

An Evaluation on the Drug Repository Landscape in Nova Scotia

By

Suzanne Saunders

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Written for EMBA 6646/6634 under the direction of Dr. Russell Fralich

Approved: Dr. Russell Fralich  
Faculty Supervisor

Approved: Dr. Wendy Carroll  
Program Coordinator

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## ABSTRACT

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In 2014, Canada spent \$33.9 billion on medications. Extrapolating from the US, it is estimated \$2.4 billion worth of medication go unused in Canada. Since 1997, at least 38 states have some form of medication reuse program, while no Canadian province does in the truest sense. The programs in the US are broken down into four types depending on structure: Closed-Focused, Closed-Broad, Open-Focused, Open-Broad. The motivation for each program is different. The evolution of programs in the US largely rested on story and power but the same factors have not worked in Canada. Five Nova Scotian stakeholders were interviewed on why this is the case. Several issues around logic, power, story, morality, validation and diffusion were identified. This paper finds story has less meaning in Nova Scotia, government is not a source of power, more data is required, and there is a lack of normative legitimacy in this area. Change in Nova Scotia will require buy-in from a group with less structural power but high connectivity to the patient group. Pilot programs should focus on high return on drug cost and/or patient need.

## EXECUTIVE SUMMARY

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Medications often go unused by patients to whom they were dispensed. This waste represents a significant portion of healthcare budgets. This waste occurs for various reasons, some of which cannot be entirely eliminated. Presently, Canada does not reuse any medications, which have been held and stored by patients. In the US however, this is not the case. Why medication reuse programs have not progressed in Canada, Nova Scotia specifically, has been the focus of this paper. This was investigated via direct interviews with stakeholders, which were then used compared to the US experience. Stakeholders' responses allowed identification of several differences between Nova Scotia and the US. These included the weakened power of story to motivate change, government disincentive for change, insufficient data, and lack of norms and beliefs. Further to this, a way forward for Nova Scotia is proposed by identifying the best positioned groups, and programs to generate change in this area. However, before pursuing program implementation, further research is needed in the area of waste data collection and patient medical need if such a program is to work in this region.

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## INTRODUCTION

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According to the Canadian Institute for Health Information (CIHI, 2014) Canada spent a total of \$214.9 billion on health in 2014, of which \$33.9 billion was spent on medication. This equates to \$6,045 per Canadian, or 11% of national GDP. Although the growth rate of health care spending has decreased in recent years, healthcare remains one of the largest expenditures for governments. Nova Scotia spends approximately 46% of its total budget on health care, the highest in the country. In the United States, it is estimated 3-7% of medication goes unused and is discarded as waste (Doyle, 2010). If similar estimates are true for Canada, then upwards of \$2.4 billion is being spent on therapies that are not actively contributing to the health and betterment of the population but, rather, are being disposed of as pharmaceutical waste. According to “Shaping the New Pharmacare Plan”, in 2006, approximately half of Nova Scotians were either underinsured or uninsured for prescription drugs. At the time, 24% percent of Nova Scotians had no prescription coverage. Since then, Nova Scotia has implemented universal Family Pharmacare, which extends prescription drug coverage to all residents but is subject to deductibles based on income. It seems logical to pursue initiatives that would reallocate resources, either the medications themselves or spending, to the individuals who actually require them. Attempts to reduce medication waste through trial prescriptions and limited dispensing quantities are utilized by many payers of prescription drugs, but these strategies alone cannot entirely eliminate waste. There will inevitably always be reasons why a patient may have to stop a prescribed therapy, including changes in therapy,



intolerance, cure, personal preference and death. Alternatively, these dispensed medications could, in theory, be redistributed or recycled and given a second life. This approach is not currently utilized in Canada. Thirty-eight American states do have laws permitting some version of redistribution, with several having operational programs. In Canada, there is only one notable exception, at Inner City Health in Ottawa (Doyle, 2010). It is not clear if this program is still operational. Current provincial regulations prevent the redistribution of medicine from one individual to another. Nova Scotian regulations only permit the reuse of medications within special care homes (Nova Scotia College of Pharmacists [NSCP], 2006).

Many industries are focusing on “greening” their supply chains and production processes, as doing so can prove to be even more profitable, an idea that was thought radical not too long ago (Porter & Van Der Linde, 1999). In addition, some industries are focusing on reverse logistics for environmentally-conscious and financial reasons, as they are now realizing not all products are necessarily at the end of their life cycles after the initial consumer (Tibben-Lembke, R. S., & Rogers, D. S, 2002). For medications, the reverse logistics of how one would repurpose the resources is undoubtedly a complex issue, but preceding this is the necessity to garner local validation and support for medication redistribution as a novel approach to recouping the value from these resources. The medical field, as in law, architecture and engineering, contains many professionals with protected titles. These same health care professionals operate in a regulated environment, albeit a self-regulated one, whereby practice standards are determined by a

cohort of the profession's own members. The NSCP, a self-regulating body, develops regulations dictating what practices are legal in the dispensary realm. Its mandate is: "Governing the practice of pharmacy in Nova Scotia in the interest of the health and well being of the public". The NSCP does not support or allow medication redistribution. The question of how one changes the current regulation requires thorough analysis, and one must borrow literature from other disciplines outside of the medical field, as rational arguments alone, based on improved efficiencies, have not driven new policy development in this area.

First, I examined the United States and its existing laws and programs in this area. The United States is often used as a comparable counterpart to Canada in medicine and culture, but in this area of medication redistribution, there seems to be a fundamental difference in values and beliefs. A historical examination of policy emergence, the mechanisms by which these policies gained support and the current state of these policies should depict a model whereby these policies garnered the local validation necessary to see them pass through law.

After gathering information on the United States, I looked to literature to help explain the process of change throughout the states. This review included analysis of stakeholder theory, institutionalization, institutional entrepreneurship, legitimization and challenging the status quo within government organizations. Together, the lessons learned from the literature and information gathered on the US could not only help identify where Nova Scotia is in the change process but may also help shape a more compelling argument for how Nova Scotia could pursue this initiative going forward.

Finally, after reviewing the literature and policy in the United States, I tested the model through interviews with key stakeholders in Nova Scotia to affirm whether it is transferrable and valid in the Canadian context.

## SURVEY OF US STATE PRACTICES (1997-PRESENT)

An Internet search with search terms such as “drug recycling”, “repository”, “medication reuse” and “medication waste” reveals that the United States is leading the way in drug redistribution. Although success across the various states is uncertain, the country has fundamentally embraced and accepted the spirit of the law, with at least 38 states having adopted some version of redistribution. (Cauchi R., Hanson, K. (2012)). This difference in acceptance of practice between the US and Canada is of interest. Following the progression of the laws up to current program status should reveal a pattern of behavior and decisions, explaining the inter-country disparity and how similar programs might be exported.

The medication redistribution systems from state to state can vary considerably. Upon analyzing the states, there seems to be four schemas for medication reuse systems: 1) Return and reuse permitted only from one institution to another, where a health care professional is continuously responsible for the medication and where there is no direct patient contact; 2) The donation and reuse of medications, from institutions to patients in need; 3) Only cancer-related medications are allowed for reuse; and 4) Open systems allowing any institution or individual to provide medications for reuse. A handful of states do not appear to have any laws permitting reuse of any kind, or the data was unattainable. On the surface, the logic for each system appears to stem from the motivation for the law itself.

In a closed system, where there is institution-to-institution reuse, the focus is on reducing costs and risk, as it is a mechanism for allowing return transactions within a regulated system. The closed system is a sensible extension of current distribution and may be the easiest to convince third parties of, based on its merits and safety. This system requires little restructuring or investment to implement.

Cancer medication reuse systems are unique in that the programs are open systems, but only for this specific disease state. The significance of cancer as a chosen system may be attributed to the high burden of the disease, due to the disproportionately high costs of therapy, the pervasiveness of cancer and the reach it has in a population and the emotional connection cancer stirs in individuals, as evidenced by the multitude of charity events and runs. This begs the question: Could other disease states, with similar characteristics, secure the same legitimacy for a drug donation program? Chronic diseases like diabetes and cardiovascular disease also carry high financial burdens and are endemic, but they are dissimilar based on their chronic nature and are less visibly connected to community-sponsored events.

The open systems allowing for all disease state reuse from any source appear to ascribe to the philosophy of medication recycling, perhaps as a rational approach to reduce costs, because it is the moral or right thing to do or as a means to reduce environmental impact and/or patient burden.

As varied as the laws are from state to state, their structures are equally diverse. Initially, government regulators enact the laws, and the procedural guidelines are delegated to state pharmacy boards. The majority of programs share a few

common characteristics: medication destined for reuse must be in a tamper evident unit dose pack and must bear the expiry, controlled medications are exempt, medications must not be expired or about to expire, participation in the program is voluntary, medications are donated to underprivileged populations at little or no cost, recipients must have a valid prescription to access donated medications and administrators of the program are exempt from liability as long as they acted in good faith. With few exceptions, most drug donation sites that accept and distribute medications in the programs are sporadic and uncoordinated, as participation is voluntary. With multiple repositories, matching donated medications with recipients has proven difficult. Recognizing these challenges, California-based SIRUM (<http://sirum.org>), an external non-profit organization, harmonizes the donation, communication and delivery between participating licensed healthcare facilities. In 2014, California passed additional legislation allowing intermediaries, such as SIRUM, to administer the drug donation program (California State Legislature, 2013). Iowa established a non-profit organization, under contract with the Department of Health, to run the state drug donation program. Iowa is one of the few states that has captured data on their program, making evaluation possible. From 2007-2015, the Iowa Prescription Drug Corporation ([www.iowapdc.org/drugdonationrepository.aspx](http://www.iowapdc.org/drugdonationrepository.aspx)) reports donations worth \$13,100,000 being distributed to 47,000 patients. Although drug repository legislation has existed in America for over 12 years, even the most extensive programs could be considered small in scale. Beyond

original legislative bills and dated articles, it has proved challenging to obtain information on the current status of programs.

Each state pharmacy board was contacted via email in an attempt to gather the most up-to-date information. Approximately half (26) of all requests received a response. The lack of awareness and availability, along with the restrictions placed on drug donation, severely limit eligible medications in the current drug distribution system and may in part contribute to the lack of uptake by both donors and recipients (Conis, 2009). Pharmacy participation has been slow in some jurisdictions. One article reported CVS and Walgreens as claiming their non-participation was due to concerns over public safety surrounding unknown drug storage (Harasim, 2011). The superior vigilance of these pharmacy banners within the permissive regulatory environment leaves room for skepticism, where lack of participation might, in reality, be due to the absence of a profit incentive. Importantly, no documented case of patient harm could be found. The article cites pharmacies as still having liability concerns, even though the law describes immunity when the program operates in good faith. Another report cites the lack of compensation to the voluntary program as a barrier to participation by profit-centered businesses (Conis, 2009). The variability in laws and practices suggests there is no “best practice” model. Excluding Iowa, the absence of performance measures indicates efficacy is not as important as the principles behind the programs. This may also be due to that fact that State Pharmacy Boards charged with developing the procedures didn’t appear to be sources of advocacy for the change. The public, government officials and non-profit organizations, such as

state cancer societies, were the primary sources of advocacy. This dichotomy presents a challenge for new states and countries hoping to install new redistribution programs. The drive for policy change can successfully come from outside the medical profession, but without the full support of the medical community, the policies fail to realize their full potential.

The earliest law was approved in 1997, and the laws have continued to evolve over the last 17 years. The first law in Georgia used strict provisions on medication reuse, only allowing reuse from long-term care facilities. Louisiana, in 1998, Connecticut, in 2000, Oklahoma, in 2001 and Montana, in 2001, all followed as conservative early adopters of medication reuse through long-term care homes. In Ohio, in 2002, the first true drug repository program was established, where medications could be donated and given to eligible residents of the state. This law marked the turning point in US state laws on medication redistribution. During 2002-2003, Florida, Massachusetts and Louisiana followed suit on drug repository programs. In 2005, 21 states put forth legislation on the topic, a further 25 states in 2006 and 15 more in 2007. From 2008 to present, states considered further legislation, and many expanded current programs (Cauchi & Hanson, 2012). From this timeline of state legislation, Ohio is identified as a pivotal state in validating the concept of medication recycling. Retrospective review also shows many states as having started with allowing small initiatives or pilot programs before authorizing broad-based programs, and laws were expanded incrementally. The pattern of state uptake shows a rapid pattern of diffusion from 2005-2009, where legislation was at least put forth in most states. This suggests



the local validation in one state was in part transferrable and granted renewed local validation in new environments.

As explained by the Ohio organization Serving Our Seniors (<http://www.servingourseniors.org>), the driving force behind Ohio's approval of the law was a man named Garry Beltz. Mr. Beltz lobbied lawmakers in the state to allow such a law after he realized he would not be permitted to donate his late wife's cancer medications. In 1999, the value of these medications were said to be approximately \$6,700. Then republican senator Kirk Schuring took up the cause with Beltz and saw "Karon's law" pass in 2003. This advocacy on Beltz's behalf illustrates the unique power of a story and how it gave this problem meaning. Ultimately, it was powerful enough to inspire action. Mr. Beltz has continued to advocate for drug recycling in other states.

A detailed policy analysis by Health Policy Monitor breaks down the evolution of the 2008 Cancer Drug Repository Program Act in Pennsylvania. The report cites drug recycling as being a politically popular policy and one that generally receives bipartisan support. The report says the policy was called to attention because of patient demand and a 2001 study, which placed the value of discarded medications at \$1 billion during 2001 in the US. Government, cancer patients and their families, advocates for the impoverished and the American Cancer Society largely supported the bill, while physicians and other medical providers were indifferent. Like Garry Beltz, Micheal Neal, the husband of pancreatic cancer patient Sherrie Neal, reached out to the American Cancer Society and lawmakers

when he realized his wife's medication, totaling \$16,000, would go unused by her (Conis, 2009).

From a review of the US states, themes regarding policy development and change in this area have emerged. Political motivation was a key factor for change, as the largest proponents of the change came from government officials' greatest stakeholder, the public. A detailed analysis of each state's political reality at the time of its bill's introduction is outside the scope of this paper, but it would be interesting to investigate whether there were correlations between legislation outcome and party power by examining a historical electoral map. In keeping with the innovation model described, the spread of policy appears to have occurred through imitation, learning from those before and the use of pilot programs by various states. Most important are the use of impression management and legitimacy. Impressions relied heavily on story, and symbolism focused on helping others and connecting with the public in a way that enabled it to sympathize with pain and suffering. Further, the conscious or unconscious decision to use the words "drug repository", "drug redistribution" or "drug donation" stood out. No official reports used the language of "drug recycling". Linking these drug programs to existing classical recycling models may have granted some legitimacy, based on environment and cost-based arguments, but it may not necessarily have been enough to supersede concerns about safety or to inspire public action. The efficacy of such an alternate strategy is thus unknown. At least two states used the term "Karon's law" to draw on the story of Karon Beltz, forever connecting the story with the motivation to act. The idea of legitimacy was integral to the

successful spread of these policies. State consideration on donation laws quickly spread after the first few states. Even though some states did not initially pass proposed legislation, it may have seemed illegitimate to not even put forth a bill. This mimicry led to state legitimacy on this topic, even if it wasn't adopted. It may be hypothesized, as a successful practice emerges for this program, that the different states become more similar in their drug donation program strategies.

## RESEARCH QUESTION

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This project asks three questions. Of the programs that exist, how are they characterized? Is there an evolution or pattern of program progression? Does this pattern apply to Nova Scotia? After reviewing my data collected directly from the 26 boards of pharmacy, Cauchi (2012) and other research outlined in the Survey of US State Practices, a pattern for securing new validation for drug redistribution in new environments is proposed and will be tested in the Nova Scotian field. Table 1 shows the four types of programs as categorized across two different domains: system and scope.

*Table 1: Program Classifications*

<b>System</b>			
		Open	Closed
<b>Scope</b>	Broad	Population Approach	Extended Systems Approach
	Focused	Individual Approach	Systems Approach

System was considered to be either Closed or Open, depending on whether medications remained within or left controlled distribution environments. Scope was defined as either Focused or Broad, depending on which entity was the final

recipient of the medication. Justification and description of each program follows in more detail.

### **Closed-Focused Program**

Preceding the laws allowing recycling programs, there existed regulatory framework allowing reuse from institutions where there was no direct patient contact. This controlled system reduced waste to the public and to private payers, while also offering a high degree of reassurance and due diligence from the view of patient safety. This concession likely derived from a cost-based argument, as medications could then be returned for credit. This regulation offered a natural reference point for progressive recycling regulations. It is classified as a Closed-Focused Program from a Systems Approach. It is Closed because medication remains within the controlled confines of a distribution channel, outside of direct patient contact. It is Focused because this system simply allows for the return of unused medication back into inventory and not donation. Although there is nothing to prevent donation in this context, it is not the aim of the program. The intent or motivation behind the program allows us to call this a Systems Approach, whereby the goal or success of the program focuses on the betterment of the system that is the institutions involved in the sale and return of medications.

### **Closed-Broad Program**

An extension of this is the Closed-Broad Program, where the same medications are donated and are given to those in medical need. This program also operates within a controlled environment, where medication never leaves the distribution

channel. This program considers the greater needs of the population but still confines its operations within existing systems and thus implies the importance of maintaining the integrity of systems above all else. This motivation keeps this program under the Systems Approach. The Extended Systems Approach matches unmet patient need to waste within existing system operations.

The existence of these first systems is important for setting the framework and concept of medication reuse under a controlled, but less-tightly controlled than previous systems, environment. The idea or concept of being able to treat medication like other recycled products is introduced. This change hinged on a logical, or fact-based, approach to medication management from a system basis, where the focus is not on individual need but, rather, the system's needs to dampen costs or reduce waste. Legitimacy was swift, as this practice would have been in line with existing norms, values and beliefs surrounding waste, it would have been done in such a way that people would have believed it could be done safely and it had the support of regulative legitimacy.

### **Open-Focused Programs**

The factor input for true reuse programs contrasts from the first reuse programs in the institutional setting. Here, both power and story aligned to shape the current thinking on medication reuse. It's not clear if one of these inputs alone would have been enough to push legislation forward. Individual patient stories were not just narratives that evoked emotional responses but were bolstered by facts on drug costs and environmental waste. Power sourced through government representatives and patient advocacy groups successfully championed the idea.

The ability to provide dollar values for the high cost of cancer treatment, along with the number of those affected by cancer, legitimized the idea. Unlike the institutional return system, the impetus for change was a specific case with a narrow focus on cancer's burden. The reallocation of medication to subset populations, like the cancer field, is classified as Open-Focused Programs from an Individual Approach. This is now Open, as opposed to Closed, because patients themselves can donate medication that has left distribution channels. This point is the most revolutionary aspect of the program, one that significantly challenges status quo and risk tolerance levels. This program remains focused in its use, for cancer patients only. The motivation stems from a desire to help individuals with their cancer burden and, thus, is classified as the Individual Approach, which aims to help the individual rather than the financial burden on the medical system.

This new type of program is best classified as institutional entrepreneurship, where innovation in the medical realm was realized because of unique subject positions and their ability to connect stakeholders through stories that appealed to collective values. From the survey, it appears Open-Focused Programs have gained at least local validation and some diffusion but not yet general validation or status quo. The adoption and legitimization of these programs was important because the framework for medication redistribution rapidly expanded after this was established. After acceptance of these programs, the idea began to spread to other states, which found their own status quos beginning to be challenged. Across the US, states found themselves having to decide whether or not to adopt

and implement these new programs. As the status quo was being challenged, groups began to expand this new way of thinking into the final and current phase of redistribution programs. The narrow focus on specific disease states opened up the larger conversation about drug access and affordability.

### **Open-Broad Program**

The fourth phase of expanded medication redistribution is defined as Broad-based programs allowing under-privileged persons access to unaffordable medications. This new way of thinking, or “know how”, reverted to broad-based population consideration and a social responsibility to “do good”, all without the use of an individual to represent the group. This model likely gained legitimacy by drawing on cognitive legitimacy, as there already existed models for specific disease states, and drawing parallels between the two models would have been easy. This loosest framework was only made possible by the cumulative changes that came before it. This last change is classified as an Open-Broad Program from a Population Approach. This system is Open, again, because it allows patient returns, and it is Broad because of wide access. Program motivation to indiscriminately help others allows us to say it comes from a Population Approach, as the desire to help others supersedes any regulatory system challenges.

Appendix A summarizes the prevalence of all 4 programs throughout the US. The majority of this data was collected from Cauchi (2012) and state email responses and was sometimes verified through state legislation documents. Cauchi describes 38 states with reuse programs, whereas my summary states there are 41. As Cauchi explains, not all programs are actually operational; in some cases,



there exists only a law enabling such a program. Of the states, 22 were considered to operate in a closed environment and 19 in an open environment outside of the normal distribution channels. As a disclaimer, I freely admit that classifying state programs was, at times, challenging, being based on dated or limited data. There exists reasonable grounds to reclassify states, should new information be made available. It is likely the 7 states not permitting any reuse do, in fact, subscribe to a closed institutional reuse policy, but this could not be included without actual verification. For the purposes of this project, however, this summary provides a rough and reasonable current representation of the state of drug reuse in the US. The spread of program structures shown in the summary and map illustrates drug reuse programs across the US are generally diffuse but not yet homogenous enough to be claimed as a new status quo.

Figure 1: US Medication Reuse Programs Mapped

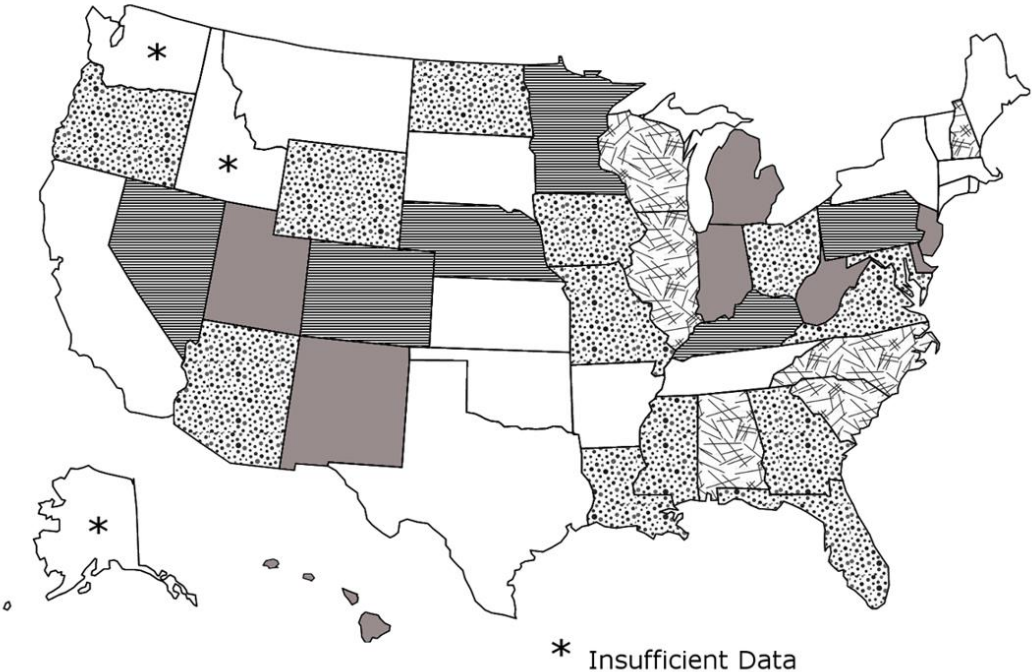


Figure 1 shows the same data, but mapped visually. The programs are identified by the following: **Shaded** - Closed Focused, **Blank/White** - Closed Broad, **Dots** - Open broad, **Lines** - Open Focused and **Crosshatch** - No programs.

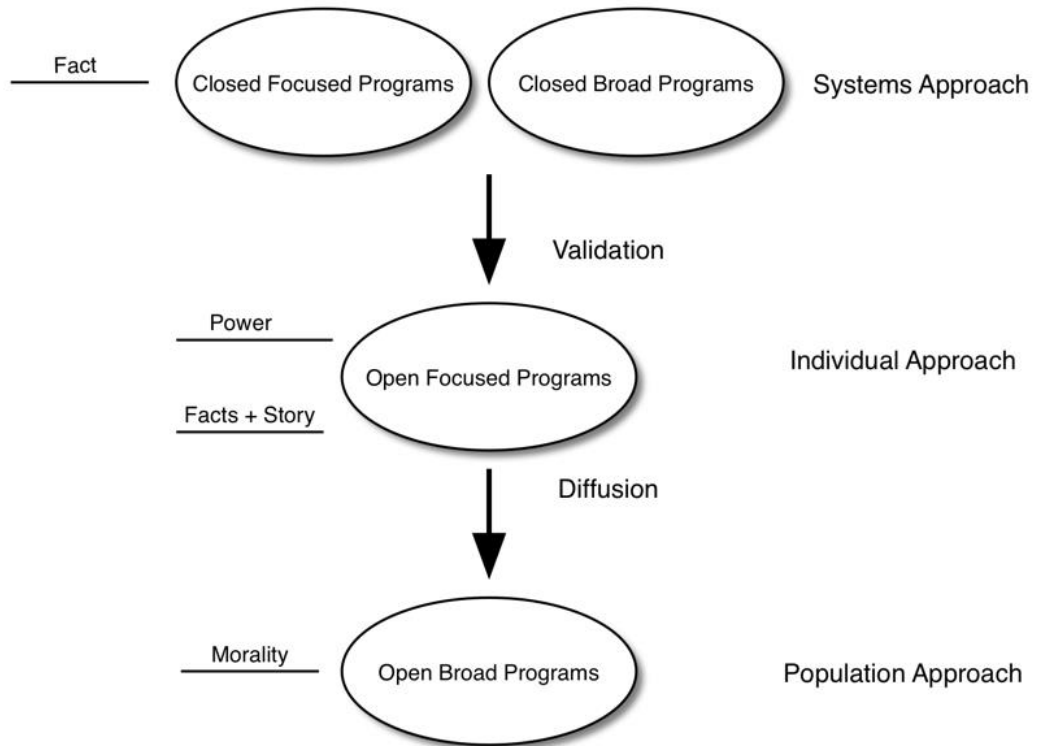
Table 2 summarizes how each program input drove arguments towards program implementation and subsequent program outputs or goals. These inputs are described as factors that drove program development whereas, the outputs are the appeal to a higher motivation or desire for supporting change. This, along with program classification, build the basis for the model described next.

*Table 2: Program Drivers and Outputs*

<u>Program Type</u>	<u>Driver Input US</u>	<u>Goal Output US</u>
<b>Closed Focused</b>	Facts on Waste	Reduced Medical System Costs
	Controlled Environment	Low Risk
<b>Closed Broad</b>	Controlled Environment	Lower Risk
	Medical Need	Moral and Ethical Appeasement
<b>Open Focused</b>	Patient Story	Increased Stakeholder Engagement
	Agent Power	Challenge Status Quo
<b>Open Broad</b>	Medical Need	Moral and Ethical Appeasement

Figure 2 models these four programs with their inputs, as described in the US summary and research question. It synthesizes the program definitions, classifications and inputs into one cohesive model. This model represents the working model that was used to interview Nova Scotia representatives.

Figure 2: Proposed Medication Reuse Program Progression Model



## SURVEY OF WASTE IN NOVA SCOTIA

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While pursuing the qualitative answers to the research question, it was important to gauge the potential scope of opportunity for a program in Nova Scotia. Is Nova Scotia large enough for such a program to matter? What is the extent of waste in Nova Scotia that could be reclaimed? After consulting with government and conducting a literature review, it appears there is no real data on the value of medication waste in NS specifically, but there exist only estimates on a national level. Does Nova Scotia diverge from national estimates of medication waste? To help answer some of these questions, from June 2014 to November 2014, the value of patient returned medications was tallied at one community pharmacy.

A larger, but similar, study was conducted in Ontario in 1995 by 29 pharmacies over a 4 month period after the Sudbury and District Pharmacists Association ran a medication take-back campaign (CPJ, 1997). Cardiovascular, pain, endocrinological and neurological medications made up the largest proportion of returned medications. The authors concluded the \$67,000 recorded during the study was representative of over \$500,000 to the pharmacies and \$40,000,000 for the province. Unlike this study, there is no apparent data specifically for Nova Scotia in the literature. The provincial drug disposal contractor was contacted for total disposal waste metrics, but these were not provided. The cost to dispose of 1kg of drug waste is \$2.10, and Nova Scotia spends over \$200,000 per annum on medical disposal, as provided by the Pharmacy Association of Nova Scotia. There are obvious limits to interpreting this small sample of one, but it helps frame whether this area requires further research. This small survey may motivate Nova

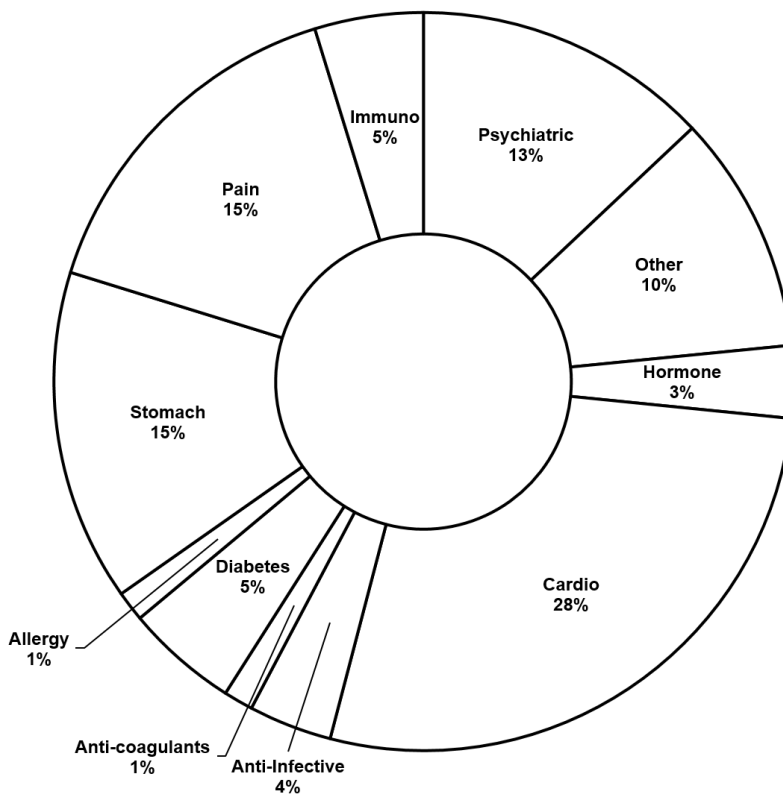
Scotia policy makers to launch a larger study to more fully understand the nature of medication waste in the province. This data may have applications beyond medication redistribution.

No narcotic or controlled substances were included. Only those inhalers, injectables, nasal sprays and topical products that were unopened were included in the data. The rationale being no current redistribution programs allow the inclusion of controlled substances, and sprays, ointments etc. are not divisible. Loose tablets were included and would necessarily elevate the value of potentially “reusable” medications, even though they did not have lot numbers or expiries. However, these were included for two reasons: First, to get a realistic sense of total waste or potential reclaim value, and second, actions can be taken to safeguard these tablets at the point of initial distribution. Drugs were classified into 11 broad categories, based on trends seen during collection. These classes were as follows: psychiatric, hormone, other, immunological, cardio, anti-infective, anti-coagulants, diabetes, allergy, stomach and pain.

Figure 3 shows the proportion of the total for each class of medication collected. Cardiovascular medications made up almost one third (28%), with pain (15%), stomach (15%) and psychiatric (13%) medications also making up a significant proportion. The total number of units collected was 32,731, with a value of almost \$34,000. The value was calculated at pharmacy purchase cost, not patient cost. Applicable pharmacy markup and dispensing fees would make the actual value of these medications much higher. Factoring in a conservative customary markup (i.e. 8%) only, the value increases to \$36,720. The dispensing fee is not factored

in, as it would be sheer speculation to estimate how many prescriptions the total number of units originally represented, and therefore, extrapolations on the data still remain conservative.

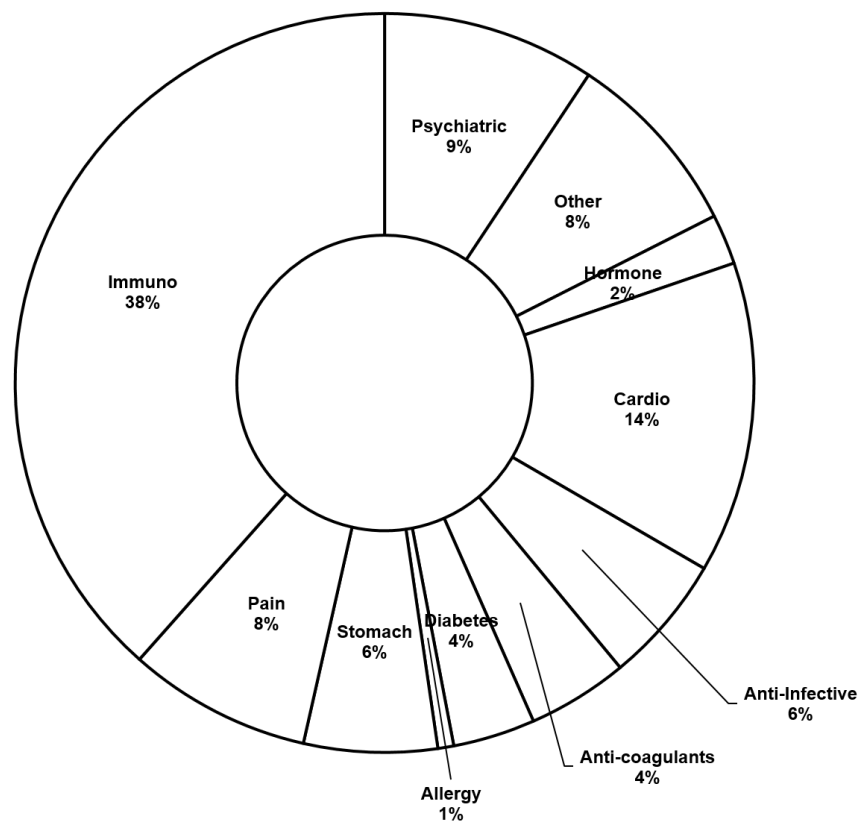
Figure 3: Proportion of Medication Waste by Drug Class



Next, Figure 4 shows the proportional value of each class to the total value collected. It was important to consider whether the number of units and the associated value of the units matched. This is a potentially important point for policy creation and implementation. Is the value of a redistribution program found in reducing the overall cost to the system, or is it found in improving access and waste reduction through reallocating the greatest number of units? Here, immunosuppressants made up 38% of the total value, even though they only

represent 5% of the total number of units. This type of disparity stands out as an obvious area for prioritization, where a reduction in this type of waste may give the greatest return. Cardiovascular medication still made up a large proportion of total cost, at 14%, but it's still significantly lower than the 38% it made up in units. The remaining classes were somewhat evenly distributed.

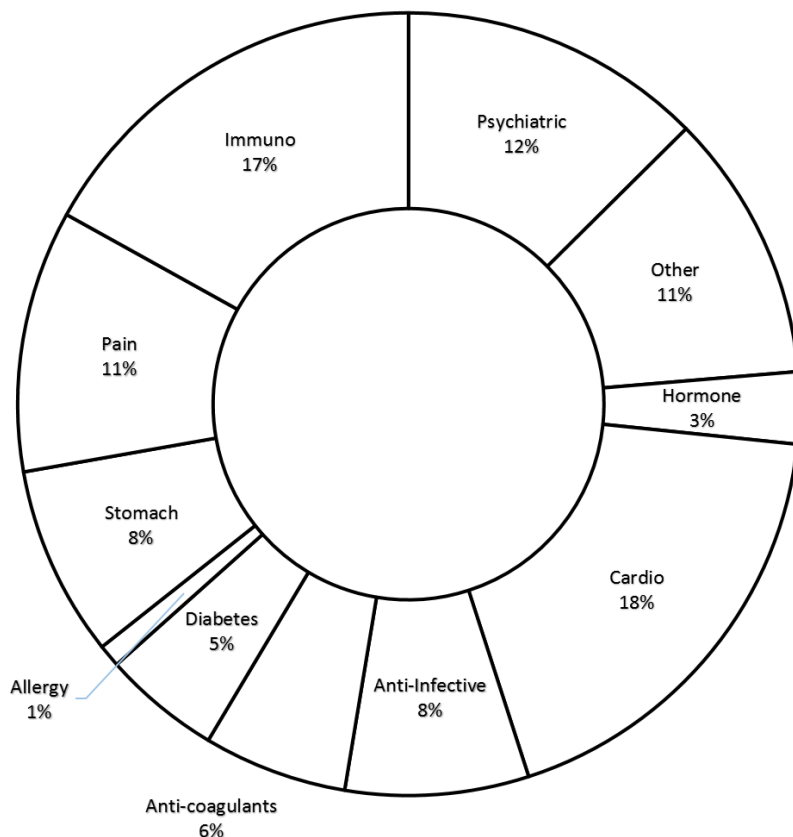
Figure 4: Proportional Value of Medication Waste by Class



The immunosuppressant cost, of the biological specifically, far exceeded other medication cost and made it difficult to meaningfully interpret the data. Another analysis was done with this data removed. When this was done, a more balanced picture emerged, as seen in Figure 5. Here, even though certain classes made up larger percentages of the unit total, the values of these same classes were

fairly evenly distributed. This would support a non-preferential approach to class inclusion for a distribution program aiming to reduce overall system costs.

Figure 5: Proportional Value of Medication Waste Excluding Biologicals



Similar to the Ontario study, a rough extrapolation can be made in an attempt to estimate the waste in the Nova Scotia. Unlike the study in Ontario, no official campaign was being conducted during the period of this collection, and the rates of collection can be assumed to be more reflective of the natural state of return. There are 304 retail pharmacies in Nova Scotia, as provided by National Association of Provincial Regulatory Authorities (NAPRA, 2015). Data on the number of patients each pharmacy serves was not available. Although the test pharmacy used to collect this data is considered to have average, or slightly



above-average, pharmacy volume, the estimates should average out and are exceedingly conservative, as the final estimate will not include hospital, practitioner or long term care facility waste. The \$36,720 collected represents known actual waste of \$26,790,000 on a value basis for the retail sector of Nova Scotia. The Ontario study also estimated approximately 56% of patients disposed of their medications by alternative methods, and Statistics Canada estimated a similar number in 2005, of 50%, as the percentage of people who returned stale medications to a pharmacy or depot (Gagnon, 2009). Using this estimate, the valuation may actually be double, at \$53,580,000. This number is significant for Nova Scotia, as it potentially represents a good proportion of the publicly-funded drug budget. Nova Scotia Pharmacare was contacted to obtain the most recent budget, but the contact was unable or unwilling to provide this information. From publicly available resources, this budget can be estimated to be almost \$1,000,000,000, where the per capita spending is quoted at \$1080, with the last official population estimate from Statistics Canada (2011) at 921,727 residents (McLeod, 2013). Therefore, the value of the waste collected in this small study represents 5.4% of government drug spending, an amount that may warrant further attention, whether the focus is on reducing the waste at the front end or back end of the product life cycle. This estimate does not include waste from institutional and industry settings. The estimate from this small survey is in line with national estimates of drug waste, as provided during this introduction.

A more in depth analysis is required to validate the findings herein, but, if true, this \$53 million naturally seems like an area of healthcare funding that requires

attention. While there are different measures that can be taken to reduce the formation of waste, not many alternatives exist for the waste that has already been created. Invariably, waste will always exist and it cannot be fully eliminated but a medication reuse program can reclaim this value for continued patient use. Similar to Nova Scotia, Prince Edward Island and New Brunswick do not appear to have data on their waste but can be reasonably assumed to follow a similar pattern. This is important to consider because the size of Nova Scotia alone may not be enough to offset program administration costs and this project may require multiple provinces working in cohort. Taken together, the Maritime provinces' waste could be combined to supply both drug diversity and volume to form a sustainable drug repository depot for its citizens.

## LITERATURE REVIEW

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Next, I looked to academic literature to better understand, and find support for, the program model outlined in Figure 2. Literature specifically examining the merits and effectiveness of medication recycling was lacking. This forced contemplation of the social concepts from other contexts and disciplines. Importantly, the idea of reusing medication is still new, and there is a lack of consensus on its place in the medical field. For this reason, I looked for academic papers explaining the idea of legitimacy and how something gains legitimacy. Of particular interest were how a new idea begins to build legitimacy and the change process. Balanced with this was an interest in how new ideas displace existing ways of doing things or the “status quo”. Studying how this phenomenon occurs in especially structured settings, like healthcare, was key to understanding the research question on medication redistribution.

### **What is Legitimacy?**

The question of how something gains legitimacy has been thoroughly explored in the literature. One of the earliest definitions of legitimacy by Weber (1924) explains an action as being legitimate if, on the whole, it is in line with the generally accepted rules of the society. The rules of the society are formed out of the collective norms, values and beliefs. Important to this definition is that an individual need not ascribe to the collective system, but need only believe that most others do (Johnson, Dowd, Ridgeway, Cook, & Massey, 2006). It stands to reason, then, that as social realities differ across populations because of

divergent values, norms and beliefs, what is considered legitimate will also differ. How an organization or idea obtains legitimacy is important in this context because not only is there a new concept here requiring legitimacy, but, from this, a new intermediary organizational form may emerge to facilitate drug donations. Scott (1995) defines three sources of legitimacy more precisely as regulative, normative and cognitive. Regulative legitimacy may come from government or others who have a capacity to confine the organization's activities. Normative legitimacy stems from individuals or groups who determine what is morally right or the "norm". Cognitive legitimacy is the presence of other like-organizations or alignment with existing patterns of thinking (Johnson et al., 2006).

### **What Makes Something Legitimate?**

Deepphouse (1996) tested whether strategic similarity, or isomorphism, between organizations confers legitimacy on the organization, as suggested in institutional theory by DiMaggio and Powell (1983) and Meyer and Rowan (1977) (Deepphouse,1996). This study found evidence supporting this link among commercial banks in Minneapolis. Banks using similar strategies to other banks were observed to have greater legitimacy. This observation also explains how new entrants can quickly gain legitimacy, but it can't necessarily explain how new innovations gain legitimacy when there are no successful comparators to mimic.

Brown (1994) examined the role that symbols, politics and myths play in gathering legitimacy. This study evaluated how a junior subsidiary of Sugar Inc. was conferred legitimacy after embarking on a new project to market and sell confectionary on behalf of a contracting company, Candy Inc. In this case, it was

noted self-interests played a role in delegating the project to the junior team and that the success of the junior team served to reinforce the director's strategic direction for the parent company. The study found that facts and outcomes, as a rational approach to decision making, were less important to the project's progression than the symbolic gestures employed by the team. The team conducted two market research surveys to identify their target markets and found the results ran contrary to their beliefs. Instead of discarding the surveys, they were able to omit some results and highlight others that were more self-serving. The team managed these symbolic surveys via manipulation and strategic emphasis of the facts, which directly influenced how events were interpreted and, ultimately, supported by others. Further, the team continued to perpetuate the myth that the project had been pursued with objectivity and rationality, even though evidence ran contrary, as a means to preserve their self-image and interest (Brown, 1994). This small study of legitimacy building lends itself as a bridge between institutional theory and politics. The legitimization of medication redistribution is, in part, political, and understanding the role of stories and symbols and how they connect to self-interest provides necessary insight into this process.

### **What is the Process to Become Legitimate?**

The process of gaining legitimacy for a new innovation is described by Johnson (2013) as having four discrete stages: innovation, local validation, diffusion and general validation. An innovation originates out of a need or as a solution to an existing problem. The innovation, being new, may not immediately fit with the

existing values, norms and belief systems, but it is the job of the developer to find a way to link it if one is not readily apparent, or at least to ensure it is not questioned. If the individual is successful, the innovation can be said to have local validation. This local validation may then diffuse to new locales, where it is likely to be more readily accepted than in the first location because it is already considered valid. The process continues with diffusion, happening more easily and quickly than in previous locations until, eventually, there is general validation, and it becomes the new status quo (Johnson, 2006).

### **How does one Change Status Quo in Highly Institutional Settings?**

Changing long-standing systems or ways of thinking known as status quo can be difficult in institutional settings. Several examples of how institutional entrepreneurship occurs were collected from the literature. Maguire (2004) reviewed the evolution of HIV/AIDS advocacy in Canada, from local AIDS service organizations comprising both treatment activists and pure AIDS activists, to the current formal national body, Canadian Treatment Advocates Council (CTAC). This new body was afforded legitimacy and power not previously known by the AIDS service organizations. Maguire found subject position, theorization and institutionalization integral to the change. Those individuals responsible for enacting change possessed legitimacy because of their connection to varied stakeholders, and they were able to connect these stakeholders. They were successful not necessarily because of any power, but because of their relationships. AIDS advocacy and the disease itself were new at the time, and there were no clearly established roles with formalized power. Individuals were

said to use theorization to create rationalizations or arguments that would simultaneously appeal to different stakeholders, while also using bargaining, compromise and negotiation to establish new coalitions. To secure the legitimacy of the new CTAC, it had to be institutionalized. This occurred by mimicking other institutional procedures, such as incorporation, annual reports, audit procedures and professional activities. In addition, the CTAC's values appealed to the values of its various stakeholders by appearing balanced between collaboration and confrontation, as opposed to previous heavily confrontational approaches. This new form of advocacy was the new norm and became institutionalized through the CTAC (Maguire, Hardy, and Lawrence, 2004).

Lockett, Currie, Waring, Finn and Martin (2012) examined institutional entrepreneurship using 4 case studies by considering individual structural (formal power and hierarchy) legitimacy and normative (trust, reputation and relationships) legitimacy as factors to successfully incorporate genetics services within cancer care in the UK. This study adds to this analysis because, unlike HIV/AIDS, it was not an emerging field but one where structures and procedures were already clearly defined and established. Unlike with HIV/AIDS, the relationships and roles of individuals could be ranked along a spectrum, from low to high, for structural and normative legitimacy. The authors concluded those with the highest structural legitimacy are the least likely to seek and pursue major institutional change because doing so may threaten their position and power. These same individuals may facilitate change if the change further reinforces their existing structural privileges. In contrast, those with low structural legitimacy are

the most likely to seek major change because they hope to achieve a shift in power and resources. In the absence of structural legitimacy, these individuals rely on normative legitimacy. The individual in this case study used language and drew on legitimacy from becoming a “patient voice”. This may have been done in the hopes of borrowing some of the legitimacy found in more powerful patient stakeholders. In reality, the study concludes these individuals find it difficult to achieve the change they seek because of the threat they present to those with high structural legitimacy. Therefore, the author hypothesizes, the group most effective in producing change is that with medium structural legitimacy, as it is not entirely privileged under existing systems and may be in a better position to consult with other stakeholders. Consultation with other stakeholders further builds on any existing normative legitimacy and both forms of legitimacy work in cohort to produce the desired change (Lockett et al., 2001).

### **How Should Stakeholders be Managed?**

An active medication redistribution program touches many groups and stakeholders who are impacted differently. Each has varying levels of influence over the implementation of such a program. In this context, there is not a single institution, but rather two that are codependent: government and the self-regulating body. Freeman (1984) focused on stakeholder theory or management from an institution’s point of view, attentive to how the institution can manage these stakeholders so that it may continue to pursue its goals. His work says the institution should identify the stakeholders, understand what it is they want and consider how they may obtain it. Mitchell et al. (1997) identified stakeholder

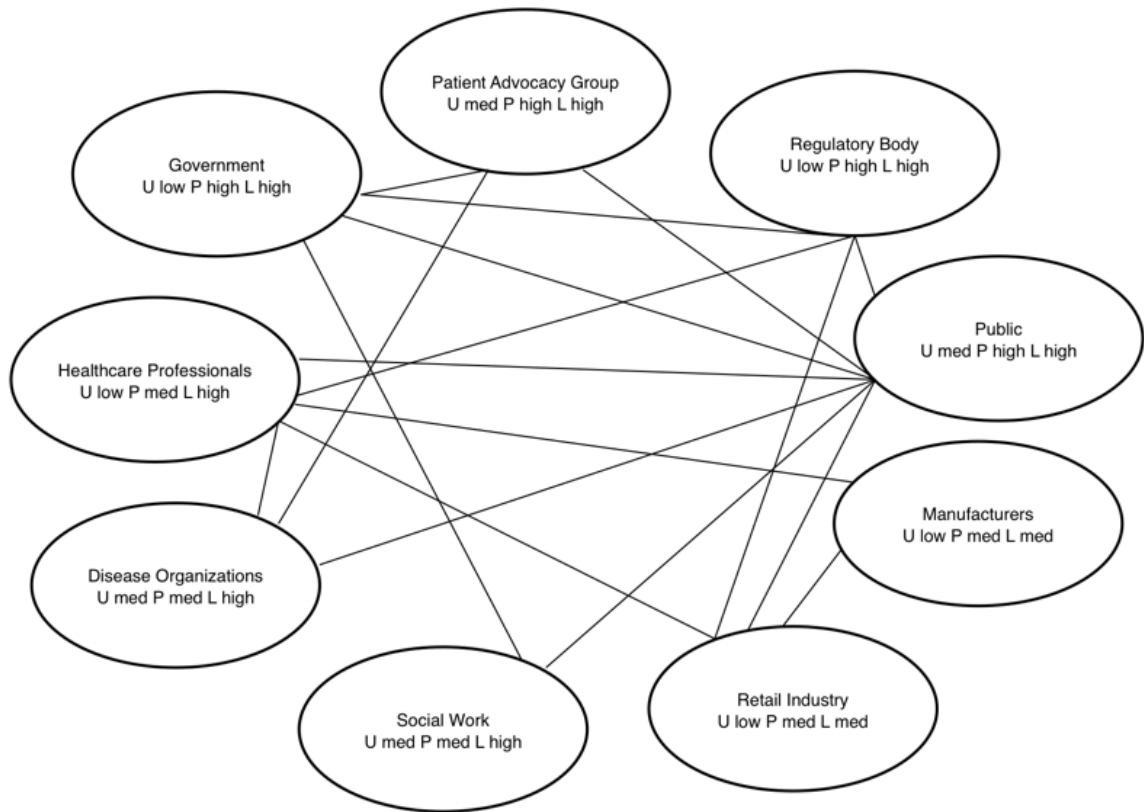


urgency, legitimacy and power as important attributes institutions consider when prioritizing stakeholders. Those ranked highest among these are traditionally thought to deserve more attention, so as not to impede or block the institution's pursuits. The goal of medication redistribution is not originating from within the institution, but from outside, and, therefore, traditional stakeholder management will not suffice. More useful is the work by Frooman (1999), which expands on the relationship between stakeholders and institutions via an analysis of Starkist, their consumers and the Earth Island Institute. The relationships here are classified based on the degree of interdependency and power between the institution and stakeholder, as a means to deciding on the most effective influence strategies to be used by the stakeholder on the firm. Frooman moves away from the linear "hub and spoke" stakeholder-institution relationship dynamic to include the relationships stakeholders may have with other stakeholders and how these may ultimately connect back to the institution. This model is especially important for those stakeholders with low interdependency and power with an institution but who would nonetheless like to influence the institution (Frooman, 1999). Stakeholders wishing to seek policy change by the NSCP and government may deploy the influence strategies of indirect/direct or withholding/usage as appropriate, according to their relationship with these institutions.

Figure 6 identifies some of the largest stakeholders having an interest in whether a medication reuse program were pursued in Nova Scotia. There are undoubtedly some groups missing, but the groups identified are hypothesized to be the most important. Each stakeholder is rated low-high on three attributes: urgency,

legitimacy and power. There are no groups left unconnected in some capacity. These ratings are somewhat arbitrary and arguable, as they are based on author opinion, but, nonetheless, the diagram shows a multistakeholder environment marked by relatively high stakeholder power and legitimacy with med-low urgency. Assumedly, this makes innovation difficult, as many groups have sufficient power to block innovation. The innovation itself may represent a risk to stakeholder structural legitimacy, thus making change a disincentive. These groups show high connectivity, where independent action is difficult without consensus. Where groups lack independent power, they may still have effect by influencing other groups with more direct power linkages. Interestingly, the public, in this context, has the highest connectivity. This may be because the public represents such a large and potentially diverse population with multiple interests. For the same reason, it may be difficult to find consensus within this group. The “public” can be a heterogeneous group with many different points of view, which can be a support or a hindrance to change. The public are directly linked to each group except for manufacturers. Either the public, or those with strong linkages to the public, are most likely to influence policymakers who hold power to create change. For those without direct links or significance to policymakers, the public acts as an important vehicle for pushing or blocking initiatives.

Figure 6: Nova Scotia Medication Reuse Stakeholder Environment



## NOVA SCOTIA CONTEXT

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The proposed model (Figure 2) was used to evaluate the current climate for a repurposing program in Nova Scotia. The validity of the model itself was also tested. It's not clear whether the same inputs and process would apply in the Canadian healthcare context. A number of stakeholders were interviewed and asked questions relating to the factor inputs of the model. The public, identified as a key stakeholder, was not interviewed due to project time and resource constraints. However, future research should consider the public perspective.

The research and ethics board of Saint Mary's was consulted prior to conducting interviews to assess interviewee risk in participating in the research. The Application for Ethics Review of Research Involving Humans was granted approval and can be found in Appendix D. Interviews followed a semi-structured style and were guided by Patton's (2002) methods on qualitative research. These included such things as avoiding questions with binary answers such as "yes" or "no" and ensuring questions had interpretable responses that could be compared across several respondents. Research planned for six interviews, but only five could be completed due to time constraints. Each interviewee was given, and signed, an informed consent document (Appendix E). Each interviewee agreed to be recorded. Four of five interviews successfully recorded and then were later transcribed. Interview transcripts from the five interviews span 16 pages of text, with a total of 8500 words. Interviews included representatives from: government, a professional regulatory body, a chronic disease management group and a professional association, as well as a practicing healthcare professional with

international experience in medical equipment donation. The groups were selected based on relative connectivity as shown in Figure 6 and availability. Each individual selected had sufficient experience and authority to speak on behalf of the organization but not necessarily experience in the research subject matter. Their responses were then used to evaluate whether the same inputs in the US model would serve Nova Scotia in pursuing this initiative.

The following sections discuss interview responses generally, across several themes. These themes were broken down into organizational issues, logic/fact, morality, validation/diffusion, power and story. A summary table of these themes can be found in Appendix B, where each theme/input is supported with specific interviewee responses or quotes. Appendix C shows these same themes and the interview questions used to assess each one.

### **ISSUES FOR ORGANIZATIONS: 1) Changing Roles 2) Rising Costs**

Interviewees identified a number of key issues for their organizations, with many overlapping themes. Unsustainable healthcare costs, drug price-effectiveness ratio and disease burden were of concern to interviewees. Given the appropriate evaluation and implementation, such a program may be viewed as helping to alleviate drug costs and patient disease burden. One interviewee, involved with redistributing medical supplies, stressed that the medical need is high in Nova Scotia but that it is dwarfed in comparison to needs in developing countries. Although scope and scale differ, the interviewee felt there are parallels between medical supply redistribution and medication redistribution. Some respondents also identified the healthcare system as undergoing a period of change, where

approaches to care and roles are being redefined. Managing public perception and inter-professionalism remain challenges. The interplay between a medication reuse program and these organizational concerns is important to consider, as the concerns may present as barriers or solutions to implementation.

**LOGIC/FACT: 1) Liability 2) Product Integrity 3) Importance of Waste**

To evaluate how facts might support repurposing, respondents were asked about the importance of knowing the value of medication wasted by Nova Scotians. This “waste” was framed as those medications that are distributed for use by individual patients but then go unused, whether due to death, adverse events, non-compliance or changes in therapy. One practitioner reported manufacturer samples and un-creditable institutional supply as important sources of waste. Respondents were told there is no data for Nova Scotia but that there are estimates on a pan-Canadian basis. All respondents identified this information as being important to their organizations, but most would not speak to any threshold that would carry significance, except one respondent, who suggested a 5% built-in waste would be acceptable, citing waste cannot be entirely eliminated. Reducing waste was considered a positive goal. Freely sharing waste data throughout the system with those “fiscally responsible” healthcare providers and patients was considered important to one interviewee. Some identified that once this number is known, the cost would have to be balanced against the infrastructure cost of delivering a program. Having objective metrics were considered imperative to assessing the validity of a new program. Some felt attempts to reduce the waste at the front end through new and existing policies

(e.g. prescription trial programs) may be a better approach. It was surmised these savings should translate into improved patient access through additional medication funding. Most supported focusing on areas where waste reduction would give higher rates of return, such as specific drug classes, end of life, opiate therapy and high cost drugs.

Next, individuals were asked about their concerns or fears surrounding such a program. Messaging was fairly consistent among respondents. The unknown quality and “integrity” of repurposed medications were cited as concerning and, for some, unacceptable. The element of the “unknown”, even with expert product validation, was difficult for some to come to terms with. Some worried reduced quality, due to improper storage and handling, may translate into harm for the patients consuming the medications. How reduced quality would harm patients specifically was not clearly outlined, but some described these pharmaceuticals as potentially being “poisonous” and ineffective. The idea of an unknown individual putting their “hands all over medication” was an unpleasant thought. The inability to track the path of medication through a program was a concern in light of regular manufacturer recalls. This scenario was described as a “potential nightmare”. Expiry dates, pre-packed medications and manufacturer’s storage design (e.g desiccants) were considered mechanisms to support quality and integrity. Despite this, one respondent reports advising patients that consuming medication past expiry dates is sometimes reasonable. Direct experience with poor quality pharmaceuticals and adverse effects was lacking among respondents.

Potential tampering was a concern, where the lay public may be in possession of medication later being supplied for repurposing. The likelihood of tampering was considered low, but the risk, even though small, was considered unacceptable. One case of harm could “kill” the entire project. Some cited parallels between Halloween candy tampering incidents, recent occurrences of Nova Scotia potatoes laced with needles and the risks associated with this project (Taber, 2014). None cited specific medication tampering examples.

Outside of medication-related concerns, one respondent simply stated the fact that this practice is banned as being the largest concern, although two respondents said they have either supported or know of “underground” redistribution. Without regulatory support, practitioners do not have the liability assurance and framework to openly address concerns. Without policy, potential disciplinary action by regulatory bodies would be certain, and individual licensure protection outweighs any moral inclinations to carry out this activity. Another respondent characterized Nova Scotia as being a highly regulated and highly legal environment. Concern for those who may be administering such a program was expressed. Where a program exists under the pretext that medication cannot be 100% guaranteed, there is a legal arena. Despite regulations, providers may be subject to liability should a negative patient outcome occur. Protecting providers was considered important.

Some felt a repurposing program, wherein potentially “lower quality” pharmaceuticals were being used, would segregate care based on social class. This is in opposition to values held by the Canadian health care system, where



everyone has both equal access and quality care. This led one respondent to say that considering a recycling medication program on the basis of need would really force society to answer the question why Nova Scotia, within a welfare state, may not be looking after its most vulnerable citizens. Some thought this may put these vulnerable populations at further risk when sustainable supply cannot be guaranteed. An interruption in therapy would be harmful for those dependent on any such system. Nova Scotia may lack sufficient scale to source enough medications, and that means it would have to work collaboratively with neighboring provinces to be viable.

Remedies to these concerns were suggested. Some suggestions included trusting provider/patient relationship for those returning medications, patient waivers, known expiry dates, tamper-proof packaging and a tablet verification system.

### **POWER: 1) Subject Position 2) Barrier/Resistance**

Respondents were asked to consider how power and influence might affect a redistribution agenda. Most cited manufacturers as potential sources of resistance. They believe manufacturer monetary interests would be at risk, not only making manufacturers disinclined to support any program of this type but perhaps causing them to act as powerful agents to block any such initiative. One interviewee felt manufacturers have a moral responsibility to fill the gap in patient medication access because of unjustified exorbitant medication costs. A couple of interviewees said manufacturers do, in fact, quite often fill the financial gap for patients who cannot afford their medication. In addition to manufacturers, it was

felt pharmacy owners would have a disincentive to participate in such a program. A large, successful, program could erode retail pharmacy profits. This was considered an important point because pharmacy owner and practitioners might also be the same group developing regulations and actually administering the program. One respondent said these two groups, manufacturers and the pharmacy profession, have considerable power.

The public was identified as a great source of influence. However, respondents were unclear on current public sentiment. Some felt their organizations are better informed on the risks of a program than the public, and the uninformed public may not be capable of assessing these macro level risks. The responsibility of the regulatory bodies to protect the public supersedes any growing public support. The public may, therefore, mistakenly attribute stakeholder resistance to “laziness” or the fact “no one is going to make any money on it”. Contrary to this, one interviewee said once the public is informed, its members may be in the best position to decide whether the risks outweigh the benefits for them personally. One respondent thought some proportion of the public might block this initiative, disliking not being refunded for returned medication while supplementing another’s healthcare costs. Another suggested that despite need, we might be surprised to see recipients rebuke the concept because of personal pride and not wanting to accept “reject product”, opting instead to go without or for trying to find a way to obtain the “real stuff”.

One respondent identified a more effective source of public power as being in the form of an advocacy group. Advocacy groups were considered to be highly

organized and an effective means of pursuing public wants. Advocacy groups have a unique direct relationship with the public, where they can gather information and patient stories. They are considered to be impressionable on government and able to push initiatives forward, even if not necessarily backed by evidence.

Professional regulatory bodies were identified as important stakeholders, with specific mention of medicine and pharmacy. All acknowledged a desire for a regulated program with policies and procedures, which would address their concerns. The body bearing responsibility for this was not always outlined. The individual healthcare providers of these regulatory bodies were considered stakeholders and important to implementation but not singularly strong. Many assume the regulatory bodies would be powerful sources of resistance. This was not the case after one was questioned. Two healthcare providers have pursued this initiative with both government and regulatory bodies, but they found they did not have sufficient influence to drive the issue forward. Any expert power exercised by providers was considered to have little influence on this type of public policy. They are thought to be more instrumental to the implementation process, and if such a program were to be adopted, their support would provide a “credible voice” necessary for success. Physicians were identified as one group that really doesn’t have “skin in the game” and could not be counted on as a champion, but which could be managed if concerns were addressed.

All respondents identified the provincial government as a powerful stakeholder. The federal government’s role was dismissed, as it is interested only in the sale

of pharmaceuticals and not their distribution. The government was considered powerful because of its absolute power to sanction and legalize any such program. In addition, potential government funding was considered a positive factor for success. Its administration and ownership of the public drug program, Pharmacare, was also considered a potential tool for success. Its central relationships with both regulatory bodies and the public position it well as a strong influencer on a redistribution program. The government, however, cannot be summed up as a single body. It is made up of opposing parties, with fluid degrees of power and control. One respondent said if the party in power decided to pursue this initiative, the opposition would almost certainly assume a contradictory position. Verbiage like “instead of properly funding the healthcare system, the government wants to reuse your old medication” could be used.

Two interviewees, both healthcare professionals, identified social workers as important stakeholders to the process. They would provide the needs assessment expertise. Being external to healthcare delivery, they may be best positioned to champion this topic.

All respondents discussed a variety of stakeholders, and none considered any one group powerful enough to see this initiative through without the support of others. Even government alone was not considered enough to lead a successful program. All agreed that this issue would require a multi-stakeholder approach in Nova Scotia. Not including all stakeholders would put the program at risk, as any one group could gain sufficient power to “kill the project”. Building “buy-in” is essential. In addition, timing and the local environment were considered important.

## **STORY: 1) Emotion**

An important component in US implementation was a singular story about a patient. Respondents were asked to either watch or listen to a short story about an individual patient struggling with disease management costs and then to comment on whether there was a role for medication repurposing for that same patient. All recognized, and seemed to sympathize with, the patient's struggle. They all believed the story to be a credible example of patient stress derived from high, relative to income, medication costs. None contested the relevance of the stories or the stories as being unusual in Nova Scotia, even though they were not necessarily examples from Nova Scotia. The medical urgency highlighted by the story led some to say patient disease risk would outweigh theoretical repurposing concerns. Tolerance for less effective or poorer quality pharmaceuticals would be increased. In this case, respondents posed "What's the alternative?", "something is better than nothing".

For some, the story elicited a more emotional reaction than for others. Some openly discussed, and drew parallels to, their own personal knowledge and experience surrounding patient hardship, while others kept the discussion at arm's length. Some respondents discussed the disproportionately high cost of specialized treatments in relation to benefits and how universal funding could bankrupt the public system. These same respondents identified this as an ethical issue for funders. A repurposing program serving as a potential solution for these patients wasn't unanimously agreed upon. Some thought alternative approaches or sources of funding would be more appropriate as practical solutions. However,

in concept, respondents considered the idea of redistributing unused medications to these patients as “admirable” or as a solution in theory. Respondents, however, cited that, in reality, repurposing isn’t an option, and they revisited concerns previously communicated.

### **MORAL: 1) Patient Access and Care 2) Waste Reduction**

Those interviewed were asked several questions to assess their organizations’ moral positions on repurposing medications. Many said waste, patient access and medication reuse all posed moral and ethical dilemmas. Respondents were asked to decidedly say whether reusing discarded medications is “the right thing to do”. All respondents agreed there is a moral obligation to at least decrease the amount of medication wastage within the system. Only one said there was a responsibility to reduce the impact on the environment. With scarce resources and rising costs, to do otherwise was seen as negligent and an “abuse of the system”. Opinions on those who should ultimately be charged with this responsibility varied amongst the interviewees. One respondent said the responsibility is shared across the system, another identified patients and another identified themselves, as policy makers who are trusted with public dollars. One respondent specifically identified prescribers, manufacturers, pharmacies and even insurers as being especially responsible for creating much of the waste, as they all have a vested interest in generating maximum prescription sales and volume. These comments on waste reduction did not organically translate into supporting repurposing as a solution to medication waste reduction.

From this, respondents were asked to comment on their knowledge of this waste knowing that there are individuals who struggle with medical costs. One respondent felt that because of Family Pharmacare's inclusiveness, the issue of access was less important in this province. Several others refuted this based on personal experience. Updates were made to the drug plan so anyone could join, regardless of preexisting conditions, income or any other privately held insurance. Family Pharmacare was said to not be adequate for a single person with a chronic disease. Even working patients on Pharmacare may find themselves struggling to pay for medications when afflicted by a high cost disease. One respondent was concerned about the initial payer for those medications, which may be re-dispensed. This payer would indirectly be paying for a non-member's treatment and subsidizing another payer's cost. All recognized those who cannot afford to take their medication as prescribed as being at risk but that reallocating medication to these same people may also put them at risk. One respondent thought the issue may rest on the patient's medical necessity and urgency to receiving treatment.

Respondents thought those afflicted by diseases like cancer, pain, irritable bowel disease, rheumatoid arthritis, chronic obstructive pulmonary disease and multiple sclerosis may be some ideal targets because of prohibitive medical costs and high needs. These disease states seemed to be mostly reflective of interviewee perspective and exposure. This led back to the issue of balancing individual patient risk of having no treatment with recycled medical therapies. Respondents thought alternatives to repurposing might exist for this population. Interestingly,

one respondent thought repurposing itself posed a moral impropriety. They drew a comparison to “crumbs from the master’s table” and said repurposing may, in effect, be segregating individuals and defining them as second-class citizens.

### **VALIDATION/DIFFUSION: 1) Success Factors 2) Learning**

Finally, questions surrounding validation and diffusion were asked. First, respondents were asked to define what success would mean for a medication reuse program. Answers varied for the interviewees. For some, improved medication access would be the ultimate goal, but they found it difficult to define what threshold would be critical to success. Some took a systems approach and said success was ultimately defined by cost effectiveness. That is, the program would be successful if new program administration costs didn’t exceed savings from reduced destruction costs and drug program costs. Some thought improved drug utilization and compliance would define success. Other outcomes, like patient satisfaction, reduced financial stress and reduced environmental impact were also discussed. One respondent went so far as to say improved patient outcomes would be the ultimate goal. Another interviewee, who said there are too many confounders in this context, refuted using health outcomes as a success factor. Two individuals identified an in-force period of 6-12 months as being necessary before evaluating a program. This length was justified by the need to have enough reliable data and to see if high initial administration costs decrease with learning.

Recycling within the institutional setting has existed since 2006 in Nova Scotia, but in the last 9 years, this practice has not evolved into a community based



practice. Respondents were asked how other environments, with successful programs, might influence them. The translocation applicability differed among respondents. Some agreed Nova Scotia could look at current US attempts to run similar programs, but one respondent thought the US practice environment was too different from that of Canada to draw any parallels. Canada's model is more akin to UK and Australian healthcare models. Although other environments may differ, a successful program could be adapted to local needs. All interviewees thought another Canadian province with a successful program would be highly influential and would impact any decision by Nova Scotia to move forward. One individual said although health is regulated provincially, all Canadian provinces work openly and collaboratively, and this type of program would be no different. A couple respondents noted that the adoption of these programs would be more difficult without any government funding.

One of the largest issues for participants was how this type of program would actually operate. They were asked if there would be an ideal "test" environment. Most identified pharmacy participation, at least as a collection touch point, as being a logical choice. Many also considered the complexities of matching the medications with patients and how they could be alleviated, in part, by having a central "processing depot". Some participants thought a depot would be best run by an external third party (e.g. clinic, hospital), outside of pharmacy. This would remove any "temptation" for pharmacies to use returned stock as their own and eliminate the burden of trying to run this program on top of an already-stressed system.

## FINDINGS

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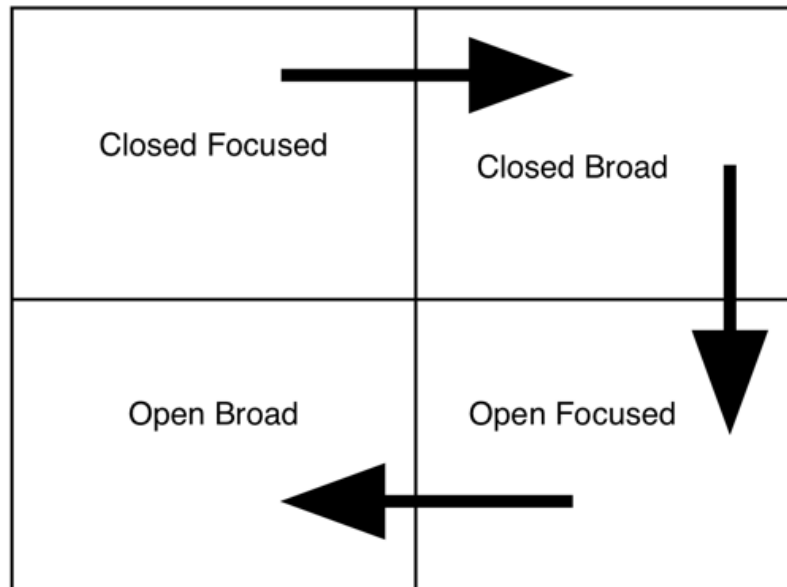
After reviewing interview responses and applying them against the proposed model, it seems the process for medication redistribution in Nova Scotia will likely follow a different path than it has in the United States. The model still applies, but it would require additional inputs and enhanced synergy among the inputs. This research paper finds six key findings on the topic of medication reuse programs in Nova Scotia. The first is, the use of story has little context in this area as the province will act as a welfare state for those in medical need. The government is not a source of power, like the US, as there is a high perceived risk and little evidence to support change. Groups are unable to use reason without program and waste cost estimates or population need data. Groups have no experience or direct knowledge of medication reuse programs and therefore cannot use normative legitimacy. The groups best positioned to drive change in Nova Scotia is the public or those strongly connected to the public without high structural power. Finally, movement in this area should begin with programs that are able to give the greatest return such as those with either or both high need and cost.

Interviewees highlighted the fact that reusing medication significantly challenges sometimes opposing Nova Scotia norms, beliefs and values. All organization representatives supported medication reuse as an altruistic activity on a theoretical basis but not yet on a practical level. First, there are no visible redistribution activities, and laws currently ban it. The norm is to dispose of any unused medication, and this has been a long-standing practice in the province. The ability to imagine a redistribution norm was lost on many interviewees. The

current system is perceived as sound and as upholding the integrity and safety of medications for consumption. The persistence of this practice forms Nova Scotia's status quo. Interviewees' attempts to validate the status quo rested on fear and speculation, as they did not have tangible experience with medication recycling. Fear seemed to rest on the unknown; these unaccountable risks were intolerable for some. The concerns of some were rationally connected to other incidents outside of the medical system, and others were less able to substantiate their concerns. Data from the US does not support their fears coming to fruition. Most interviewees reported reuse programs would always have an element of risk despite regulations, and they believe the potential for risk is too high a price to pay, with safety being highly valued by interviewees. On the other hand, interviewees revealed that looking after Nova Scotia citizens' health needs is important and a moral responsibility. Many recognized patient health deteriorates without treatment, but the prevalence of high need in Nova Scotia was not clear. The sustainability of the healthcare system and waste reduction were also valued. The challenge for interviewees was to see how a medication reuse program would serve as a solution to health spending woes and patient need, while at the same time being able to allay their concerns around safety. On the whole, the interviewees believe that the current system should be preserved in its entirety until significant population needs are demonstrated and there are solutions addressing new system risk. The interviews suggest the current environment is primed for change but still requires both expert advisement and drive to motivate the change.

Nova Scotia has been supporting a Closed Focused Program through its special homes act since 2006, but it has not progressed to Closed Broad or any Open Programs, despite attempts by at least one physician (Doyle, 2010). The precise reason why this physician was unsuccessful is not clear but, as demonstrated in the multi-stakeholder model, it may be that he was unable to sufficiently engage all partners and that his position within the environment is ill-suited for this type of project. Expert opinions, like those of physicians, are important for validation, but they do not drive change in this context. It is more important to manage experts towards supporting change and to block their opposition than it is to position them as change leaders. The progression from a Closed Focused Program has a logical pathway, as shown in Figure 7, from Closed Focused to Closed Broad to Open Focused to Open Broad. This stepwise progression builds on learning from the system before it. It is possible, like many states have done, to bypass the flow of system progression by jumping to the most comprehensive systems when preexisting models are present in similar environments, like in the US. This is unlikely in Nova Scotia, as there are no comparable programs in Canada. It's likely that the first Canadian environment to pursue this will follow this model and will do so slowly.

Figure 7: Program Pathway



This project revealed an unexpected barrier to program application. Initially, it was thought government would be an important supporter, but it turns out this powerful body is currently a strong opponent, despite a potential financial incentive. This is in striking contrast to the US, where government actually championed the idea. Juxtaposing this is the professional regulatory body, which was surprisingly supportive. These two stakeholders work jointly in the interest of their most important stakeholder, the public, and it appears these two groups are more codependent than their US counterparts. Influencing the government through the public is likely a more effective approach than presenting rational arguments to change. How the public feels about this initiative would eventually drive the opposing sides together. As stated earlier, failure to gather public opinion was another limit to this research. Although public sentiment is unclear, it is worth noting a growing trend in Nova Scotia in the area of copayment cards, like Innovicare, that could impact perception. These cards are contributing to

reinforcing, and even reverting, existing norms of brand name product quality being perceived as greater than that of generics, despite provincial formulary interchangeability (STI, 2013). This association of original product quality stands in opposition to acceptance of recycled medication and may reinforce status quo in relation to medication recycling.

The remaining interviewed stakeholders were hesitant, but they were optimistic there exists a mechanism to develop some version of redistribution. Their responses suggest they would contribute and collaborate, as necessary. The pharmaceutical industry and drug retail chains were also not interviewed but are hypothesized to be other important sources of opposition. Doyle (2010) points out, however, the program is unlikely to actually threaten profit levels, and actively blocking social programs on principle alone may do more to harm their reputations. The reality may be that these groups have the ability to oppose a program but may have little interest in doing so.

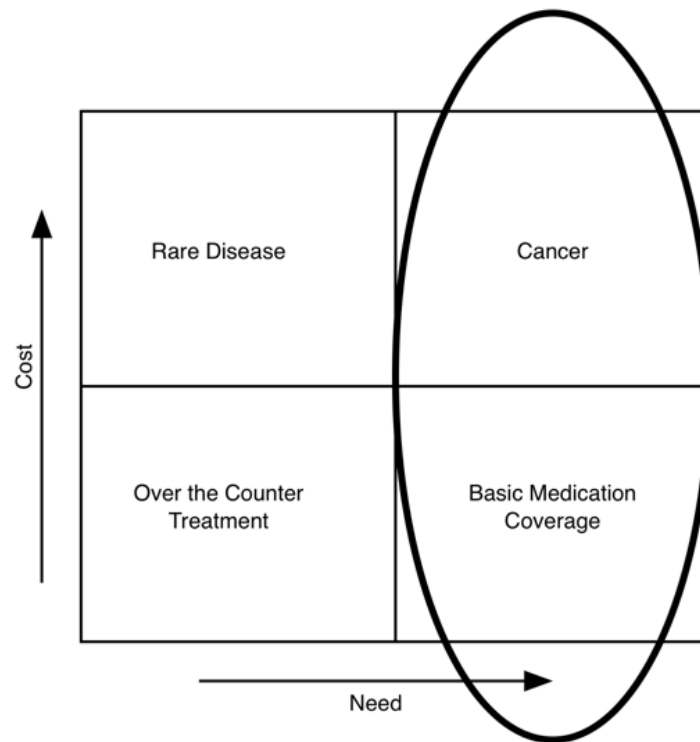
In Nova Scotia, gaining legitimacy through regulative means, like in the US, is unlikely. Those with sufficient power as regulators to push the agenda forward are either not interested or not prepared to do so. Even though the regulatory body was in favor, it was not prepared to become the project's lone advocate, and there currently seems to be little momentum on the topic. Conversation pushing legitimacy on the issue through normative means is lacking, as there are no groups drawing connections between waste and patients struggling with medication costs. Cognitive legitimacy also seems unlikely without waste and need data. Without this information, it is difficult to draw conclusions on whether

such a program makes sense. Although the interviewees cited the healthcare system as unsustainable, it is not in crisis, and it is still being supported. Ballooning health spending budgets could stimulate change in the years to come, as reactive, versus proactive, responses to crises are typically more effective at encouraging alternative thinking. Also, there were mixed responses among interviewees about whether US models actually influence our approaches in Canada. It was difficult for interviewees to compare the two countries on this topic. As drug repository success grows in states like Iowa, the issue may be harder to avoid. The ability to gain legitimacy through isomorphism is lost on novel approaches like this, where there are no visible organizations to mimic. Determining the means by which medication redistribution is to gain legitimacy in Nova Scotia will be challenging if Nova Scotia is to be the first province to adopt such a program.

Story, in the US, has been a powerful motivator, but the use of story had less meaning in Nova Scotia. Patient strife is less relatable here because there are mechanisms in place to support the vulnerable, either through the publicly funded drug plan or through manufacturer assistance. Reports of people losing their homes in Canada are not commonplace. The assistance manufacturers provide gives them considerable power, as governments increasingly rely on them to finance some of the healthcare system. This doesn't mean story hasn't a place in the change model but, rather, story needs to resonate with individual experience or knowledge, or it has no context. The adjustments to the provincial Pharmacare program are thought to have addressed medication accessibility, but data

examining this may be required to verify if there are still gaps in the system. Figure 8 considers four possible system gaps, along two categories; cost and need. Those with high need, with or without high cost, are natural areas of focus for this initiative. Which category should be chosen will depend on program goals.

*Figure 8: Program Selection Criteria*



Patient advocacy and social work groups may be best positioned to provide the powerful stories in Nova Scotia, as stakeholders seem less convinced there is a real need. Without explicit need, a singular patient story does little to represent the population. Due to this, conversations about the program often became more of a rational debate, focusing on cost outcomes and risk. Patient advocacy and social work groups hold less structural legitimacy, but they may have the



connections within the multi-stakeholder environment to bring the issue to the forefront. They also draw their power from patients, who are the largest and most connected group in the system. They may also be more likely to champion the idea, as they have lower levels of risk exposure and wouldn't necessarily be charged with drafting the policies and procedures around program execution. Further research should confirm my claim and, if true, which group, specifically, has sufficient subject position and connection. As these groups are not subject matter experts, they would have to form coalitions with other groups so that rational arguments could simultaneously be presented credibly in order to appease stakeholder concerns.

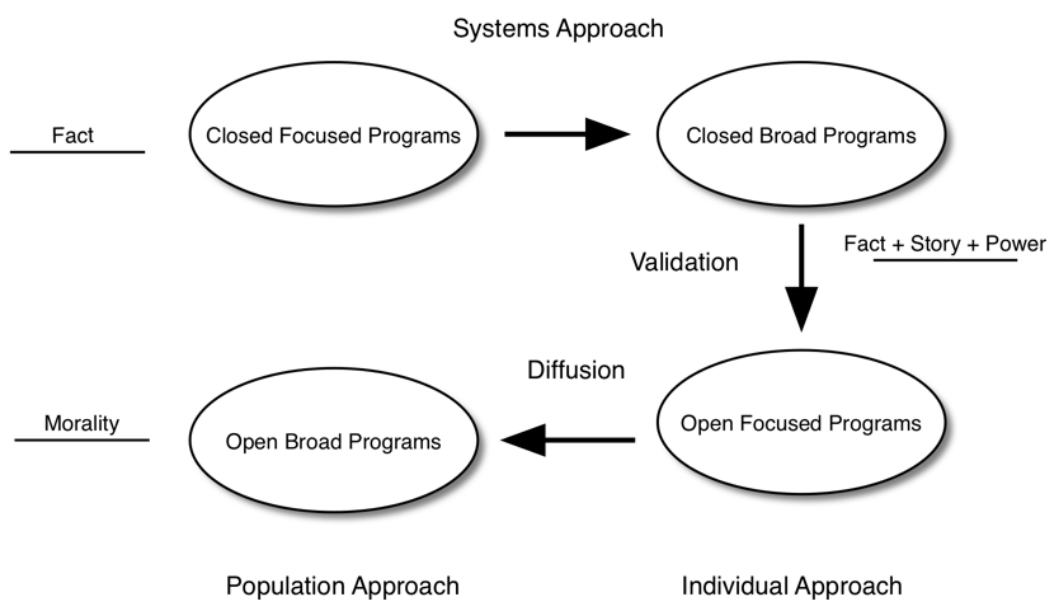
*Table 3: Nova Scotia Program Drivers and Outputs*

<u>Program Type</u>	<u>Driver Input US</u>	<u>Goal Output US</u>	<u>Driver Input NS</u>	<u>Goal Output NS</u>
<b>Closed Focused</b>	Facts on Waste	Reduced Medical System Costs	SAME	SAME
	Controlled Environment	Low Risk	SAME	SAME
<b>Closed Open</b>	Controlled Environment	Lower Risk	SAME	SAME
	Medical Need	Moral and Ethical appeasement	*No apparent need	
<b>Open Focused</b>	Patient Story	Increased Stakeholder Engagement	*Without need, no impact	
	Agent Power	Challenge Status Quo	* No one with significant subject position/power	
<b>Open Broad</b>	Medical Need	Moral and Ethical appeasement	*No apparent need	

Table 3 summarizes the program driver and outputs discussed for any potential Nova Scotia based medication reuse program as discovered through interviews. This table highlights important differences from the US found in Table 2. This table helps explain why programs have progressed to date in this province.

From Table 3 and Figure 7, it has become clear the proposed model in Figure 2 has not and will not work in Nova Scotia. The new model in Figure 9 shows how changes might be required for a Nova Scotian program moving forward. More facts are largely required during the initial and expansionary phases of program progression. Facts are needed to adequately assess whether the current problem of medical waste is above tolerable levels and whether Nova Scotia is sufficiently large to source enough for a viable program. This may require funding in the form of a larger scale study, like the one conducted in this paper.

*Figure 9: Revised Medication Reuse Program Progression Model*



Second, a needs assessment would be required, to collect facts on whether Nova Scotians are actually adequately insured and whether there exists a need. These facts could then be combined to support innovation and the approval of a trial program for finding a solution to the researched problems. A patient advocacy group or social work group, as previously mentioned, may be best to suggest such a trial through contextualizing the research. This pilot would likely be granted authority to operate if kept under a closed system. A program such as this might only collect donations from physician's offices, pharmacies and long-term care facilities, where the integrity of the product was ensured, alleviating stakeholder concerns. The reuse of medications from facilities has local validation and is conducted, albeit not routinely, as anecdotal stories suggest there is still high waste in long-term care. One limit to this paper was the inability to secure an interview with an important long-term care facility's director, which could have substantiated this claim. The waste in this controlled medication environment may serve as an important starting point. The new organizational form could then continue to collect data to support possible expansion to broader based programs. It would be important for the organization to mimic existing institutional structures so its activities are legitimized. Having a new organizational form that distributes medications efficiently addresses one aspect of program challenges: the timely connection of those in need with the medications. With this information, the potential scope and effect of broader programs may be better understood. The challenge of program risk in Open Programs would still exist, however.

With a structured pilot under a Closed Broad Program, the idea of redistribution then has a place within societal norms. With this type of organizational experience in Nova Scotia, policy makers may then be able to connect to, and draw on, more of the US experience. The pilot, with local data and the facts from the US, may be enough to motivate groups with power. The program may then swiftly move to either Open Focused or Open Broad Based Programs. This pattern shift diverges from the US experience because the movement would be based initially on fact, rather than on story or morality. Last, it is hypothesized that the diffusional process would occur throughout Canada but that programs would look more similar than dissimilar, like in the US. This would be due to the greater reliance on fact versus story and stepped program progression. This is in line with Canada moving towards a more national approach to healthcare, as suggested by media reports on a potential National Pharmacare plan and dialogue from a health care department representative.

This project realistically only scratches the surface on redistribution issues. It does, however, demonstrate that there exists a hidden cognitive understanding of the merits a redistribution program might bring to the province. It would be worth evaluating how Nova Scotia compares to other provinces on the topic. It is not clear whether another province may be better suited or have fewer barriers. Jurisdictions with greater government backing and funding may ultimately have greater success. The most remarkable differences between the US model and the one purposed here are the predominant use of story and concentrated power in the US, with the thought that facts would later come to support the change. The

model for Nova Scotia postulates that fact should first be gathered to build story, and then one may draw on less structural power to form a coalition of stakeholders. These three factor inputs of fact, story and power cannot happen in isolation but, rather, should occur sequentially. Because of this and program path progression, the final program configurations will be unique from the US. Which model endures and is most effective remains to be seen.

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## APPENDIX A – STATE SURVEY SUMMARY

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<b><u>State</u></b>	<b><u>System</u></b>					
	Closed		Open			
	<b><u>Scope</u></b>					
	Focused	Broad	Focused	Broad		
Alabama					✓	
Alaska						✓
Arizona				✓		
Arkansas		✓				
California		✓				
Colorado			✓			
Connecticut		✓				
Delaware	✓					
District of Columbia						✓
Florida				✓		
Georgia				✓		
Guam		✓				
Hawaii	✓					
Idaho						✓
Illinois					✓	
Indiana	✓					
Iowa				✓		
Kansas		✓				
Kentucky			✓			
Louisiana				✓		
Maine		✓				
Maryland				✓		
Massachusetts		✓				
Michigan	✓					
Minnesota			✓			
Mississippi				✓		
Missouri				✓		

Montana		✓				
Nebraska			✓			
Nevada			✓			
New Hampshire					✓	
New Jersey	✓					
New Mexico	✓					
New York		✓				
North Carolina					✓	
North Dakota				✓		
Ohio				✓		
Oklahoma		✓				
Oregon				✓		
Pennsylvania			✓			
Puerto Rico						✓
Rhode Island		✓				
South Carolina					✓	
South Dakota					✓	
Tennessee		✓				
Texas		✓				
Utah	✓					
Vermont		✓				
Virginia				✓		
Virgin Islands						✓
Washington						✓
West Virginia	✓					
Wisconsin					✓	
Wyoming				✓		
<b>TOTAL</b>	<b>8</b>	<b>14</b>	<b>6</b>	<b>13</b>	<b>7</b>	<b>6</b>

## APPENDIX B – INTERVIEW THEME/INPUT RESPONSES

Topic	Issue	Respondent				
		R1	R2	R3	R4	R5
Organization	Rising Costs		Need to keep drug funding affordable and sustainable	Expensive new therapies being marketed to patients without necessarily proven outcomes		We discard “perfectly good” equipment in Canada
	Changing Roles	“We have been pursuing expanded scope for the last 4-5 years”			We need to find a way to work collaboratively within our new scope without “butting heads”	
Logic & Fact	Importance of drug waste	“Less waste should translate into reduced cost to the system”	I don’t know if there is an “magic number” that would make it important	“It would be important to share this information with those fiscally responsible”	“we should be aware of the cost of meds that are going to waste”	5% may be an acceptable threshold for waste but 10% would be too high
	Product Integrity	Once the product has left the distribution channel we can’t be sure	Drugs in someone’s home may not have been stored or handled properly and may even be tampered with	There may be issues in regards to drug potency.  Also issue of potential tampering.	Reusing is risky.  Medication may be mixed, or expired.	“There would always be an element of unknown”  Need expert validation.  Risk of medication mix up.
	Liability	Manufacturers have liability insurance for donations but not all health care professionals do	Poor integrity may translate into patient harm		The regulatory body currently bans it. We can’t jeopardize one’s license.	“We operate in a highly regulated and legal environment”

<b>Power</b>	<b>Barrier</b>	Government and medical community who have a “cringe factor”	Industry because of monetary interest  All regulatory bodies would need involvement.	Pharmaceutical industry. Could be strong opponents.	Regulatory bodies as their job is to protect public not ensure they have access to medications.  The government would be concerned about risk.  Healthcare professionals.	Pharmacies and manufacturers as they would be “undercut”.  This could be spun negatively for the government.
	<b>Strong Subject Position</b>	The public may be willing to accept the risk. They sometimes say we get “locked up in our ivory towers”.	“No one or group that is important enough.”	Patient advocacy group who “lobby government well and effectively”  Specialists in the medical community.	Some public consumer group.  Public seems to support this on the whole.  Social work.	Requires a multi-stakeholder approach with interests and needs in this area. Those for and against.
<b>Story</b>	<b>Emotional Reaction</b>	Having to make a decision on whether [s]he lives or he destroys his family's life. That is wrong	“I think that the drug company has a moral obligation to help”  “this is not taking drugs to Africa where people are all dying and an expired drug is better than nothing or no drug at all. Its a different system. There are alternatives here”	“These are real people. Something has to give. This all across Canada. We hear about the working poor. These are the ones that are most vulnerable and most stressed by the system”	“I think because without the medication the patient would deteriorate faster that we have a higher tolerance for any kind of lack of 100% effect. Its better than nothing”	n/a

<b>Morality</b>	Reducing waste	<p>“Its really an abuse of the system, is what it is. There is so much waste out there”</p> <p>Manufacturers push these products</p>	<p>“As a funder, we don't like waste”</p> <p>Why is the drug being wasted?</p> <p>[we] have a number of policies to try and decrease the waste from that angle because there are a whole host of issues with repurposing</p>	<p>“There should be some incentive to reduce that waste.</p> <p>There is no incentive for patients to bring meds back to ensure it is properly disposed of.”</p>	<p>“So when that medication comes back it is untouched. That is where I see the most tragic waste of resources.”</p>	<p>“It is a moral and ethical issue. Our healthcare system as is, is not sustainable”</p>
	Provide access and care	<p>“Its a matter of medical urgency. It speaks to a broader issue. The availability of drugs to the people who can't afford them. We are basically saying there are a class of people who cant afford drugs and they are going to have to make do with “good enough” ”</p>	<p>“Family pharmacare is available to every Nova Scotian. Anybody can join. They are at risk because they can't afford or they are not taking their drugs but we can't also put them at risk by giving them a drug where the integrity is not ensured”</p>	<p>“Family pharmacare is not a great benefit for a person with a single disease. I think that people could benefit from these medications - yes but I don't think we need to beat ourselves up for not having offered it to date.”</p>	n/a	<p>“There are about 1/3 rd of patients who really have no insurance and they are caught in between especially when it comes to high cost medications. They are not even necessarily the “working poor”. Some medication costs can be catastrophic.”</p>

<b>Validation &amp; Diffusion</b>	<b>Success Factor</b>	<p>“There would have to be some dollars put into it. Would need a single center. You would need the economy of scale where things would all go to one place and then need to find out who those are that are in need.”</p> <p>“[My goal] would be to have the people to receive the drugs.”</p>	<p>“The goal would be to improve access, compliance and health outcomes. You would have to measure health outcomes that you hope would improve via access.”</p>	<p>“In NS I think it would have to be done through a phased approach where it wouldn't overburden the system. It has to be something simple, a quick win, and relatively easy.”</p> <p>“Did this program 6-12 months later change how patients take their medication. Im not sure you can look at clinical outcomes.”</p>	<p>“a non-pharmacy almost. A hospital would be place to return all medications.”</p> <p>“So year over year you can see if things are improving, are administration costs going down?”</p>	<p>“a central processing depot where meds go after they have been returned to pharmacies. We could at the very least consider the “low hanging fruit” as a test. Could do an analysis on this.</p> <p>1) reducing the environmental impact 2) Patient satisfaction 3) Financial relief for patients 4) Decreased prescribing costs on Pharmicare and Third Party Providers”</p>
	<b>Learning</b>	<p>“ a well run [US} program , you could run that here. If Ontario had a program... you could probably just take that and just adopt that unless there was a lot of government funding. It would be important to have the provincial government involved. “</p>	<p>“The US is a totally different environment. We do everything on a pan-Canadian basis. If the government of BC was implementing a repurposing program, I have no doubt that would be shared with the other provinces. We do everything together.”</p>	<p>“We should never start from scratch. If we have someone out there is already doing it, you look to them to see how they are doing it to learn the pitfalls, and the quick wins, what did their successes look like.”</p>	<p>“We do a lot of borrowing and copying from the UK and Australia because we are similar in our socialist type countries. The US is very different.”</p>	<p>Yes, we can learn from the US.</p>

## APPENDIX C – INTERVIEW QUESTIONS

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Interview Questions:

### **[General]**

What are the three largest issues facing your organization?

### **[Logic/Fact]**

If we had data on this (i.e. the \$ value of medical waste) how important would this information be to your organization?

What is your greatest fear around medications reuse? What is this fear based on? E.g. What historical experience do you have with this fear or what facts substantiate your fear?

How do you think this policy impacts our ability to finance our health care?

### **[Power]**

Who do you think should be responsible for this? If there was a champion in this area, who would you support? How would you lend your support?

What roadblocks would you anticipate?

Who or what groups do you see resisting such a program?

What organizations do you see as the most important stakeholders for this project?

### **[Story]**

Viewed Link: [http://www.cbc.ca/player/News/TV+Shows/The+National\\_/Canada/ID/2441374211/](http://www.cbc.ca/player/News/TV+Shows/The+National_/Canada/ID/2441374211/)

OR

A typical dilemma presents with a patient receiving Canada Pension Plan (Disability) benefits. For example, Lyndsey has a limited income with no drug coverage. She has type 2 diabetes, high blood pressure and dyslipidemia. Prescriptions include oral diabetes agents and/or insulin, in addition to blood pressure & cholesterol lowering agents. Ideally, the patient should be testing their blood sugar 2 - 4 times per day. On presentation to clinic, she is not testing as recommended (sometimes not at all) due to cost, and have either discontinued or



not filled some of her medications, particularly for blood pressure & cholesterol (as these are often the most expensive). Sometimes, Lyndsey receives medication samples from her family doctor when they are available. Generally, this situation results in sub-optimal control and contributes to stress (which further increases blood sugar).

How does this story influence your thoughts on the feasibility of a medication redistribution program?

**[Moral]**

What moral obligation do we have to reduce this waste?

What do you think about our current situation where we throw out unused medications, knowing that there are others who could benefit from it?

Is there a particular subset of the population that you feel would benefit the most from this type of program? Which populations would be ideal recipients of these medications?

**[Validation/Diffusion]**

What type of environment do you think would be the ideal “test” environment for this type of project?

How would your organization be influenced if there was a highly successful operation in the US? CAN? How would a negative outcome influence?

How would you define “success” in this context? How would it be measured?

How long would a program need to exist, in your view, to be considered “successful”?

# APPENDIX D – REB CERTIFICATE



## RESEARCH ETHICS BOARD

Department Office  
 T 902.420.5728  
 F 902.496.8772  
 E ethics@smu.ca

### Certificate of Ethical Acceptability for Research Involving Humans

This is to certify that the Research Ethics Board has examined the research proposal:

<b>SMU REB File Number:</b>	15-047
<b>Title of Research Project:</b>	Drug Repositories in NS.
<b>Faculty, Department:</b>	Sobey School of Business, Management
<b>Faculty Supervisor:</b>	Dr. Russell Fralich
<b>Student Investigator:</b>	Suzanne Saunders

and concludes that in all respects the proposed project meets appropriate standards of ethical acceptability and is in accordance with the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2) and Saint Mary's University relevant policies.

Approval Period: November 18, 2014 – November 18, 2015\*

**Continuing Review Reporting Requirements**

**ADVERSE EVENT**  
 Adverse Event Report: <http://www.smu.ca/academic/reb/forms.html>  
 Adverse events must be immediately reported (no later than 1 business day).  
 SMU REB Adverse Event Policy: <http://www.smu.ca/academic/reb/policies.html>

**MODIFICATION**  
 FORM 2: <http://www.smu.ca/academic/reb/forms.html>  
 Research ethics approval must be requested and obtained prior to implementing any changes or additions to the initial submission, consent form/script or supporting documents.

**YEARLY RENEWAL\***  
 FORM 3: <http://www.smu.ca/academic/reb/forms.html>  
 Research ethics approval is granted for **one year only**. If the research continues, researchers can request an extension one month before ethics approval expires.  
 FORM 4: <http://www.smu.ca/academic/reb/forms.html>  
 Research ethics approval for course projects is granted for **one year only**. If the course project is continuing, instructors can request an extension one month before ethics approval expires.

**CLOSURE**  
 FORM 5: <http://www.smu.ca/academic/reb/forms.html>  
 The completion of the research must be reported and the master file for the research project will be closed.

\*Please note that if your research approval expires, no activity on the project is permitted until research ethics approval is renewed. Failure to hold a valid SMU REB Certificate of Ethical Acceptability or Continuation may result in the delay, suspension or loss of funding as required by the federal granting Councils.

On behalf of the Saint Mary's University Research Ethics Board, I wish you success in your research.

  
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 Dr. Jim Cameron  
 Chair, Research Ethics Board, Saint Mary's University