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Canadian Speaker Session 10: Canada and U.S. Approaches to Cross-Border Sales of Pharmaceuticals - Canadian Speaker

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CANADIAN SPEAKER

Jennifer A. Orange[†]

Thanks very much, Sara. That was very helpful in setting the stage for my presentation, which is on the Canadian perspective on cross-border pharmaceutical trade, in particular on the rise of Internet pharmacies over the last several years.

First, I want to thank you for inviting me to speak to you today. I am really honored to be here. I am going to review the background of the rise of Internet pharmacies and look at the regulatory framework in Canada that has allowed them to be profitable. I will look at the arguments for and against the pharmacies from the Canadian perspective, what the regulators are doing, and what they may do in the future to curtail the growth of Internet pharmacies.

Just one small anecdote: This morning I met a friend for coffee, whom I have not seen for some time. She recently moved back home to Cleveland. She asked me what I was speaking about today, and when I told her, she said, "Oh, that is funny. I just ordered some drugs online from Canada last week." And she works in the healthcare industry, so this got me thinking. Since I think most of the people in this room are Americans, I will not be so bold as to ask you whether you have ordered drugs online, but I was wondering if you could raise your hand if you know someone who has ordered drugs online from Canada.

(Large number of hands raised – laughter.)

There are a fair number of people here who know someone who has done so. Before the popularity of Internet pharmacies, the U.S. and Canadian markets operated in two separate spheres. The United States uses market prices, and Canada has price controls on its drugs, with the maximum price for a patented drug in Canada set by the PMPRB, an acronym for the Patented

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Medicines Prices Review Board.¹ The PMPRB sets this price by taking prices in seven western industrialized countries and using the median price for any single drug.² It is notable that these countries have high living standards and very well regulated health services and health systems. We are talking about the United Kingdom, France, Germany, Italy, Switzerland, Sweden, and the United States. So these are not countries with inexpensive drugs, but because Canada takes the median price, its drug price will never be the highest. Although Sara has referred to the minimal cost savings of online drugs, the Canadian price will typically be somewhat less than the U.S. price.³

The Internet pharmacies capitalize on this difference between the Canadian and U.S. prices by using a price in between the two.⁴ In 2001, we started to see the surge of Internet pharmacies, and by 2002, they were doing \$400 million worth of business.⁵ In 2004, it was reported that these pharmacies did \$850 million worth of business.⁶ Reports about the volume of business differ. Some people think that this \$850 million is a plateau and will not go any higher,⁷ but if the United States actually legalizes the importation of Canadian drugs, or if other states or municipalities further encourage their citizens and employees to import drugs from Canada, we could see further growth in the area.

Although it is illegal in the United States to bring in prescription drugs from Canada, there is a "personal use exemption." An individual can import 90 days worth of drugs for his or her own use,⁸ and Internet pharmacies tend to sell drugs in 90-day amounts.⁹ Although there may be only minimal cost

¹ Dr. Carlyle Farrell, *Canadian e-Pharmacies – Ethics, Law, Politics and the Death of Free Enterprise*, (Ryerson University School of Management, Toronto), March 2005, at 2.

² See Patented Medicines Price Review Board, *Frequently Asked Questions, How Does the PMPRB Review the Pricing Information for all Patented Medicines Sold in Canada?*, <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#16>.

³ See generally Patented Medicines Price Review Board, *Frequently Asked Questions How do Drug Prices in Canada Compare to Prices in Other Countries?*, <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#14>.

⁴ See generally Consumer Reports, *Prescription Drugs, The Facts about Canada*, <http://www.consumerreports.org/cro/personal-finance/prescription-drugs-from-canada-1005/overview.htm> (Oct. 2005).

⁵ See generally Graeme Smith, *Any Drug Shortages Manageable, Generic Firms Say*, GLOBE AND MAIL (Toronto), Nov. 1, 2003, at A4.

⁶ Susan Todd, *Canada Mulls Limiting Exports of Affordable Medicines*, NEWHOUSE NEWS SERVICE, available at <http://www.newhousenews.com/archive/todd021405.html> (Feb. 14, 2005).

⁷ See generally *id.*

⁸ Ted Sickinger, *Internet Prescription Sales Fly Not Quite Under the Radar*, THE OREGONIAN (Portland), Oct. 16, 2005.

⁹ See generally *id.*

savings for some drugs, for others, the numbers are significant. The price for Clarinex, the allergy drug, is \$27 in Canada, and \$70 in the United States.¹⁰ For Lipitor, a very popular cholesterol-reducing drug, the price is \$144 in Canada, and \$200 in the United States.¹¹ And for some drugs, the price difference is quite striking. Tamoxifen (Nolvadex), a breast cancer fighting drug, is almost \$300 cheaper in Canada.¹² So for certain drugs, especially those for long-term use, such as Lipitor, you can see why people are searching online to get these cost savings.

One interesting note: Americans who are going online to buy drugs are not the poor. It is not the poor American who is getting these cost savings. Surveys have shown that it is upper-middle-class Americans who are buying drugs online.¹³ They are the people who have ready access to the Internet. They are computer savvy, and they are out there saving their money.

Within Canada, we have heard a lot of criticism about Internet pharmacies, but there is a strong lobby supporting Internet pharmacies. An argument in favor of Internet pharmacies is that this is a strong local business, which began in Manitoba, and now employs about 4000 people.¹⁴ The other favorable argument we hear is that Canadian drugs are safe.¹⁵ Canada has a highly regulated healthcare system, and although there are always some risks in transporting drugs, Canadian drugs are safe.¹⁶ However, more recently, Canadian regulators have been highly critical of Internet pharmacies. The primary issues being that Canadians are going to face drug shortages and an increase in drug prices.¹⁷

The concern over drug shortages arose in the fall of 2004, after a shortage of the flu vaccine in the United States. Canadians were worried there would be a run on the vaccine in Canada, leading to a domestic shortage.¹⁸ Fortunately, that did not happen. Internet pharmacies do not sell wholesale in bulk

¹⁰ Justin Thompson, *In-depth: Drugs Cross-Border Rx*, CBC NEWS ONLINE, <http://www.cbc.ca/news/background/drugs/> (Aug. 12, 2004).

¹¹ *Id.*

¹² *Id.*

¹³ See generally Melissa Lambert Milewski, *Drug Importation Carries Unseen Risks*, Washington Policy Center, <http://www.washingtonpolicy.org/HealthCare/OPEDMilewskiDrugImportationApr2004.htm> (Apr. 28, 2004).

¹⁴ Dr. Carlyle Farrell, *Canadian e-Pharmacies – Ethics, Law, Politics and the Death of Free Enterprise*, (Ryerson University School of Management, Toronto), March 2005, at 2.

¹⁵ See CanadaDrugs.com, *Welcome to Canadadrugs.com*, <http://www.canadadrugs.com/>

¹⁶ See generally *id.*

¹⁷ Thompson, *supra* note 10.

¹⁸ Public Health Agency of Canada, *Frequently Asked Questions - Influenza Vaccine Shortage in the United States*, http://www.phac-aspc.gc.ca/influenza/vaccine_faq_e.html (Oct. 24, 2004) [hereinafter *Influenza Vaccine Shortage in the United States*].

to physicians in the United States; they sell to individuals.¹⁹ Since the vaccine has to be administered by a doctor, there was no mass export of flu vaccine from Canada.²⁰ But we can imagine a situation where some day the flu vaccine is in the form of a pill that you can order online, and the United States has a similar shortage, prompting mass orders that lead to a drug shortage in Canada. For now, it is unclear whether there have been drug shortages. Some pharmacists, particularly in areas where there are a lot of Internet pharmacies, have reported that they have had trouble getting certain drugs.²¹ Other pharmacists in similar areas have said that they have been able to source them.²² So it is not clear whether we have actually run into supply problems. Diane Gorman, Assistant Deputy Minister of the Health Products and Food Branch of Health Canada, did say that cross-border sales of prescription drugs via the growing business of Internet pharmacies raises the potential for drug shortages domestically.²³ Health Canada regards this as a very serious matter due to the inherent risk to Canadians' health. So it is a concern, and it is at the forefront of most Canadian consumers' minds.

It is also difficult to know for certain whether there have been price increases as a result of Internet pharmacies. It was reported that in 2004, Canadian pharmaceutical prices increased for the first time in a decade.²⁴ There are many factors that go into the price of pharmaceuticals,²⁵ so it is hard to know if the Internet pharmacy trend is one factor; but it might be more than a coincidence when \$850 million worth of sales took place last year.²⁶ It will be interesting to watch in the next few years, to see if the trend continues.

In addition to supply and price issues, Canadian regulators have seen Internet pharmacies as posing health and safety concerns, which is interesting because that also seems to be the U.S. concern. To get a prescription drug from Canada, you have to fax an American doctor's prescription to the Canadian Internet pharmacy. The Internet pharmacy then needs a Canadian doctor to sign that prescription because in Canada, a foreign prescription is

¹⁹ See generally Robert McMillan, *Canada: Down on the Pharm*, Washington Post, July 1, 2005, <http://www.washingtonpost.com/wp-dyn/content/article/2005/07/01/AR2005070100611.html>.

²⁰ See generally *Influenza Vaccine Shortage in the United States*, *supra* note 18.

²¹ Press Release, Canadian International Pharmacy Association, *Canadian International Pharmacy Association Requests Evidence of Alleged Drug Shortage in Canada* (Nov. 21, 2003) <http://www.ciparx.ca/art-cipa-requests-evidence.html>.

²² See *id.*

²³ *Internet Pharmacies Could Lead to Drug Shortage: Official*, CBC NEWS, (Oct. 29, 2003).

²⁴ See Thompson, *supra* note 10.

²⁵ Patented Medicines Price Review Board, *Frequently Asked Questions, What factors affect the cost of prescription medicines?*, <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#13>.

²⁶ Todd, *supra* note 6.

not valid. So the Internet pharmacy hires a Canadian doctor to “co-sign,” or “countersign” the prescription. The Canadian doctor reads the prescription and signs off.²⁷ Then the pharmacists can fill the prescription and send the drug to the American client.

However, Canadian doctors are signing prescriptions without ever meeting the patient. So from a health and safety perspective in Canada, they are not following the “principle of assessment and diagnosis,”²⁸ which is something we are all familiar with from our visits to the doctor. The doctor takes your history, conducts a physical examination, and asks you a few questions. The doctor then comes to a conclusion, offers you a prescription, and says, “If it does not clear up within the next week, or you have the following side effects, give me a call.” So Canadian doctors are not following basic practices in their own discipline. This has led to a strong statement by our health minister: “The practice of countersigning prescriptions by doctors without actually having a relationship with the patient, and not properly assessing the patient, is absolutely unethical and unprofessional.” This calls into question the integrity of our own health system if our doctors are not following these basic practices.

Now that we have looked at some of the concerns of Canadians regarding Internet pharmacies, let us look at who could regulate this system. I have set out a chain of parties that may be involved in this system, which is not complete by any means. We have American patients, and obviously, we have American doctors. We have the web providers, such as Microsoft Internet Explorer and Google. These provide access to the Internet, which in turn provides access to Internet pharmacies.

In addition, we have the pharmaceutical companies, both the manufacturers and the suppliers of the drug; the pharmacies, the businesses themselves in Canada; Canadian doctors; and shippers, such as Canada Post, UPS, FedEx, who play a major role. Americans received about 2 million packages of drugs last year,²⁹ so this is big business for the shippers. And finally, we have the Canada Customs and Revenue Agency.

What can the regulators do about Internet pharmacies? It is a complicated system and, in March 2005, our health minister said that he is nowhere near a decision on how to restrict Internet pharmacies. Despite his indecision, there has been some movement in the last twelve months, and it has been mostly against the regulated professions: doctors and pharmacies.³⁰ There is also a

²⁷ See California Healthcare Foundation, iHealthBeat, *Regulators Focus on Canadian Internet Pharmacies*, <http://www.ihealthbeat.org/index.cfm?Action=dspltem&itemID=107928> (Dec. 13, 2004) [hereinafter *Regulators Focus on Canadian Internet Pharmacies*].

²⁸ See *id.*

²⁹ Thompson, *supra* note 10.

³⁰ See generally Todd, *supra* note 6.

potential for regulation regarding customs and exports.³¹ The public moved against the doctors first,³² and the doctors' own association took the strongest action early last year.³³ The Canadian Medical Protective Association is an association that, among other things, helps doctors defend themselves against lawsuits. It announced in February 2004, that it will no longer assist physicians in legal actions arising from inappropriate co-signing.³⁴ Assistance will not be extended, regardless of where the action is launched, inside or outside Canada's borders. So with the litigiousness of the American public, and higher damage awards in the United States, this could cause a lot of stress for some co-signing physicians in Canada, who are regulated by the provincial Colleges of Physicians and Surgeons.

Recently, the Colleges of Manitoba, New Brunswick, British Columbia, and Ontario, have taken disciplinary action against doctors.³⁵ Quebec and Alberta have also taken some action, but they have really only just been able to prosecute a handful of doctors, and the penalties that they have imposed have been meager.³⁶ The most severe penalties we have seen are those in New Brunswick, which fined one doctor \$25,000.³⁷ The harshest penalty was suspending a doctor from practicing for two years.³⁸ But few doctors have been prosecuted. In Ontario, four doctors have been prosecuted, and they have all received mere reprimands.³⁹ There has been no significant fine.⁴⁰ The courts have awarded legal costs, the highest amount being \$5,000 against a doctor who made over \$200,000 in six months just from co-signing prescriptions.⁴¹ He made \$10 a prescription.⁴² So it is somewhat disturbing that the colleges have not been able to take more aggressive action against members of their profession.

³¹ *Id.*

³² *See generally Regulators Focus on Canadian Internet Pharmacies, supra* note 27.

³³ *See Canadian Docs Who Co-Sign Rx Left Without Coverage*, US DEPT OF HEALTH AND HUMAN SERVICES: INDIAN HEALTH SERVICE, http://www.ihs.gov/Medical_Programs/PharmacyIssues/Acquisitions/I_19_04.asp.

³⁴ *See id.*

³⁵ *See Lisa Priest, Doctors in Hot Water Over Web Prescriptions*, GLOBE AND MAIL, October 11, 2004, at A1.

³⁶ *See id.*

³⁷ *Id.*

³⁸ Marguerite Higgins, *Canada Prescribes Penalty for Doctor*, THE WASHINGTON TIMES, February 3, 2005.

³⁹ *See Priest, supra* note 35, at A1.

⁴⁰ *See id.*

⁴¹ James Rusk, *MD Fined \$5,000 for Net Drugs Role; Ontario College Too Easy on Doctor Who Signed U.S. Prescriptions, Critic Says*, GLOBE AND MAIL, March 11, 2005, at A11.

⁴² *Id.*

We are also seeing some action by the colleges of pharmacies⁴³ – for example, the Manitoba Pharmaceutical Association says it plans to take action against pharmacies that do not follow provincial medical standards.⁴⁴ This would mean that if a pharmacist gets a U.S. prescription that a Canadian doctor has just co-signed, the pharmacist is not to fill it. The prescription would not meet Canadian medical standards. But again, it is taking some time to get the regulatory ball rolling.

The customs and export arena offers potential for helpful regulation, although the options may be somewhat problematic under NAFTA.⁴⁵ One option is to use export restrictions under the Export and Import Permits Act, which can restrict which drugs are exported to the United States, or restrict the exports of price-controlled drugs – those drugs under the PMPRB's area of jurisdiction.⁴⁶ Another potential course of action would be to create a list of drugs that would be banned if shortages actually did occur. Any absolute export restriction would be challengeable under NAFTA. The third option may be able to survive a NAFTA challenge if Canada could show that there was a health and safety concern in the event of a drug shortage that needed to be addressed for the health and safety of Canadians. At this point, however, we do not have any indication of how Health Canada may proceed.

While the governmental entities have been acting slowly on these issues, private actors have been swifter. As we can imagine, the pharmaceutical companies are very concerned about this issue and have brought lawsuits against Internet pharmacies,⁴⁷ especially where the companies find an illegal version of the drug being sold.⁴⁸ Pharmaceutical companies for approximately the last year and a half have been limiting supply to wholesalers that

⁴³ See Nat'l Ass'n of Bds. of Pharmacy, Position Paper on the Importation of Foreign Prescription Drugs (March 2003), available at <http://www.nabp.net/ftpfiles/NABP01/foreigndrug.pdf>.

⁴⁴ Canadian Health Minister Welcomes Pharmaceutical Assoc's Action Against Pharmacists, MEDICAL NEWS TODAY, December 5, 2004.

⁴⁵ See generally John R. Graham, *Prescription Drug Prices in Canada and the United States – Part 4: Canadian Prescriptions for American Patients Are Not the Solution*, PUBLIC POLICY SOURCES, September 2003, available at <http://www.fraserinstitute.ca/admin/books/files/PDP4John.pdf> (evaluating various prescription drug policies from a free trade perspective).

⁴⁶ See Martin O'Hanlon, *HL: Canada Considers Banning Sale of Cheap Patented Drugs to U.S.*, AP Alert – Bus. 21:04:25, February 18, 2005; see also generally *Drug Patents and Drug Prices: The Role of the PMPRB*, Patented Medicine Prices Review Board, <http://www.pmprb-cepmb.gc.ca/English/view.asp?x=134&mid=71> (provides overview of the PRMPB's role and jurisdiction).

⁴⁷ See e.g., Press Release, Pfizer, Unlicensed and Illegal Online 'Pharmacies' Deceive Consumers, Intrude on Their Privacy and Pose Public Health and Financial Risks, August 3, 2004, available at <http://www.prnswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/08-03-2004/0002223913&EDATE=>.

⁴⁸ See *id.*

sell to Internet pharmacies as a way of cutting off the supply at the source.⁴⁹ They are not limiting supply to regular pharmacies that are legitimately serving the Canadian public, but to Internet pharmacies that are then exporting the drugs to the United States.

It will also be interesting to follow discussions about the use of technology to trace the flow of drugs coming from the pharmaceutical companies. Internet pharmacies themselves are considering establishing a self-regulated standard⁵⁰ so that when customers come across the standard, they will know that this Internet pharmacy is following certain regulations, is not breaking any laws, and is legitimate. But for now, that standard would mean that the Internet pharmacy is not exporting drugs to the United States. The standard would be used only for Internet pharmacies that sell exclusively to their own nationals.

Canada is clearly grappling with how it can limit the cross-border trade of drugs through Internet pharmacies, but the Internet pharmacies keep going. David McKay, a very outspoken Executive Director of the Canadian International Pharmaceutical Association (the association that represents Internet pharmacies), stated: "We are like the mosquito that they cannot seem to kill."⁵¹ This is not the most flattering self-description I have ever heard, but he is right. They keep on surviving, and the drugs keep flowing from Canada to the United States. And if, for some reason, they are stopped, and Canadian Internet pharmacies can no longer sell drugs to Americans, I have no doubt that American consumers will continue to find low-price pharmaceutical drugs from further afield.

Thank you.

⁴⁹ See Tom Cohen, *Internet Drug Firms Ailing Big Drug Makers Strangling Supplies to Stifle Upstarts*, GLOBE AND MAIL, September 2, 2003, at B12.

⁵⁰ See e.g., Nat'l Ass'n of Pharmacy Regulatory Authority, Verified Internet Pharmacy Practice Sites (VIPPS) Letter of Agreement, available at http://www.napra.ca/VIPPS_site/forms/0307letterofagreement.pdf (laying out the agreement between the Canadian regulatory body and the association representing Canadian pharmacies).

⁵¹ Priest, *supra* note 35, at A1.