

## REIMPORTATION FROM CANADA AND BEYOND

ANDY TROSZOK, R.PH.\*

### ABSTRACT

Importation of drugs from Canada is safe, as long as there is a strict and strong regulatory structure. Canada has such a structure. Importation through the use of mail order pharmacies is appropriate, safe, and can provide at least a partial solution to the U.S. problem of high cost medicines. There are no absolutely safe alternatives, but decisions must be made upon the evidence. At the current time, there is no evidence that drugs from legitimate Canadian pharmacies and, in addition, from parallel importation from the European Union are problematic. Ultimately, those who criticize Canadian drug importation are fear mongering and not relying upon evidence, or else they have a vested interest. If we are going to consider importation, we need to consider what regulations are available in the countries that are going to import, how to make them stronger if necessary, the reality of safe drugs coming from those countries, and the people who need the drugs. A system that works is the Canadian system and mail order pharmacies. We need to have the regulators, the pharmacies, and the patients together to discuss this, so that everyone gets the benefits of the availability and the use of appropriate medications.

### INTRODUCTION

Thank you for the opportunity to speak before you. I have spoken at many conferences on the topic of importation, and they tend to be very one-sided. It is a pleasure to speak at a conference with a balanced forum, where we can generate debate and discussion. When I was asked to speak at this conference, I asked myself what should I speak about? There are a lot of very reputable people here. I was told

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\* President, Canadian International Pharmacy Association. Extended Care Pharmacy, 109, 2915 - 21 St NE, Calgary, AB, T2E-7T1 Canada. Email: Andy.Troszok@extended-carepharmacy.com.

to speak on safety and on the appropriateness of reimportation. As we've seen today, maybe it's better to be called importation. But there is this area of safety. So let's jump into this issue.

### SAFETY AND IMPORTATION

Is reimportation/importation safe? Yes and no. This is the answer: I think if anybody says reimportation is safe, they are irresponsible. At the same time, I think if people say it is not safe, they either have a vested interest, or again, I think they are very irresponsible.

It's very easy to look at the e-mails we get on a regular basis: ads for Viagra, ads for OxyContin, and say "reimportation is not safe." But it's also very difficult to look at a patient who is choosing between eating food and taking a prescription medication, and say, "oh, reimportation is bad."

With regard to our operations in Canada, I think it is important to make certain clarifications about what we are doing because it is very easy to criticize organizations that do not function properly. We are not really dealing with an Internet pharmacy. This has been a frustration for the past four years that I have had to address. I am a registered pharmacist. I have never practiced Internet pharmacy. I'm not even sure if Internet pharmacy is a practice. To me it's illegal, unprofessional, unethical, and puts patients at risk.

What we are is an international mail order pharmacy. I own one of these pharmacies. What do I utilize the Internet for? I utilize the Internet for information, for education, to post my prices, and for patients to register with my pharmacy by filling out a form. That's all they can do. We're not talking about third-world countries. We're talking about Canada and some other countries that may qualify.

I testified in front of the U.S. Congress, and I specifically testified on the issue of reimportation of medications from Canada. The hearing was chaired by Dan Burton from Indiana. At the time, William Hubbard of the FDA was testifying. Dan Burton asked him, "Do you have evidence of counterfeiting from Canada?"

"Yes."

He stood up. He held a package of medication and it was in powder form, mislabeled. He went into a fifteen-minute explanation of how the FDA had obtained this package of counterfeit drugs.

Again, he was asked, "Where did this drug come from?"

He stated, "Thailand."

It is very convenient for organizations that oppose importation to

utilize examples. Organizations such as the Illinois Pharmacists Association fear mongers what credible, legitimate pharmacies are doing and tries to associate them with illegitimate organizations. The FDA does it. The pharmaceutical industry does it. But I think that is very irresponsible. We are not talking about criminal organizations. We're talking about licensed, legitimate pharmacies, licensed in Canada or licensed within the European Union, for example.

Now, do organizations, Internet pharmacies, illegitimate organizations from third-world countries exist? Absolutely they do. And I, probably more than anybody in this room, want to make sure they are put out of business because they make me look bad, and I am proud of what I do. But let me give you a bit of information about the mail order industry in Canada.

Reimportation has occurred for decades. As soon as there was a price discrepancy between the two countries, we started to see people driving across the border. It tended to be individuals. Then, in the 1990s, we actually saw bus tours from Illinois, from Minnesota, from Maine, heading up north. There was a bit of politics around these trips, but no real issue. The pharmaceutical companies didn't stand up and say "drugs aren't safe from Canada." The FDA did not say drugs were unsafe from Canada and from all of these organizations. Neither Canada nor the United States, including the Canadian Medical Association and the Canadian Pharmacists Association, said this was a bad thing. They did not object until we introduced mail order pharmacy from Canada. We were able to reach a much broader group, and the economics started to become a real factor. Then, reimportation became an issue.

So, what is the current situation right now? Unfortunately, my information is somewhat dated. However, annually, we are probably reaching about 1.5 to 2.0 million Americans.

#### SAFETY IN CANADA

What I also think is irresponsible is to fear monger and to put scenarios into place without evidence. At the end of the day, if we are scientists, if we are professionals, we should make our statements and our judgments based on evidence. And to date, there is no evidence of any safety issue from a licensed, legitimate Canadian pharmacy. Are there counterfeit pharmacies or Internet pharmacies somewhere in Canada? There probably are. And if there aren't today, there will be, because we saw what the incentives are for criminal organizations to

get into this business. But again, when we're dealing with licensed, legitimate Canadian pharmacies, there is no evidence of problems. There's no evidence of counterfeiting. Again, you can create fear of counterfeiting or of transshipping; "Al Qaeda's going to transship mass amounts of medication through Canada." But where is the evidence? Ask the FDA themselves. Are there any cases of counterfeiting and transshipping out of Canada through licensed legitimate pharmacies? The answer is no. And it's too bad that Health Canada is not here, because Health Canada should be here. It's a disgrace that we are challenged globally about our standards, and no one in Health Canada is willing to stand up and talk about that.

### WHO ARE THE CUSTOMERS?

Who is ordering these drugs from Canada? Well again, we saw statistics. What was it—fifty or sixty million uninsured? There are other statistics. Maybe there are 100 million underinsured. I deal with these patients. These are elderly patients on fixed incomes, and they cannot afford their medication. Now another thing that we do, and again this goes back to regulations and being professionals, we only deal in chronic, life-saving medications. My pharmacy does not sell Viagra, even though I would make a lot more money selling Viagra. I do not ship insulin. We do not ship narcotics because that would be completely illegal. Not "somewhat illegal," which I guess is what I am doing. I always wonder if I am ever going to be handcuffed at the border.

What kind of states and municipalities are ordering drugs from Canada? Currently, we have about five states that have active programs. I would say I am contacted about once a month from a state wanting to look at our activities. I was involved with Illinois. I was involved with Minnesota, very closely with Governor Pawlenty's office, to help set up their program. I think both programs are doing quite well and have very good guidelines. There are four cities doing it. Springfield, Massachusetts is one that has been in the news and actually showing major savings. Now I am not sure if these types of organizations should be ordering, but they are; and they are growing, probably weekly.

What about other organizations? Who else is ordering? There is the National Association of the Terminally Ill. This organization is very interesting because you have to look at who is addressing the issue of pricing. I will give credit to the Illinois Pharmacists Associa-

tion who has gone out and looked at how we can get patients the best, cheapest medications possible. Utilize the pharmaceutical card programs. Utilize generics. But in that whole mix, Canadian reimportation can be part of that mix. Ironically, the National Association of the Terminally Ill does that exactly. They take a patient and they say, where can we get your medications the cheapest way possible? They utilize all those resources that the Illinois Pharmacists Association does, plus they look at reimportation. If none of the former work, and in many cases they do not, then they utilize Canadian reimportation.

#### SAFETY REFRAIN

Hopefully, I am not going to beat this issue to death, but let us consider safety once again. I look at three parameters: quality control, regulation, and trained staff. As was mentioned, Health Canada is the department responsible for drug management in Canada, and Canada does have one of the most advanced and safest drug approval systems in the world. The FDA would like you to think that they know nothing about Canada and nothing about Health Canada. Again, these were the statements that William Hubbard made to Congress, including that the FDA had no jurisdiction and had no information, even though we are the U.S.'s largest trading partner. The FDA would like you to think, and would like U.S. citizens to think, that it knows nothing about Canada. But that is completely wrong. There are common agency mandates. There are coordinated efforts between the two organizations, in terms of research, in terms of drug approval, in terms of actual counterfeits. These organizations work hand-in-hand.

What is actually more important from a Canadian perspective is how the Canadian agencies involved in drug distribution are licensed. This is similar to the United States. Federally, we license drug approval. The wholesale market in Canada is a very closed system. How do I know? Because I actually own a wholesale business, and to get a wholesale license in Canada is very difficult. There are application processes including inspections, criminal checks, and ongoing inspections. And correct me if I'm wrong, and there's a wholesaler in the room, my understanding is that in the United States, all it takes is a driver's license and \$1000. I could be wrong. I apologize if I am. But, that is why cases of counterfeiting have been almost a non-issue in Canada.

Provincially, just like in the United States, pharmacy and pharmacists are managed and regulated at the provincial level, as they would

be at the state level. So, in terms of safety, we have great regulation. One thing that we did touch on, manufacturing is starting to become centralized. Why is it starting to become centralized? Because the pharmaceutical industry realized that if we centralize things, we pay less.

Now we are not dealing with FDA-approved drugs. The argument is that the drugs we are dealing with in Canada, and let us say in the United Kingdom, are equivalent because they are manufactured in one facility. Is that to say that there's a conveyer belt that runs for the United States, and there is a conveyer belt that runs for the rest of the world? No. It wouldn't make any cost sense to do so, and it does not happen that way.

Let us look at what actually is out there. Congress commissioned a research report in May 2003. Experts went to Canada and met with Health Canada. They did massive inspections, and Canada is as safe, if not safer, than the United States. And the "if not safer" was the wholesale system. We've been inspected by numerous state pharmacy boards and came up with good results.

There was a comment from the doctor this morning that there were some issues with Canadian pharmacies. Absolutely. There are issues with U.S. pharmacies. But we function in a regulated system that allows us, if there are issues, to correct them; if you do not correct them, you are not going to get accredited. Again, we work in a system that works.

There was also discussion about the current Congressional bills on importation. But again, I go back to the evidence. There is no reported case of harm, and no case of counterfeiting or transshipping through Canadian pharmacies.

For the health care professionals in the room, let us look at a safety issue. And again, to the critics of importation, I know you have criticisms or you think you have criticisms, but why don't you have solutions? Solutions are what we really need. What are you going to tell the little old grandma who is choosing between eating and taking her prescription medication? What are you going to tell the couple who are sharing drugs because they think "well, if I take half my Lipitor, I'm going to get at least half the benefit." Well, that is not the way drugs work. You and I know that.

You know I'm not here to beat up on the pharmaceutical industry; I worked for the pharmaceutical industry, and they treated me very well. But what I would like to be able to do is put this issue of safety aside. If there is a safety issue, then our Canadian government better

start making inquiries to Pfizer and Merck about sending substandard drugs to Canada. You are not seeing a lot of dead Canadians because they are using Canadian prescriptions. That is reality. They are the same drugs.

### PROFITS AND PRICING

Let us talk about profits because this is what it is all about. Again, in a country that is focused on profits, I envy the capitalistic spirit in the United States. If we consider profits, then reimportation will negatively affect research and development. There is a notion that Canada, and the rest of the industrial world, is getting an unfair ride. They have unfair policies. And these poor drug manufacturers are not making any money in Canada.

They are publicly traded companies. You can see how much money they make, return on revenue: Pfizer; Eli Lilly; 28.4, 24.4%, plus 18.6% profit for the pharmaceutical industry. Then you see community pharmacies at 2.1%. I am somewhere down there unfortunately. But again, this shows you that these industries are incredibly profitable, and they will continue to be profitable. What is ironic is that Boston University did a research study that showed reimportation would make pharmaceutical companies actually more profitable in the long-term.

What about research and development? I have seen numbers as low as 12% of research and development costs relative to marketing. I actually had the pleasure of speaking with Dr. Arnold Relman. He's a medical doctor at Harvard, and the former editor of the *New England Journal of Medicine*. He said the rhetoric is stirring, but the arguments simply do not hold. First, research and development constitutes a small portion of the budgets of the large drug companies, whereas their marketing and advertising expenditures are much greater. Furthermore, they make more in profits than they spend on research and development. That is the reality.

Let us address the issue of unfair pricing. In Canada, if a company wants to have a monopoly on a product, they can, through a patent. Our federal government says, "Well, we will not negotiate with you. If we are going to give you exclusivity in the market to recoup your investment and to have the opportunity to make a profit (and they do make extensive profits in Canada), we should actually have a say in how you price the medications." It makes sense to me. But I am Canadian, and we do not really make sense all that often.

Brand name manufacturers impede generic manufacturers getting into market. The first thing that happens when a generic manufacturer comes to market is they sue it. Why? Because they tie it up in the courts and the amount of money they spend in courts is a fraction of the amount of money they are going to make in the next six months to a year.

One thing we do differently in Canada than in the United States and in the European Union is that we do not allow direct-to-consumer advertising. (It is an extended amount of spending that the consumer has to pay for. And lobbying by the brand name companies too, that is a lot of golf games.)

#### APPROPRIATENESS OF IMPORTATION

Let us look at this issue of appropriateness. Is reimportation appropriate? Well, if we are only tapping two million Americans, we are not affecting or solving the problem in the U.S. And I'll be the first one to say that reimportation is not the ultimate solution. But you know an immediate solution. And why do I know that? Because every single day, I send medications to people. I am not going to sit here and say all my clients are choosing between eating and taking their medications, but some of them are. I know that if I were not around, those people would not be taking their medication, which would result in their being hospitalized and maybe dying.

We have a proven system if it is done appropriately. Again, to the Illinois Pharmacists Association, we have an actual pharmacist-to-pharmacist model. I have developed it myself and presented it to three states. We are looking at implementing it with U.S. pharmacists. U.S. pharmacists should provide the cognitive service, the care, the one-on-one interaction. There is enough differential to pay for the pharmacist in the U.S. and to allow the Canadian pharmacist to fill and dispense the prescription. Create a collaboration. It can be a solution. It can work. But when I showed it to the FDA, they told me the pharmacist would be charged with aiding and abetting.

The message of our minister Ujjal Dosanjh was actually correct. We cannot be the drugstore for the U.S. But that is why direct-to-consumer works, because the people in need, the people that really do not have any other options, are coming to Canada. Not all of them. Some of them are going to Mexico and some of them, yes, are unfortunately going to rogue sites, and there is a health issue. But we can solve that issue. The problem is the agencies that I am willing to work



with will not discuss the issues. I went to the FDA and asked, “what do you guys want? Do you guys want to inspect my facility? Do you want me to get extra licensing?” They basically said we do not even want to talk to you. We did this for political relations.

There was mention of VIPPS, VIPPS certification. I applied for VIPPS certification. I could be certified as a VIPPS pharmacy if I had a pharmacy in the U.S. I could be VIPPS-certified if I had a Canadian pharmacy that only sold to Canadians. But as soon as I sell to Americans, I cannot be VIPPS-certified. It is complete hypocrisy.

### REIMPORTATION BEYOND BORDERS

I think we have an ability to go beyond the borders, but the countries selected have to have comparable safety, quality, and regulatory parameters to Canada. Otherwise, there is no point in going. I think patients need to be part of the process. For example, my pharmacy, if you come to my mail order pharmacy with a legitimate prescription, you have the choice of having your prescription filled in Canada or in the United Kingdom. These are the only two countries where I feel comfortable going because I have inspected the facilities in the United Kingdom. Now again, there is fear mongering, and there are statements made by Canadian pharmacists who say, “we are going elsewhere.” Well, go elsewhere. But if you are a Canadian pharmacy, and there are regulatory parameters which can be implemented, preventing you from sending a drug from India, then we can regulate that kind of practice out of business.

I have also looked at parallel trade. Again, it does have its challenges. But again, if we look at the evidence, it actually does work. There have been no cases of counterfeiting. The German commission said that in the ten years that they have been doing parallel trade, not a single case of counterfeiting has been encountered. We have to look at the evidence.

### CONCLUSION

Reimportation can occur if it starts safely. I am the first to say we need stricter and stronger regulations. But we need to have the people who control the regulations at a table discussing this. We all lose with counterfeiting and transshipping. We all lose when patients cannot afford their medications because those patients will suffer. They will become a further burden on the social structure of a country. I think

reimportation can be beneficial to pharmacists, pharmacies, pharmaceutical manufacturers, and governments. But most of all, I think it can be most beneficial to patients. Thank you.