinsurance or can be covered by Medicare Part B (National Academies of Sciences, 2021). As many weight-based drugs are wasted due to standard vial sizes that a patient will not fully utilize, the Centers for Medicare and Medicaid Services (CMS) have implemented a requirement for healthcare providers to report the portion of drugs that is discarded. Unused drugs are reported with a specific billing code called the JW modifier. The portion of drugs that are wasted is reimbursed to the healthcare provider, not the patients. Healthcare providers can include hospitals, care homes, and any other primary provider of health services. Further, the rebate applies to all wasted medication, not just medication bought by Medicare. It was reported in 2019 that the CMS had paid $725 million for the discarded medication (CMS, 2019). A different analysis determined that in 2016 the money spent on discarded cancer medication (specifically single-dose vials) was closer to 1.8 billion (Bach et al., 2016). Unfortunately, the number of claims made with the JW modifier is inconsistent. Often medicine is wasted that is not claimed by a health care provider. For this reason, the estimations above are likely lower than the actual value of discarded drug cost (National Academies of Sciences, 2021).

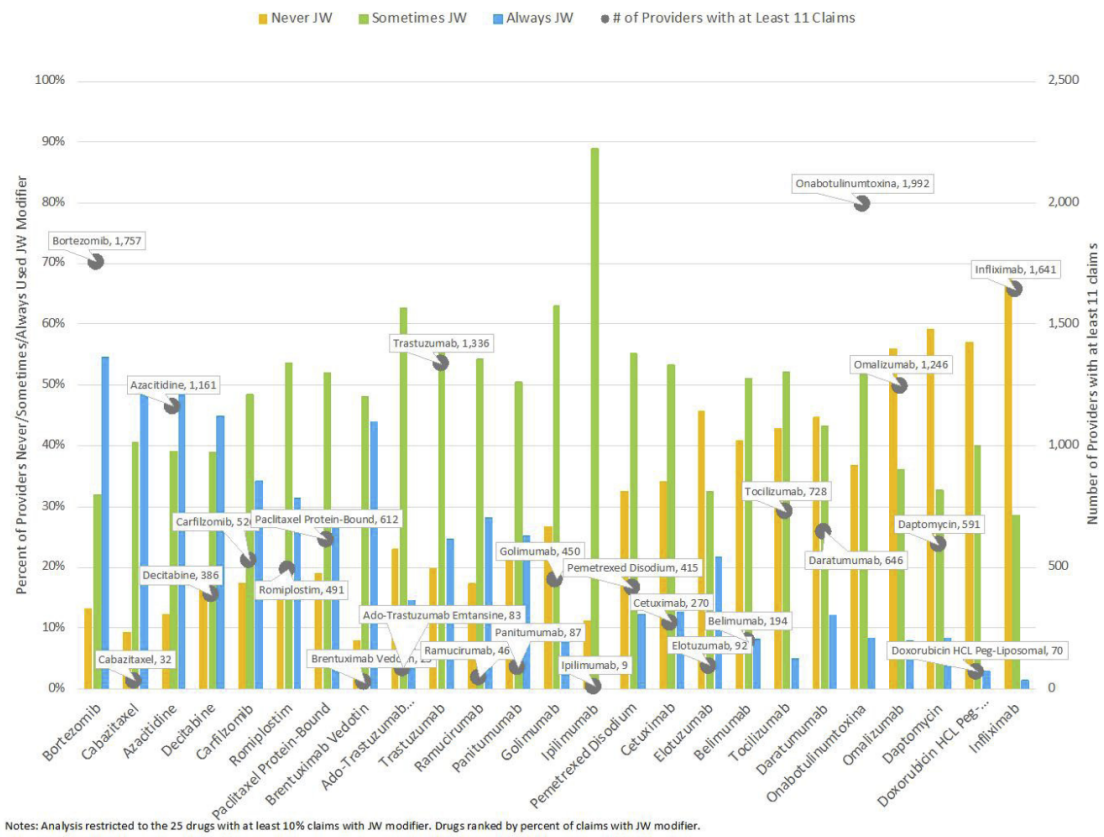


Figure 3-3: The number of healthcare providers who do or do not use the JW modifier for drugs.

Figure 3-3 demonstrates the severe lack of the JW modifier used in the United States. When one uses the JW claim, the healthcare provider correctly indicates the amount of medicine wasted. On the other hand, when it is not used properly, medicine is wasted and not reported. The orange lines indicate a lack of use for the JW claim on certain medications. The green lines indicate a partial use of the JW modifier. For example, 65% of the time, Infliximab has no claim made with the JW modifier. This means that 65% of the time when the medicine was wasted, it was not adequately reported to the CMS. Many healthcare providers do not report drug waste.

The issue of drug waste is much more severe than reported. The more drugs are wasted, the more economic hardship for those who must pay for them.

In correlation to injectables, there is a large amount of prescription drug waste in the form of pills. It has been estimated that in 2014, over three billion prescription drugs were being written annually (Nelson, 2015). Further, the number of individuals using one or two prescription drugs daily has increased significantly. The percentage of using more than five prescription drugs almost doubled in a seven-year time span (Nelson, 2015). This drastic increase has had effects on both the economy and the environment. Prescription medications are wasted for a number of reasons, such as adverse effects that the medicine causes that keep a patient from utilizing it, a drug may expire before it can be used, a patient may simply not take their prescription, and finally, in a medical center, a patient may be discharged or die before the prescription can be used (Nelson, 2015). This causes unnecessary economic strain on patients and hospitals as money is often spent on prescriptions. With all the impacts of drug waste, potential solutions are being experimented with to reduce drug waste. These solutions will reduce the economic burden on patients by reducing waste from single-dose vials and prescription medicine.

2.4 Existing Solutions:

Governments have been attempting to solve the issue of preventable drug waste to save billions of dollars. Multiple solutions have been attempted and successfully reduced medical waste (Suzuki, 2019). By analyzing these methods, we can see how the United States can reduce its drug waste nationwide.

The most well-known method to reduce drug waste in weight-based drugs is vial sharing which uses Drug Vial Optimization (DVO) and Closed System Transfer Devices (CSTD) to address flaws in its strategy. Vial sharing attempts to eliminate the notion of one vial per patient to optimize drug usage and minimize drug waste (National Academies of Sciences, 2019). To illustrate this, Figure 4-1 shows what occurs in the United States with existing medical practices. In this example, with three patients, 120 percent of a single vial's contents would be discarded.

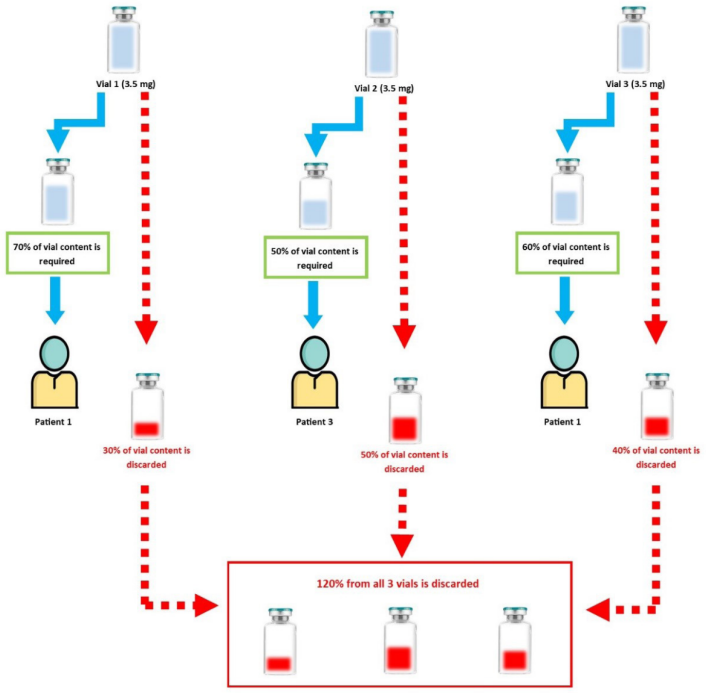


Figure 4-1: Current use of single-dose drug vials in the United States (National Academies of Sciences, 2021).

In contrast, Figure 4-2 shows that the remainder of each vial can be optimized and used for another patient, this results in only 20 percent of a vial's content needing to be discarded. This represents the basic idea behind vial sharing.

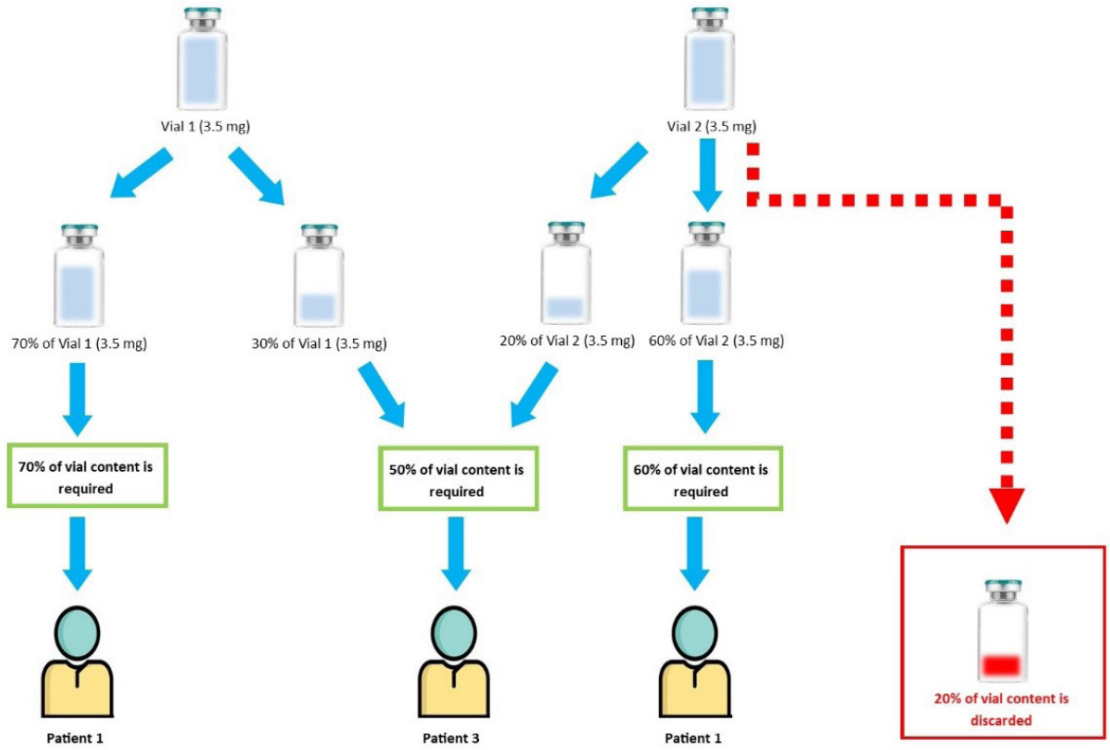


Figure 4-2: Example of how vial sharing can reduce waste in a hospital setting (National Academies of Sciences, 2021).

Multiple countries endorse vial sharing currently. It is common in Australia, where the Therapeutic Goods Administration, similar to the FDA, provides robust guidelines for using partial vials. The situation is similar in New Zealand and the United Kingdom, where both have guidelines on vial sharing (Gilbar, 2020). Some difficulties arise with this strategy that can

hinder its implementation. To implement vial sharing appropriately, hospitals must schedule multiple patients requiring the same drug simultaneously. Given the stability rules on vials, the contents must be used within the first 6 hours after it is opened (United States Pharmacopeia, 2008), which gives a small window to schedule patients. Since medications are prepared in advance, utilizing vial sharing could magnify drug waste when patients miss an appointment or a clinician reevaluates and decides to cancel the treatment for that day (Dobson et al., 2015). These shortcomings can be overcome by implementing Drug Vial Optimization (DVO).

DVO alleviates the shortcomings of vial sharing by utilizing Closed System Transfer Devices (CSTDs) to extend the amount of time the drug remains sterile. The National Institute for Occupational Safety and Health defines closed system transfer devices as "a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of the hazardous drug or vapor concentrations outside the system" (NIOSH, 2004). Once a drug is punctured to be used, it is generally thought to be no longer considered safe and effective. CSTDs isolate the drug and do not allow it or its vapor to escape into the environment or contaminate the vial or syringe. Using CSTD, the drug can last much longer than the United States Pharmacopeia's (USP) guidelines of 6 hours and remain sterile for up to seven days (Gilbar et al., 2019; Juhász et al., 2016). The United States was the first to use DVO. However, because the strategy is not supported by recent guidelines from the USP and some state pharmaceutical boards, its usage is not universal within the country (Amerine et al., 2019).

Another solution being used is dose banding. Under dose banding, if a dose falls within a predetermined range based on body surface area, a set dose is given to the patient instead of a specific dose.(Chatelut et al., 2012; Gilbar & Chambers, 2018; Plumridge & Sewell, 2001). Each range is called a band, and the set dose given to the patient is called a banded dose (Chatelut et

al., 2012; Gilbar & Chambers, 2018; Plumridge & Sewell, 2001). It reduces drug waste because a drug product may only be available in 100mg bags, but if the patient needs 125mg, it would result in 75mg of the medicine being wasted. Using dose banding would produce an extensive range of bag sizes, thus giving the patient close to precisely what they need. Generally, the max variance between the dose calculated from the patient's body surface area and the set band sizes is six percent. This strategy is widely used in the United Kingdom and other countries but has not yet become popular in the United States (Guinto & Szabatura, 2013; Oswald, 2016; Plumridge & Sewell, 2001). An example of dose banding is Figure 4-3, provided by the National Health Service in England below.

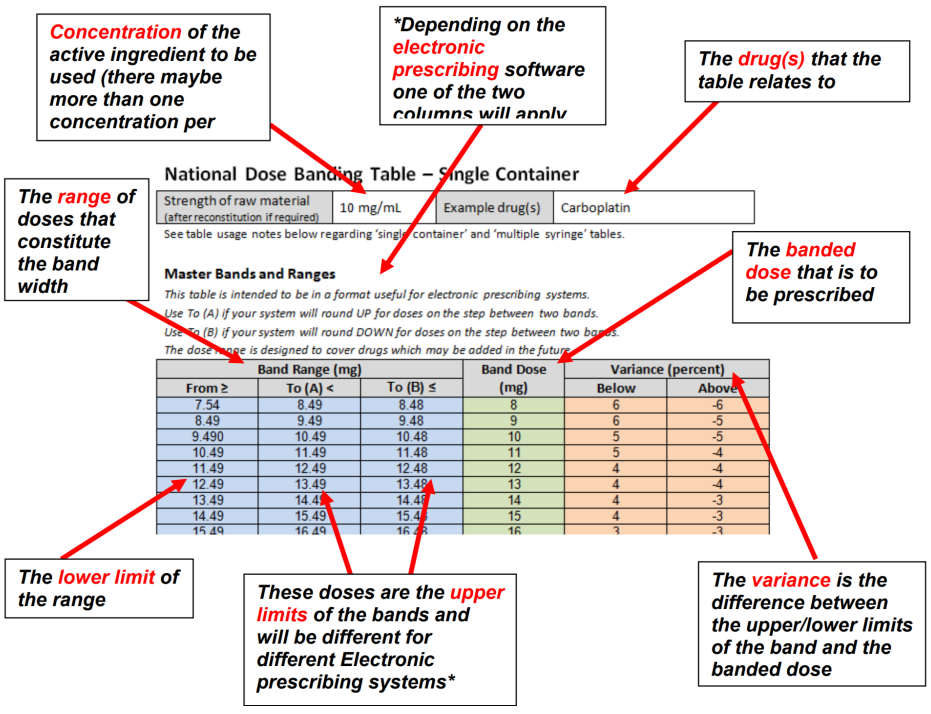


Figure 4-3: Explanation of a dose banding table with explanations included.

2.5 Legislation:

With solutions being attempted worldwide, legislation in America has failed to address this issue. Congress has tried to address the economic impact of drug waste, while governmental agencies such as the FDA, CMS, and CDC have conflicting recommendations on implementing the methods above.

As of today, there has been no overarching legislation on drug waste. However, Congress has attempted to address specific aspects of this issue. The 115th and 116th Congresses have considered giving rebates to healthcare providers for wasted medication. However, they have never considered giving patients rebates, which would reduce the financial burden of purchasing expensive drugs that they will not use. (National Academies of Sciences, 2021). The bills that considered giving rebates to healthcare providers ultimately never left the committee.

The governmental agencies that most effectively implement the methods above are the FDA, CDC, and CMS. Each of these agencies has different guidelines for each method. In vial sharing, the FDA does not give a definitive answer on sharing vials but conveys caution, saying, "Consumers and/or healthcare providers should not be routinely required to use more than one vial to administer a typical single dose of the drug product." (FDA, 2015b). With this, the FDA does not actually provide any guidance. The CMS allows repackaging saying that "Under certain conditions, it is permissible to repackage single-dose vials or single-use vials into smaller doses, each intended for a single patient." (CMS, 2012). Meanwhile, the CDC disallows any repackaging of drugs with a single dose being used for a single patient only (CDC, 2019). Overall, it can be observed that there is no guidance.

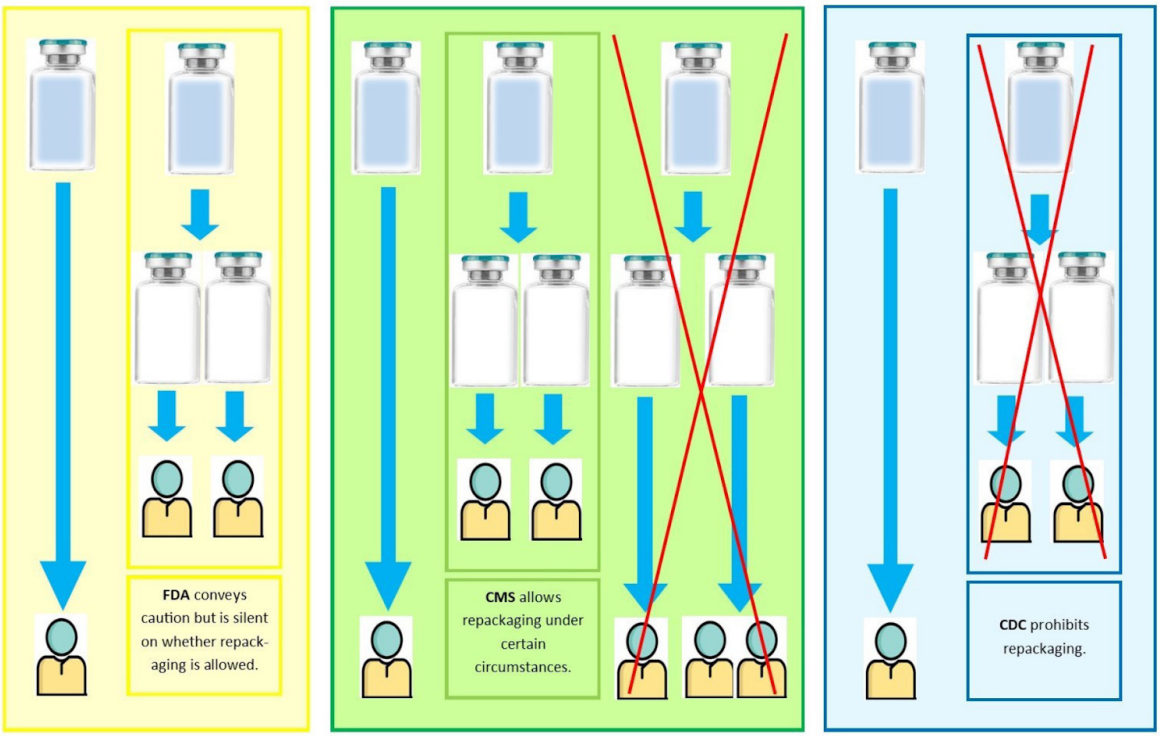


Figure 5-1: Figure of different governmental agencies' recommendations on sharing single-dose vials (National Academies of Sciences, 2021).

For prescription drugs, local governments have had the most effect on reducing drug waste. Alameda County adopted the Safe Drug Disposal Ordinance in California, which holds pharmaceutical companies responsible for collecting unused medications. A similar law was established in King County in Washington, creating a drug take-back system operated by drug manufacturers (Nelson, 2015). The FDA suggests that all prescription drugs should be brought to a drug take-back site. However, if those are unavailable, certain drugs should be flushed and disposed of in the trash.

The lack of drug dosing and disposal legislation makes it hard to contain drug waste. The FDA has provided instructions on disposing unused pharmaceuticals; the U.S. Drug Enforcement Administration (DEA) sponsors National Drug Take Back Day in communities nationwide. Many communities also have their own drug take-back programs (FDA, 2021). Drug Take-back programs are the best option for disposing of leftover drugs as they are disposed of using high-temperature incineration at a secure, permitted facility (Nelson, 2015). If a drug waste disposal drop is not readily available, the FDA also provides a "Flush list" that allows consumers to flush certain pharmaceuticals. Prescribed drugs are on this flush list to keep them from being misused or abused and to keep consumers from dying if a single dose is inappropriately taken. (FDA, 2020) While the FDA does encourage people to take advantage of the take-back programs as it helps prevent leftover pharmaceuticals from being misused, Drug take-back programs only allow for facilities such as hospitals to make back money lost from leftover drugs that went unused. Those impacted are patients who pay the total price for a drug that is not fully used.

2.6 Conclusion

In conclusion, by preventing potential drug waste, the impact on the environment can be reduced, and patients and hospitals can save millions of dollars without bearing the consequences of disposal. By recognizing the shortcomings and issues facing drug waste, we can start taking sizable steps to improve the lives of those affected. In the next chapter, we will take our research further and focus on three main objectives that can be answered through interviewing and studying case studies to gather more information on drug waste.

Chapter 3: Methodology

The goal of this project was to research the causes of drug waste as well as the economic and general impacts to propose recommendations to Representative Mary Keefe. To achieve this goal, we developed the following research objectives.

1. Investigate stakeholders involved with preventable drug waste.
2. Review of State and Federal Legislations Aimed at Preventing Drug Waste.
3. Propose recommendations to Representative Keefe on preventable drug waste.

In the following chapter, we describe the methods we utilized to gather data from stakeholders, those who are either directly affected or have an influence on drug waste, and how the results of this analysis assisted us in the recommendation we presented to Representative Keefe.

3.1 Investigated stakeholders involved with preventable drug waste

We investigated how stakeholders react to preventable drug waste. We have conducted semi-structured interviews with nurses, pharmacists, doctors, patients, companies, and government employees. We used semi-structured interviews as it allowed us to pursue areas past our questions (Berg, 2012).

Stakeholder:	Amount:	Objective:
Nurses	5	To find the effects and causes of drug waste in ICUs and hospitals.
Pharmacists	4	To find causes and solutions to drug waste.
Patients	1	To find the effect of drug waste on the economy and community.
SIRUM (Company)	1	To find solutions to drug waste.
Government Officials	3	To find legislation and solutions regarding drug waste.

Table 3-1: A Table containing the stakeholders we interviewed

One of the five nurses we interviewed was a family nurse practitioner; the other four worked in the hospital/ICU setting. All four pharmacists we interviewed worked in both the medical field and academia with one working with insurance companies. One of the government officials was a senator, and one was a congressman. Outside the formal meetings, we also sat in on a caucus meeting regarding pharmacy practices. The members were doctors, senators, representatives, and community members. The company we interviewed was SIRUM. Interviewees were located in Massachusetts, New York, New Hampshire, and Texas, with the majority being from Massachusetts. We started each interview with a broad question to create a more comfortable environment. We took notes and recorded each interview using a recording

software named Grain to help us review the data collected. The interview questions for this objective are in Appendix A.

3.2 Review of State and Federal Legislations Aimed at Preventing Drug Waste

We analyzed legislation to dive further into this objective. We focused on legislation enacted in Massachusetts while also looking at legislation in other states in the US. Additionally, we examined relevant federal legislation and guidance from governmental agencies. We met with legislators to assess if any laws were in progress or if they had knowledge of any relevant legislation. Our interview with Senator Markey's office revealed legislation focusing on regulating Opioids. The meeting with the pharmaceutical caucus revealed that legislation was being worked on to limit the role of Pharmacy Benefit Managers (PBMs) in reducing pharmaceutical costs. Further, we reviewed legislation in New York, New Hampshire, and Texas. Below is a table of the legislation and guidance we reviewed, where it originated, a short description, and whether it succeeded. The in-depth analysis and major takeaways are provided within our findings chapter.

Title	Origin	Information Covered	End Result
Prescription Drug Pricing Reduction Act of 2020	FEDERAL	Requires drug manufacturers to issue rebates to the CMS for discarded amounts of certain single-dose drugs covered under Medicare	In Committee
An Act Relative to Substance Use, Treatment, Education, and Prevention	MA	Any pharmaceutical product manufacturer selling or distributing a covered drug to consumers in the commonwealth shall operate a drug stewardship program approved by the department	Enacted
Senate Bill S7605	NY	Requires a personal use pharmaceutical disposal system be provided at the time of dispensing an opioid prescription at no cost to the ultimate user of such prescribed opioid.	In Committee
Section 90004 of the Infrastructure Investment and Jobs Act, (REFUND Act)	FEDERAL	Requires manufacturers to provide a refund to CMS for specific discarded amounts from a refundable single-dose container or single-use package drugs.	Enacted
Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy	CMS	Contains a description of the JW and JZ modifier and how it is used to follow section 90004 of the Infrastructure Investment and Jobs Act	Policy
H.B. 2088 86(R)	TX	Requires that all pharmacists who dispense Schedule II controlled substances provide written notice on the safe disposal of controlled substances	Enacted
“Dose Banding” Guidance for Industry	FDA	Provides guidance on dose banding within the United States. Provides guidance only. It does not have the force and effect of law and is not meant to bind the public in any way	Guidance
National dose banding tables	NHS	Provides an example of dose banding for our project and how it could be implemented	Policy

New Hampshire Pharmacy Laws & Rules	NH	Includes all rules in New Hampshire regarding expiration dates and how it relates to samaritan laws	Laws

Table 3-2: Table of important legislation reviewed.

3.3 Propose recommendations on preventable drug waste to the state legislation.

We have researched drug waste and presented our findings and recommendations to state legislators. State legislators will mainly reference Representative Mary Keefe and aides from different congressional and senate offices. We analyzed our data by searching for common themes between interviews which became the basis for each finding and recommendation. Our proposal was successful as those involved in the meeting understood the gravity of the issue.

3.4 Ethical Considerations

The WPI Institutional Review Board reviewed this proposal to ensure it met all ethical considerations. We used the informed consent script, which can be found in Appendix C. All participants were informed of the purpose of our research, that their participation was voluntary, and that they could choose to remain anonymous. To ensure confidentiality, we did not ask any personal medical questions and allowed interviewees to skip any question they wished. We followed this procedure to maintain ethical research practices.

Chapter 4: Findings

4.1 Finding 1: Safety Protocols Can Lead to Excessive Drug Waste

From interviews with nurses and pharmacists, we found that liquid drug waste can occur from safety protocols implemented in hospitals or healthcare facilities. Safety protocols are important to keep patients healthy but can lead to preventable drug waste.

While interviewing a nurse who worked in Boston hospitals, they informed us that IV drip bags are often replaced even when the medication is not completely used. A safety protocol requires drip bags to be replaced 96 hours after they are exposed to room temperature. Further, due to contamination risks, vials that are not used in their entirety must be discarded. Rarely does a patient require the exact amount of medicine from a vial, leading to excess medication. This safety protocol also restricts nurses from using fresh needles to extract medicine from a used vial. Once a vial has been opened, it can only be used once.

4.2 Finding 2: Dropbox Areas and Cactus Devices Can be Improved to Prevent the Impact of Drug Waste

According to the pharmacists and nurses we interviewed, there are two kinds of disposal devices: drop boxes and Cactus Devices. Drop Boxes are typically found at police stations or pharmacies and allow patients to dispose of any unused drug. Unfortunately, the general population is unaware of these boxes, and using them is inconvenient.

We found from these same interviews that hospitals use a machine called the ‘Cactus’ to safely dispose of drugs by isolating leftover medicine. The Cactus is a secured medical device

that captures partially administered or unused controlled substances and renders them non-retrievable and unusable. Although the Cactus does dispose of waste it does not control the creation of waste. Nurses have also informed us that it is time-consuming and is often overfilled. Due to this, nurses tend to dispose of the medication in the trash or down the sink. The improper use of the Cactus and its design flaws have led to more drug waste in the medical industry.

4.3 Finding 3: A Culture of Overmedication Has Led to Excessive Drug Waste

According to multiple pharmacists, the United States has a culture of overmedication which is part of the training in medical school. They informed us that medicine could cause a cascade effect where a drug causes a side effect cured by another drug. This effect is more common with older patients. Often many medications patients are on are unnecessary. For example, according to a pharmacist from a well-known pharmacy university, Bronchitis is often treated without medication as the infection often improves on its own, however, doctors still prescribe antibiotics. This could be due to the patient complaining about Bronchitis and wanting to be treated faster. Research is often designed to see the effects of medication instead of the effects of stopping the medication. These factors lead to more pharmaceuticals being circulated in society, leading to more drug waste.

A symptom of overmedication is excessively large dose sizes. Medications are often distributed in either 30 or 90-day prescriptions for solid drugs or large vials for liquid drugs. According to one patient, this is the best choice as it increases convenience and can reduce cost. These patients tend to have many drugs that must be administered and tracked. In this case, having a large prescription reduces the burden of frequently following up on prescriptions.

However, if the patient's prescription changes suddenly (such as a dose change or ineffective medicine), the extra medication is wasted.

4.4 Finding 4: Medication Often Expires Before it Can be Utilized, Leading to Drug Waste.

According to most pharmacists and nurses we interviewed, expiration dates are included with drugs to gauge their potency and not their lethality. The medication may not be dangerous to the patient, but simply not as potent as it was before it expired. According to a patient we interviewed, large quantities of medication will expire before it can be used. This patient has thousands of dollars' worth of expired medication. The expired medication also creates drug waste in hospitals. A nurse explained that staff members go through the supply of pharmaceuticals weekly to dispose of expired medication. Further, a pharmacist in academia explained that in New Hampshire, a pharmacy can not sell a prescription medication that expires within a year. Due to this rule, pharmacies struggle to sell medication that is not as commonly used. The medication may still be viable (as it has not expired) but cannot legally be sold. This creates excess drug waste.

4.5 Finding 5: Pharmacy Benefit Managers Affect the Price of Medication and Can Exacerbate the Burden of Drug Waste

Prices of pharmaceuticals are directly related to the Pharmacy Benefit Manager (PBM) and the patients purchasing these medications. Through interviews with pharmacists, we have learned that PBMs are primarily responsible for processing prescription drug claims, they can either be a third-party administrator or part of a pharmacy. The PBM manages all formularies (drugs in a prescription plan), benefits from a pharmaceutical company, and directly impacts the copay a patient has to pay. Usually, the PBM negotiates discounts and rebates with drug manufacturers and contracts with pharmacies. This influences how insurance companies pick which prescription drugs they cover.

According to the pharmacy caucus, PBMs can increase the price of pharmaceuticals by 10%. This is due to their direct influence on formularies and their actions as a ‘middleman’ between insurance companies and pharmacies. The higher cost of medication affects patients and their copays negatively. The role of PBMs influences the cost of drugs, exacerbating the financial burden of drug waste. However, PBMs have a complex role, and more research needs to be done to clarify this finding.

4.6 Finding 6: Diversion is an Overlooked Aspect of Drug Waste

Diversion is when medical personnel take controlled substances home to use or sell. The American Nurses Association and the Substance Abuse and Mental Health Services Administration state that approximately ten percent of nurses and doctors have diverted drugs once. An example of this statistic would be at a hospital like Massachusetts General Hospital, with a staff count of over 26,000 people, roughly 2,600 people in that hospital have taken controlled substances. Diversion is a consequence of drug waste, as excess drugs left over from treating patients are most commonly stolen and abused.

The most common way medications are diverted is from the excess drug left when administering a controlled substance. For example, if the patient only needs 30 ml and the smallest vial size is 50 ml, it presents an opportunity for the nurse to swap out the drug for another clear liquid or steal it outright. Eliminating that preventable drug waste would also close the possibility for diversion in this scenario.

Diversion happens at every hospital, and according to a nurse who has diverted that we interviewed, many hospital administrators are ignorant that it could be happening at their institution. That expert has presented at multiple hospitals about diversion and has testified that the ignorance is widespread. There is a sizable education gap in what diversion looks like and how to spot medical personnel that are addicted. The education gap stems from administrators not wanting to address the issue, and even when it is talked about, it is said in whispers. Hospital administrators do not want to face the possibility that ten percent of their staff are diverting drugs. Low reporting numbers could mean that lots of cases are going undetected. Drug diversion stems from the available medication created by preventable drug waste. Stopping this drug waste would reduce the possibility of easy diversion and increase the hospital's overall

safety. Legislation aimed at preventing drug waste should take note of diversion and how it comes as a result of preventable drug waste. Legislation should mandate more robust drug waste checks while reducing the amount produced.

4.7 Finding 7: Legislation regarding drug waste is either nonexistent or weak.

Federal legislation regarding drug waste has been progressing slowly. As seen in table 3-2, the most critical piece of legislation from the federal government comes in Section 90004 of the Infrastructure Investment and Jobs Act (REFUND Act). This section is built from many bills introduced, such as the Prescription Drug Pricing Reduction Act of 2020. In short, the act mandates that manufacturers provide a refund to the Center for Medicare and Medicaid Services (CMS) for certain medications in single-dose containers. Notably, once the refund goes to the CMS, it is not stated in the section where the funds go to. The act states that manufacturers would use the JW modifier to assess the amount refunded. Therefore, we also reviewed the CMS's JW and JZ modifier policy. In the policy, a portion of the enactment dates have not yet passed, meaning that the modifiers are not yet in full effect despite it being created in 2019. We reviewed these documents to see how the federal government dealt with the economic consequences of drug waste on the consumer. We found out that even though manufacturers are required to pay the CMS, the consumer does not see any money personally.

As for state legislation, we found legislation in Texas and New York that deals with the disposal of prescription drugs. In Texas, H.B. 2088 86(R) requires that any class 2 controlled substance, at the moment of prescription, must be accompanied by written notice on the safe disposal of controlled substances. Additionally, New York suggested that a personal disposal

system must accompany any opioid prescribed. Although the New York legislation failed to be enacted, both are great ideas to inform consumers how to reduce drug waste at the point of sale. Currently, there is no similar legislation in Massachusetts, and it provides the opportunity to include it in future legislation. However, Massachusetts is the only state to enact a drug stewardship program statewide. The drug stewardship program mandates manufacturers to finance the disposal systems to collect unused drugs. While this law exists, it could be leveraged more effectively, as when talking to Congressman McGovern, he stated that collection points need to be made more accessible with incentives given to increase compliance. In New Hampshire, robust laws exist on expiration dates and concerning donations. The donation exceptions allow organizations to operate successfully.

Governmental agencies have some guidance on how to reduce the drug waste produced, including dose banding. The FDA has released industry guidance on dose banding that describes what dose banding is, why it is beneficial, and how manufacturers could begin to implement it. However, with it being guidance, it is not binding, and manufacturers can decide whether to follow it. Examples of successful dose banding are present in the United Kingdom, and all their resources are available to the public. We reviewed these documents to assess what the federal government was doing to try to minimize the creation of drug waste.

Chapter 5: Recommendations

Introduction: Variables to Consider

Before considering any of our recommendations, we were sure to consider any variables that may be affected by each solution we recommend. This includes safety, cost, addiction potential, treatment, and insurance. With the information gathered from our findings chapter, we have developed the best solutions to limit drug waste. We want to consider the safety of patients and ensure a cost-effective solution that does not affect the consumers economically whilst limiting drug waste. We also want to propose a solution that limits the creation of drug waste but also moves away from diversion, keeping patients and medical personnel healthy and safe.

5.1 Deprescribing

From interviews with multiple pharmacists, deprescribing was found to be a viable solution to reduce drug waste from overmedication and large prescription doses. With overmedication being prevalent in the United States, deprescribing would reduce the number of drugs given to consumers, thus reducing waste.

Further, along with eliminating unnecessary prescriptions, reducing the quantity of medication in a prescription would also be beneficial. With this, patients could receive smaller doses (perhaps a 15-day prescription instead of a 30-day prescription), effectively reducing drug waste. Legislation should be aimed at creating incentives for doctors to prescribe less medication. Incentives could include tax breaks and rebates for pharmaceuticals. To create an incentive, pharmacies could offer lower prices for smaller prescriptions. Further, additional training could be required that teaches the benefits of deprescribing.

Deprescribing has many benefits of being a solution but could also negatively affect patients. Creating a culture of deprescription could lead to a more challenging time for certain patients to receive the drugs they need. For example, according to a patient who has a long list of pharmaceuticals that they rely on, they are nervous about not being able to receive specific medication, such as narcotics, and often opt for a longer prescription for convenience. The longer prescription gives the patient assurance that, if needed, the medication is available. While deprescribing has many benefits, it should be known that it will not affect all equally, and larger prescriptions and medication should still be available to those who need it.

5.2 Public Awareness of Disposal Sites

When patients have medications that have either expired or that they do not need anymore, they take multiple options to dispose of the medication. Often this medication is thrown in the trash, the sink, or flushed down the toilet. These pharmaceuticals will become API's in the environment. A public awareness campaign could be beneficial to help reduce drug waste. As mentioned by many nurses and doctors we interviewed, many police stations have take-back programs for unused medications. These yellow bins allow people to drop off unused medication with no questions asked. This could be anything from expired Motrin to illegal substances such as methamphetamine. While take-back programs do not reduce drug waste, they can certainly help to reduce the impact of drug waste. These yellow bins are then taken and adequately disposed of (typically at an incineration plant). Legislation could help increase public awareness. Massachusetts should adopt a similar program to New York or Texas. As discussed in Finding 7, Texas has implemented legislation that requires prescribed medicine to be accompanied by written instructions for safe disposal. New York suggested that personal

disposal systems be included with opioids. Either of these legislations could help the disposal of pharmaceuticals and could be implemented in Massachusetts.

5.3 Safety Protocols

In our findings, we discussed that safety protocols lead to preventable drug waste. Solutions that can help alleviate drug waste include reviewing these safety protocols and assessing if they can be reworked. The two major aspects of safety protocols that can be reworked are expiration dates for prescription drugs and safety protocols within hospitals.

We found that expiration dates are a significant producer of drug waste. Many medical personnel we interviewed said that drugs can still be potent past their expiration date. In New Hampshire, the Board of Pharmacy mandates that all non-controlled substances must be valid for a year, and controlled substances must be valid for six months. We recommend that legislators look at these expiration dates and assess them for potential legislation. Specifically, pharmacists, doctors, and researchers should investigate the ability to improve the accuracy of expiration dates on medication.

As for safety protocols within hospitals, we recommend that the state gather a task force of doctors and experts in their field to look at and review the existing safety protocols. Investigating which safety protocols are effective and necessary while keeping in mind the safety of patients. For example, can drip bags be used after 96 hours? Or can Cactus designs be redesigned for a better waste capture device? Once their findings are complete, we recommend that the state government draft and push out definitive legislation on what safety protocols should be followed.

5.4 Minimizing Drug Waste Creation

In our background, we covered potential solutions for preventing drug waste. During our research, we narrowed the list down to dose banding, which can be implemented immediately. The list was narrowed to dose banding because of the complexity and lack of industry guidance by federal agencies. Dose banding would also improve the efficiency of nurses as they would only have to calculate what vial the patient would need then administer the whole vial. With dose banding being prevalent in the United Kingdom and Australia, there is already a framework for how dose banding can be retroactively fitted to chemotherapy drugs. As for new drugs, we recommend passing legislation that mandates all future drugs manufactured or sold in Massachusetts be considered for dose banding under the FDA's dose banding guidance for industry. This would make dose banding a more prevalent idea and would have the possibility of reducing future drug waste.

5.5 Creating an Environment for the Donation of Excess Medications

Integrating a drug reuse company into the state would better utilize the pills left over from patients and reduce drug waste. During our project, we discovered a company called SIRUM that operates throughout the United States. SIRUM is an organization that redistributes unused drugs to those who need them. Healthcare facilities, nursing homes, and individuals would donate unused medicine to SIRUM, which would then be redistributed throughout the state to partner pharmacies. They work in multiple states but have not yet established a foothold in Massachusetts. The Massachusetts government would need to work with companies similar to SIRUM to create a suitable environment for them to operate successfully. This would reduce the amount of leftover medication and provide low-cost medications to those needing them.

Chapter 6: Conclusion

6.1 General Comments and Thoughts

Through this project, we came to a deeper understanding of the severity of drug waste and its impact on the environment, economy, and the Worcester community. In interviews with stakeholders, we became aware of many factors that contribute to drug waste and the overall complexity of the issue. We realize that more research should be done on each of the findings and recommendations we have considered to fully understand each of their impacts. In conclusion, more research should be done on drug waste, specifically into diversion, the role of PBMs, and overmedication. These are complex issues with a multitude of factors that need to be fully understood to acknowledge their full impact.

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Appendix A

Interview questions:

- Has (insert hospital name) taken any actions to reduce drug waste? If so, what is this approach?
- Does the high price of pharmaceuticals have a direct impact on your life? If so, to what extent?
- How much has your insurance company helped with covering highly priced Pharmaceuticals? What insurance company do you use?
- How does (Insert insurance company) determine which drugs to approve for insurance?
- Do you have any knowledge of the impacts of drug waste? What are your experiences with this project, if any?
- Are you aware of any methods to help reduce drug waste? If so, do you know if these methods are being applied?
- Have you ever considered opting out of your prescribed drugs due to the high pricing?
- How do you connect to this project personally? How has drug waste impacted you both economically and environmentally?
- Has the increase in drug prices affected your medical treatment? Has drug prices gotten better? Worse?

Appendix B

- Do you believe a large amount of pharmaceutical waste is reduced?
- How do you connect to this project personally? How has drug waste impacted you both economically and environmentally?
- Are you aware of any methods to help reduce drug waste? If so, do you know if these methods are being applied?

Appendix C

Informed Consent:

We are a group of students from Worcester Polytechnic Institute in Massachusetts. We are interviewing hospitals, care homes, pharmacists, patients, local organizations, and insurance companies to learn more about drug waste in Worcester and Massachusetts. This research will be used by Representative Keefe to create potential legislation.

Participation in this survey is voluntary, and you may withdraw anytime. Please remember that your answers will remain anonymous. No names or identifying information will appear on the questionnaires, project reports, or publications.

This is a collaborative project between Representative Keefe and WPI, and your participation is greatly appreciated. If interested, we can share a copy of our results with you at the end of the project.

Appendix D:

Tasks:

Task	PQP	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
Identifying hospitals								
Impact of drugs on patients								
Exploration of existing methods								
Exploration of legislation								
Propose recommendations to Rep. Keefe.								

Table 2: A table of the roadmap for the project next term.