

Is importation of drugs from Canada the answer?

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Increasing medication costs have driven patients to seek alternative avenues to traditional pharmacy distribution systems for filling their prescriptions. Widespread constituent frustration due to the cost of medications in the United States has resulted in a wave of state-sponsored legislation supporting the importation of medication from other countries, in particular Canada. Canada continues to attract the attention of United States residents as a cheaper, safe alternative outlet for their medication. Self-employed groups and municipalities are circumventing laws on importation and offering benefits that include medications from outside the United States. Patients are individually seeking prescription medications through pharmacy internet sites claiming to be Canadian in origin. While the cost of medications in foreign countries may be less expensive, there are many factors worth considering in regards to foreign acquisitions which include, but are not limited to, the safety and efficacy of these medications, including purchases from Canada.

The Food Drug and Cosmetic Act (FDCA) of 1906 and its amendments are the safety net for our current drug approval and distribution process. These laws work to strengthen the manufacturing and distribution systems to ensure that the supply of United States medication is safe and effective. The Prescription Drug Marketing Act of 1987 banned the re-importation of medications into the United States, with exemptions by manufacturers who manufactured the medication or for emergency use.¹ The Drug Supply Chain Security Act of 2013 was passed in an effort to guarantee the pedigree of medications distributed through the system. This act requires entities participating in the distribution systems to have the ability to track and trace the pedigree of a medication from production through dispensing.² These amendments were passed to ensure the safety of United States medications and minimize the counterfeit, adulterated, misbranded, reduced potency, or expired medications that might otherwise reach United States patients. Protection of United States patients from harm has not prevented the federal government from allowing the importation of medications from Canada. The Department of Homeland Security Appropriations Act of 2007 includes a provision that allows the importation of a Food and Drug Administration (FDA) approved medication from Canada. The provision stipulates that medication may not exceed a 90-day supply and the individual must carry the medication on their person. This act prohibits controlled

substances or biologicals from being imported.³ However, the Controlled Substance Act does allow for a personal use exemption for controlled substances but a patient is limited to 50 dosage units which again must be transported on person, not shipped into the United States.⁴

The exemption allowing for personal importation of medications from Canada is of limited value for most United States patients. The demand for access to these less expensive prescription alternatives has been growing throughout the country. In December 2017, Kaiser Health News chronicled the growing number of entities, such as school systems, municipalities, and cities, that are quietly offering their employees the option of using foreign medications at a reduced employee contribution to healthcare by reducing deductibles and copays. Employers cited these cost savings as enabling the continuation of their employer-sponsored health plans.⁵ A Kaiser Family Foundation poll in 2016 reported 8% of respondents had or knew individuals who had used a non-United States entity for their medications.⁵ Currently nine states, Colorado, Louisiana, Missouri, New York, Oklahoma, Utah, Vermont, West Virginia, and Wyoming have submitted legislation to operate state-administered wholesale operations with the intention of importing medications from Canada and selling to pharmacies.⁶ Vermont's bill was passed by the legislature but is currently being examined by the Governor's office as to the implications of importation on Medicaid and other federally funded programs.⁷

For those patients with geographical limitations preventing personal importation, individuals across the country often look to obtain lower cost prescription drugs from Canada through internet sites. Concerns regarding the authenticity of "Canadian" drugs coming into the country via online pharmacies have been raised as legislative debate ensues in the states. The National Association of Boards of Pharmacy (NABP) conducted a review of 108 websites between July 1, 2016 and June 30, 2017 that included "Canada" or "Canadian" as part of their advertised name or URL. The purpose of this review was to validate that medications sold by these "Canadian"-identified websites originated from non-Canadian pharmacies that distributed medications that had not been approved by Health Canada. NABP's review found 80 websites (74%) included language that their medications were not from Canada, they had not been approved by Health Canada nor were they legally sold

within the country itself. The remaining websites omitted information regarding origin of the medication used to fill the prescriptions.⁸

Fifty-four of the 108 (50%) online pharmacies included in this review provided India or a combination of India and other countries, such as Hong Kong and Singapore, as the country in which the medication was manufactured, or from where the internet site purchased their medications (which may be different than the country it was manufactured in). Various countries were cited as the origin (location) from which the medication was shipped to the pharmacies; however, 22 (20%) listed unspecified locations abroad while 28 (26%) omitted origin of distribution altogether. These unidentified sources and origins of distribution increase the likelihood of counterfeit, adulterated and misbranded products reaching United States patients. Also, none of the 108 websites reviewed required a valid prescription and 29 (27%) of these internet-based pharmacies were dispensing controlled substances.⁸ This is increasingly problematic as healthcare professionals work to prevent the diversion of narcotics that is fueling the opioid epidemic in the United States. Each of the pharmacies reviewed in this report appear to be neither Canadian, nor operating within the confines of United States or Canadian law.

These NABP findings support concerns that have been raised regarding the authenticity of Health Canada products actually making it to the United States. The need for affordable medications is often balanced against the safety concerns presented by importation of medications. As an example, an online pharmacy named Canada Drugs was fined \$34 million for importing unapproved drugs, including counterfeit oncology medications to the United States in April 2018. Though claiming to be Canada's largest internet pharmacy, its drugs were sourced from around the globe.⁹

NABP accredits United States internet pharmacies through the Verified Internet Pharmacy Practice Sites (VIPPS) program. Accreditation ensures that the proprietor is operating as a safe and legal pharmacy. Full criteria and listing of approved pharmacies can be accessed through the VIPPS website (<https://nabp.pharmacy/programs/vipps/>). Approved pharmacies have met the criteria which reviews pharmacy practice standards, safety, quality, security, and legal compliance by the pharmacy. VIPPS accreditation seals will be displayed on internet pharmacy sites that have been reviewed and have met the NABP criteria. All future VIPPS applicants must first apply for a .pharmacy domain, also signifying the legitimacy of the internet pharmacy within its internet address.¹⁰ VIPPS accreditation and .pharmacy recognition is an important tool for patients looking to utilize safe and legal online pharmacy services. As of June 2017, NABP reports that 95% of the approximately 12,000 pharmacy

sites reviewed are functioning outside of recognized U.S. pharmacy practice standards and laws.⁸

The focus on Canadian medication should be reviewed in context to the current United States health system. Health Canada is a universal health plan that does not include medication coverage. Residents of Canada acquire their medication through public and private plans that vary across the provinces, with some residents having no medication coverage. The cost of medication in Canada has been reported to be second only to those of the United States. The lack of a unified purchasing system eliminates the ability to negotiate deep discounts for their medications. The pharmaceutical cost per capita in Canada is 25% greater than those of the next country with a high expenditure per capita, Germany.¹¹ Canada's Patented Medicine Prices Review Board (PMPRB) does moderate increases on patented medication by ensuring that medication drug increases are not excessive. In addition, the provincial governments implemented policies in 2010 that reduced the cost of generic medications but Canadian generic prices still remain high. The PMPRB's report, *Generic 360*, reported that generic cost in the last quarter of 2016 was slightly less than the United States but the seventh highest in the Organization for Economic Co-Operation and Development.¹² The cost advantage to importation from Canada might be less advantageous as the United States market has shifted and currently has a generic prescription rate approaching 90%.¹³

Federally, importation of foreign medications, otherwise commercially available in the United States, is prohibited under the FDA. As individual state governments and their legislators consider to legalize importation of Canadian drugs, systems must be in place to ensure medications being shipped to their wholesale sites are from verified sources within Canada. Additionally, the safety and integrity of medications being sourced from other countries cannot be guaranteed by individuals purchasing from the internet. Increased monitoring of medications being distributed through internet websites is needed to protect those seeking cheaper venues for their life-saving medications as internet pharmacies claiming to ship "Canadian" internet pharmacies are likely not dispensing prescription medications approved by Health Canada or legally sold in Canada. Lastly, economics analysis should be performed to ensure the cost of importation ultimately meets the demand for less expensive medications. As various states investigate wholesaler legislation being proposed, the cost of building the infrastructure to become a wholesaler, with little to no control on the negotiated pricing of products in Canada, may be a tenuous way to ensure long-term control of medication cost for United States' patients.

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The Long Birth and Short Life of The Recovery Navigation Program

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If you blinked, you missed it. For a year and a half, Rhode Island had a comprehensive answer to the plight of the homeless alcoholic. The Recovery Navigation Program (RNP) was born in the Venn diagram overlap of addiction treatment, housing, state politics, city policy, fire departments, hospitals and Medicaid. In theory, everyone would benefit. Medicaid would save precious dollars by keeping its members out of the hospital, addiction treatment would be more accessible, EMS would be unburdened from picking these people up on a daily basis, and intoxicated people would now be off the streets and out of the Emergency Department (ED).

But it didn't happen this way. Perhaps we should have realized from the outset that this position would be unsettling to those surrounding it. For the RNP to function, the Venn diagram itself would have to be radically redrawn. Our community wasn't ready for this.

The Conception

In 1972, Rhode Island enacted a series of laws that decriminalized public intoxication. One particular law (23-1.10.10), detailed that someone "incapacitated by alcohol" be brought to a designated facility for emergency treatment.

At the time this facility was the State Detoxification Center, or Ben Rush, as it was commonly known. It was located on the Pastore Complex in Cranston (you know, where the DMV is now). It was publically funded through the state with federal grants. Access to Ben Rush was easy, there was no insurance authorization, medical staff was on site and intoxicated people could sober up and then transition to a detox bed. Most importantly, they accepted people intoxicated directly from the street, and cared for much of the state's homeless population, many of them hundreds of times.

In the 1990s Ben Rush was becoming increasingly expensive and federal grants were drying up, a phenomenon not unique to Rhode Island. As the state closed its only public detox facility, it privatized alcohol detox to many independent contractors. These facilities quickly developed practices and policies making it complicated to access their services from the street. However, being intoxicated and in public was still defined by law as a medical condition. Now effectively barred from the detox centers and without any other options, they wound up in our EDs, like orphans on the church steps.

The Long Birth

And come to the EDs they did. In 2015, at Rhode Island Hospital alone, 177 high utilizers (patients who made five or more visits for alcohol intoxication) totaled 2,812 visits. Twenty-two of these patients made more than 30 visits each. While staggering, these numbers underestimate the phenomenon because they do not include those who made less than five visits, nor do they account for visits where they were admitted or days as an inpatient in the hospital. Here we find the frequent user at his most prolific, with much of the health expense attributable to a few individuals.

National data on this phenomenon mirrors our experience in RI. An estimated 9% of all ED visits are alcohol related.¹ Only 12% of these resulted in admission², and many of these visits might have been avoidable. "Avoidable" however, turns out to be a loaded word, and implicit in this conversation is the question of, "What is a necessary ED visit?" While this question could be applied to any chief complaint, most visits for alcohol intoxication could be avoided if an alternative existed.

Local policy makers have long recognized this. Substantial work leading to the RNP began in 2012 in a State Senate subcommittee. This committee sought solutions and included a diverse group of people representing public safety, hospitals, homeless services, ED doctors, substance abuse experts and others. A law was passed in 2012 (23-1.10-20) allowing for a three-year pilot project to take persons "incapacitated by alcohol" to an alternative care facility. The Providence Center won a contract to provide these services, and the Providence Catholic Diocese offered the use of its building above a homeless shelter (Emmanuel House). \$250,000 of state money was allocated for renovations of Emmanuel House. It looked like it was ready to go.

Then nothing happened. The problem was, as it always is, the funding. There was no money stream to provide the services projected to be around one million dollars annually. No single entity (hospitals, insurers, Medicaid) would financially benefit enough by keeping these people out of the ED to make it worth their while to fund it. At the same time everyone lamented the expense in treating this population in the ED. The economic problem of the homeless alcoholic was everyone's and no one's at the same time.

Meanwhile the Affordable Care Act and Medicaid expansion was growing. This population we were seeing in the

EDs was changing from an uninsured to Medicaid predominance. Now, the difficult question of “Who is paying for this?” became easier to answer. RI’s state Medicaid office recognized its responsibility and expenses. Through a federal Medicaid waiver, the RNP was shaken from its slumber and given the infusion of funding it needed to keep the doors open.

By autumn of 2016, the renovations at Emmanuel House were finishing up, and the new staff was working out the clinical protocols. The RNP was to open 7 days a week between 11a.m. and 11p.m. A registered nurse would be on site, as well as an administrator, recovery coaches and social workers. Providence EMS staff toured the facility and protocols were developed to facilitate EMS transfers. Providence would join San Francisco as the only communities in the country to operate sobering centers that accepted intoxicated people from EMS.

Here’s how it would work: An intoxicated client would come in and be assessed by the nurse on duty. If the client passed a brief screening exam including vital signs and a glucose check, he or she would be allowed to rest until reasonably sober. During this time, periodic assessments would be made much like nursing rounds in the hospital. Upon sobriety, the client would be offered detox referrals, case management and shelter beds for the night. If a medical condition arose, EMS would be called to take the patient to the hospital. A physician was on call to handle any questions about client care. All this was funded en bloc from Medicaid. There was no billing for services.

The Short Life

The RNP opened on December 1, 2016 and was quickly in a fight for its life. One immediate issue was finding staff comfortable with this new model. A number of patients transported by EMS were being turned away for a variety of reasons. This reluctance to accept patients soured the relationship between EMS and the RNP’s nursing staff from the start. Very few people were admitted in those early months. Sometimes days would go by without an admission.

Eventually a core staff of nurses (including one who was also an EMT) served the RNP better. No longer were they looking for reasons to send the patient out, but they were looking for reasons to keep the patient there.

However, the damage with the fire department had been done. While the leadership within the fire department promoted the RNP, the EMS crews on the street continued to take potential clients to the EDs. Ultimately, the EDs were convenient. The RNP often was not. There was always a chance that the nursing staff would reject the patient, and they would be sent to the ED anyways. In the end a few dedicated EMS crews were invested in the mission of the RNP, and over time most of the slow trickle of EMS drop-offs came from these few crews.

While the struggle to bring patients in was developing, the struggle to place patients after sobering grew. At the outset,

the Department of Behavioral Health, Developmental Disabilities and Hospitals set data points that would determine the success and safety of the RNP. One of the main benchmarks was the percentage of patients placed in detox services. However, the very barriers the private detox centers imposed after the closure of Ben Rush also affected the RNP (which ironically was the community’s response to these barriers).

The first barrier was the availability of beds. To determine bed availability, caseworkers would call each detox center individually, as there is no centralized reporting center. Frequently beds were available but new patients were not accepted until business hours the following day.

However, the most restrictive barriers were the “medical clearance” and insurance authorization policies imposed by detox centers. Frequently, clients were told to go from the RNP to the ED for medical clearance. To be clear, these were clients who would have otherwise been discharged to the shelter had they not wanted detox. Medical clearance is a nebulous term that means different things to different detox centers. Some wanted labs drawn, some wanted toxicology screens and some even required psychiatric evaluations before admitting patients. It also became apparent that “medical clearance” also meant “insurance authorization”. These centers want their patients vetted, able to pay and only during business hours.

Furthermore, very quietly, in January of 2018, the state detox contract for uninsured patients expired. Clients without insurance then had no detox program available to them at all. Still, at the RNP, we were held to the metric of placing these clients in detox.

As the RNP census grew to almost 500 in the first year, it became apparent that many of our clients were undocumented immigrants (not on Medicaid), walking in or coming by an outreach van. At the same time the budget for the RNP was running at \$70,000 per month, all funded through Medicaid. Medicaid was not getting a return on its investment, and there were no other financial supporters. Hospitals, municipalities, businesses and nonprofits were supportive in its mission but not in funding.

On August 8, 2017 Governor Gina Raimondo and Dr. Nicole Alexander-Scott, the director of the Department of Health, descended on the RNP with an entourage of politicians, advocates and TV crews. Quite ironically, the occasion was not related to alcohol abuse, but instead was the ceremonial signing of three bills addressing the opioid epidemic. The RNP was born into this climate. Public and media attention, funding, legislation and resources have been poured into the opiate epidemic. Alcoholism has taken a back seat (although it still kills more Americans than opiates³), and the RNP fell victim to this. There is only so much money, media and attention that a community can give to substance abuse, and the RNP never developed the robust support that it needed in the shadow of opiates.

The Death of RNP

Death for the RNP came as it usually does for public health projects, in the form of decreased funding. In the spring of 2018, Medicaid, in a series of cost-cutting measures, changed the way it funded the RNP. Instead of bloc funds, it would create a billing structure so that the RNP would bill Medicaid clients for each visit. The problem was, undocumented immigrants made up 50 percent of the visits. Only able to bill for half the services, the RNP was doomed. It closed quietly on July 1st of this year. And with that our State's innovative response to this national public health epidemic was quietly put to rest.

At the end it was open for only 18 months; 1,200 visits were made, about 30 percent of them by EMS diversion. There were no adverse medical outcomes. This was a success for all the clients served, just not for Medicaid.

When the state decriminalized public intoxication in the 1970s, it created a medical framework to deal with this problem. Now we are stuck in the medical model without the public infrastructure to address it as intended. At the RNP, we tried to demedicalize public intoxication. Instead we found out how difficult this was and how far reaching its ramifications are. If we are going to change this cycle for our patients, we are first going to have to change our community.

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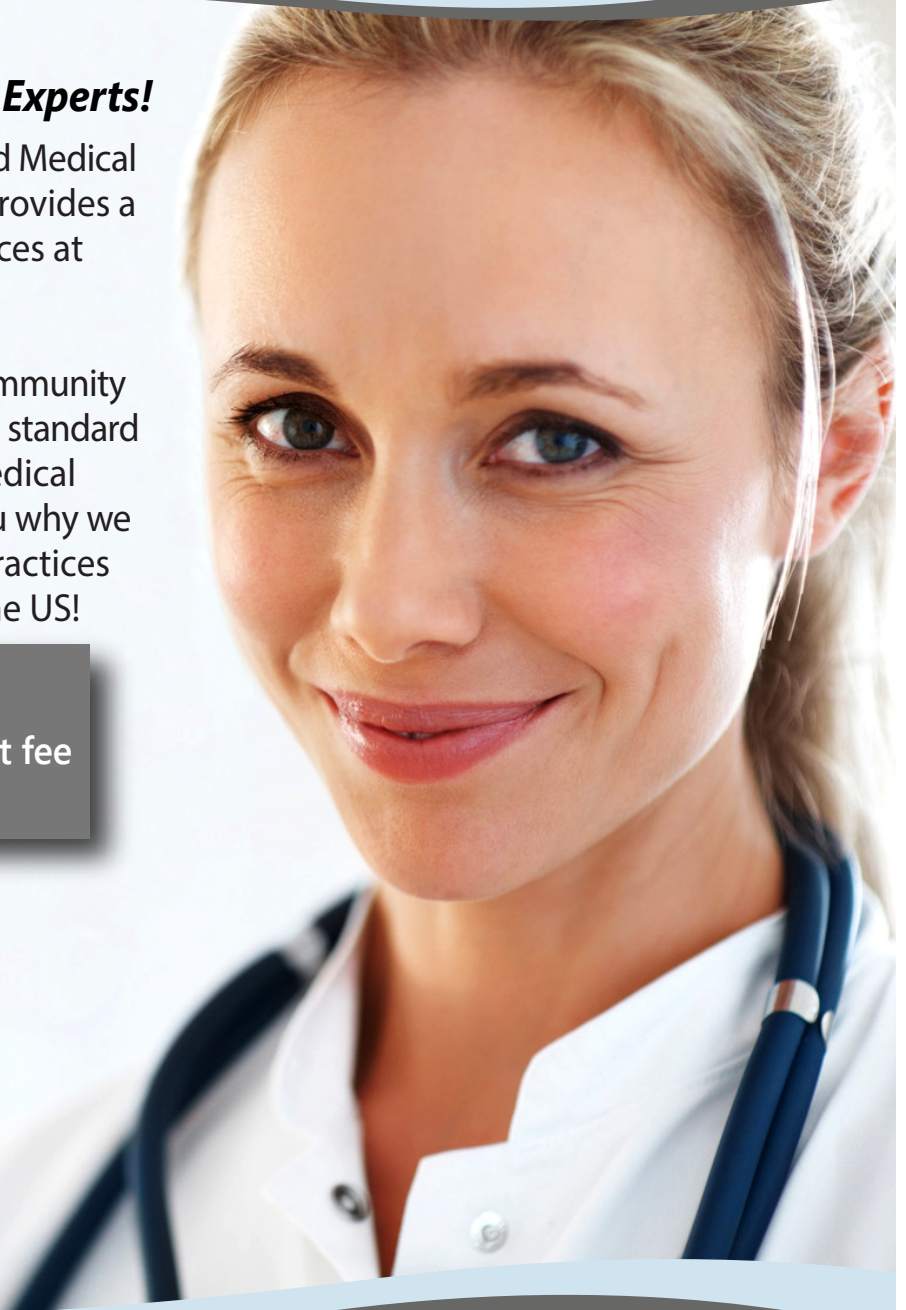
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