

BILL C-83: PROPOSED LEGISLATIVE RESPONSE TO THE INTERNET PHARMACY INDUSTRY AND POTENTIAL SHORTAGES IN THE CANADIAN DRUG SUPPLY

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INTRODUCTION

THE INTERNET PHARMACY INDUSTRY has skyrocketed since 2000, when a University of Manitoba pharmacy graduate from Minnedosa, Manitoba started selling Nicorette gum to Americans on eBay.¹ Andrew Strempler discovered that the non-prescription gum used to help individuals stop smoking was significantly cheaper in Canada. In as quickly as three months, Mr. Strempler was informed by his distributor that “he was selling more Nicorette than any drugstore in Canada.”² At the same time, another University of Manitoba pharmacy graduate, Daren Jorgenson, was selling glucose-monitoring equipment to the United States. Eventually, both Jorgenson and Strempler started Internet pharmacies CanadaMeds.com and RxNorth.com, respectively.³

Although the industry has grown significantly in a short period of time, there are suggestions that the growth has leveled off and actually started to decrease. The value of the Canadian dollar, a new American prescription drug plan,⁴ and the growth of Internet pharmacies in other parts of the world have negatively affected the Canadian industry.⁵ Moreover, an increasing percentage of the industry involves generic

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¹ Roger Parloff, “The New Drug War Pharmaceutical companies need profits to develop new drugs. Patients need pills that they can afford. Their interests are colliding at the Canadian border” *Fortune* 149:5 (8 March 2004), online: CNNmoney.com <http://money.cnn.com/magazines/fortune/fortune_archive/2004/03/08/363677/index.htm>.

² *Ibid.* at para. 2.

³ *Ibid.*

⁴ Michelle MacAfee, “Internet pharmacists anxiously await fallout” *Canadian Press* (15 December 2005), online: Canoe Network <<http://cnews.canoe.ca/CNEWS/Special/2005/2005/12/15/1354557-cp.html>>.

⁵ Brett J. Skinner, “Price Controls, Patents, and Cross-Border Internet Pharmacies: Risks to Canada’s Drug Supply and International Trading Relations” *The Fraser Institute* (February 2006), online: The Fraser Institute <<http://www.fraserinstitute.ca/admin/books/files/PriceControls&XborderPharmacies1.pdf>>.

drugs, which have a smaller profit margin than brand-name drugs.⁶ In fact, Canadian generic drugs are generally more expensive than their American equivalents; however, some drugs that are already available in Canada in a generic form may still have patent protection in the U.S.⁷ Consequently, there may be large scale intellectual property theft occurring through the Internet pharmacy industry. To fully understand the industry, I will begin by looking at the response to the Internet pharmacy industry and will examine why Canadian brand-name drugs are cheaper than American ones. This will be followed by a thorough discussion of Bill C-83 and the legislative debate surrounding it. Finally, I will discuss the efficacy of the proposed legislation. Does it go too far or not far enough? Should anything akin to it be re-introduced by the new Conservative government?

RESPONSE TO THE INTERNET PHARMACY INDUSTRY

THE MASSIVE GROWTH OF THE INTERNET INDUSTRY has caught the attention of both American and Canadian lawmakers. The U.S. Food and Drug Administration (FDA) has claimed that drugs imported from Canada are dangerous, declaring that there is the potential that Canadian drugs are counterfeit or may not meet U.S. regulations. However, studies by both Health Canada and the U.S. General Accounting Office have refuted these claims, concluding that drugs purchased from Canadian Internet pharmacies are as safe, if not safer, than their American counterparts.⁸

Moreover, it is currently illegal for American consumers to import drugs from other countries. Until now, discretion has been used in enforcing these laws and no charges have been laid against any individual American consumer.⁹

The pharmaceutical manufacturing industry has come out strongly against the Canadian Internet pharmacy industry. Although the losses experienced by the pharmaceutical manufacturing industry to this point have been minimal, as the bulk-buying potential increases in the U.S., it fears the growth of the industry.

⁶ *Ibid.*

⁷ *Ibid.*

⁸ Michael Geist, "No good reason to bow to U.S. pharma's lobbying," *Toronto Star* (February 2005); see online: Michael Geist <http://www.michaelgeist.ca/resc/html_bkup/feb72005.html>.

⁹ Aidan Hollis & Aslam Anis, "Rx for Canada: Close the Internet Pharmacies," *C.D. Howe Institute* (October 2004), online: C.D. Howe Institute <http://www.cdhowe.org/pdf/commentary_205.pdf>.

There are two main reasons for the lower prices of Canadian pharmaceuticals; first, Canada is a smaller market than the United States, and second, American citizens have the ability to pay more for brand-name drugs. If more and more brand-name pharmaceuticals are imported into the U.S., the market size will increase greatly, as will the ability to pay higher prices.¹⁰ Pharmaceutical companies, including Eli Lilly and Co., Pfizer Inc., and GlaxoSmithKline PLC, have already started to restrict supplies to Canadian Internet pharmacies. This has created a threat that supplies will not be available for Canadian consumers, and that the prices of some drugs will be higher than in the U.S.¹¹

Canadian Internet pharmacists believe they are simply filling a void to ensure that senior and low-income Americans can afford brand-name drugs, which are expensive for individual consumers.¹² On the other hand, in an article written by Steven Morgan and Jeremiah Hurley, they argue that large drug plans in the U.S. (government, insurance companies and Health Maintenance Organizations (HMOs)) pay less than the Canadian prices, due to the significant amounts of capital available to negotiate lower prices for their bulk purchases.¹³ These agreements are private and not disclosed. However, the prices must be less than the price of purchasing brand-name drugs from Canada, or else insurance companies and HMOs would also be lining up to purchase drugs from Canada.¹⁴ Nonetheless, all that the Canadian Internet pharmacy industry needs to succeed is uninsured Americans, as their numbers are estimated at somewhere between 23 and 46 million.¹⁵ Even using the conservative estimate of 23 million, it is more than two-thirds the entire Canadian population.

In the wake of the Avian influenza outbreak and the only potential drug treatment, Tamiflu, in limited supply, Canadian legislators have been forced to accept that the success of Canadian Internet pharmacies may result in a shortage of drugs for Canadian consumers. In response to the threat of an Avian influenza outbreak in June 2005, then Health Minister Ujjal Dosanjh, initiated a strategy to ensure that Canadians

¹⁰ *Supra* note 5.

¹¹ "Cross-border Rx" *CBC News* (17 January 2006), online: CBC News <<http://www.cbc.ca/news/background/drugs/>>.

¹² Adam Lezack & Mike Guthrie, "International Prescription Services: An Aerial view of the Industry With A Manitoba Perspective," (2005) 5 *Asper Rev. Inter. Bus. & Trade L.* 19.

¹³ Steven Morgan & Jeremiah Hurley, "Internet Pharmacy: prices on the up-and-up" (2004) 170 *Canadian Medical Association Journal* 945, online: CMA Media Inc. <<http://www.cmaj.ca/cgi/content/full/170/6/945>>.

¹⁴ *Ibid.*

¹⁵ *Supra* note 5.

would have adequate access to medicines they need.¹⁶ A consultation period was undertaken and Bill C-83 was tabled on 25 November 2005.¹⁷

WHY ARE CANADIAN DRUGS CHEAPER?

THE INTERNET PHARMACY INDUSTRY IS NOW WORTH more than a billion dollars annually, with Americans buying “more than two million packages of prescription drugs per year.”¹⁸ The industry has thrived due to the low Canadian dollar and the fact that Canadian brand-name drug prices are on average 40 percent less expensive than American brand-name drugs.¹⁹ Even with the value of the dollar rising, Canadian brand-name drugs continue to be much cheaper for Americans. Part of the reason for this is that Canadian law does not allow pharmaceutical companies to advertise directly to consumers; in the U.S., approximately three billion dollars annually are spent on direct-to-consumer advertising. Consequently, the cost of advertising is passed on to the consumer in the U.S., while in Canada, consumers do not have to subsidize any advertising costs.²⁰

The most significant reason for the lower cost of Canadian brand-name drugs is the role of the Patented Medicine Prices Review Board (PMPRB). The PMPRB, created under the *Patent Act*,²¹ is a quasi-judicial tribunal that controls the prices set by manufacturers on patented medicines sold in Canada.²² To determine if the price of a brand-name drug is excessive, the PMPRB compares its cost with that of pre-existing medications for similar diseases. If it is a new type of drug, the PMPRB limits the price to the median price of those found in seven other countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States).²³ Moreover, according to the PMPRB’s policy, Canadian brand-name drug prices can never be the highest in the world and once prices are set, they cannot increase by more than the Consumer Price Index yearly.²⁴

¹⁶ “Proposed legislation to protect Canada’s supply of safe and affordable prescription drugs” *Health Canada* (November 2005), online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2005/2005_131bk1_e.html>.

¹⁷ Bill C-83, *An Act to Amend the Food and Drugs Act (drug export restrictions)*, 1st Sess., 38th Parl., 2005 (first reading 25 November 2005).

¹⁸ *Supra* note 11.

¹⁹ *Supra* note 16.

²⁰ *Supra* note 11.

²¹ *Patent Act*, R.S.C. 1985 c. P-4.

²² “Frequently Asked Questions,” online: Patented Medicine Prices Review Board <<http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#1>>.

²³ *Ibid.*

²⁴ *Ibid.*

Some analysts have questioned the real effect of the PMPRB on Canadian brand-name drug prices.²⁵ For example, it has been suggested that drug prices are set in accordance with population size and ability to pay, instead of the price controls put in place by the PMPRB.²⁶ Historically, pharmaceutical companies have not increased prices in accordance with the Consumer Price Index, which may suggest that the profit maximizing price set by the pharmaceutical companies is actually lower than the rates set by the PMPRB.²⁷ Therefore, if drugs are to stay in Canada and not be imported to the U.S., it may not be necessary to have the PMPRB to keep Canadian drug prices low. However, there have been significant lobbying efforts by Americans and pharmaceutical companies to abolish the PMPRB if the industry is to continue importing drugs into the U.S. In a publication by the Fraser Institute, an organization that advocates for free market solutions, it was concluded that the best option for dealing with the Internet pharmacy industry is to abolish the PMPRB and remove its price control functions.²⁸ Otherwise, the pharmaceutical companies will (as GlaxoSmithKline, Pfizer, AstraZeneca and Merck already are) restrict the number of drugs coming into Canada, causing potential shortages of prescription drugs for Canadian consumers.²⁹

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Background

In June 2005, the Health Minister initiated public consultations on proposed legislation designed to control Canadian consumer access to safe and affordable medicines. The proposed legislation included a system for monitoring the Canadian drug supply, an export restriction scheme for a supply shortage, and the necessity for a physician-patient relationship for prescribing medications. The public consultations dealt with the first two parts of the legislation, beginning in October 2005 and ending in November 2005, prior to the tabling of Bill C-83 on 25 November 2005.³⁰ As was stated earlier, the primary reason for the legislative move was the potentially inadequate supply of Tamiflu, which

²⁵ *Supra* note 5.

²⁶ *Ibid.*

²⁷ *Supra* note 9.

²⁸ *Supra* note 5.

²⁹ *Supra* notes 5 & 9.

³⁰ Health Canada, News Release, 2005-131, "Minister Dosanjh introduces a Bill to protect Canada's supply of safe and affordable prescription drugs" (25 November 2005), online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2005/2005_131_e.html>.

is believed to be the only medication available to deal with a potential Avian influenza pandemic. There were reports that Internet pharmacies were selling large amounts of Tamiflu and that Hoffman-La Roche, its creator, would not have a large enough supply for potential Canadian consumers.³¹ This fear forced the federal government to address the situation.

Comments from the Consultation Period³²

A number of issues relating to the proposed legislation were raised during the consultation period; one of them related to drug supply monitoring. The concern was that by the time the Minister of Health became aware of any issues concerning the drug supply, the information may already be outdated. Therefore, drug supply monitoring would be ineffective in ensuring sufficient drug supplies for Canadian consumers. Moreover, there were suggestions that wholesaler and manufacturer inventories would provide the most efficient system of monitoring. Some suggested that provincial governments could monitor supplies, which could be forwarded to the federal monitoring system, while others raised concerns as to whether this was the best use of government resources. Finally, many worried about potential breaches of confidentiality that may arise due to the monitoring system.

Concerns were expressed about the effectiveness of the export restriction scheme. In particular, did it really deal with why shortages exist? What level of risk had to be created by the shortage in order for the export restriction scheme to begin operation? How would the federal government be able to deal with the various regulatory schemes involved? What drugs are really necessary and what effect do alternative therapies have on export restrictions?

It was decided that export restrictions should be the last option after all other potential remedies had been exhausted. There were differing opinions on whether the reporting scheme should be voluntary or mandatory. The voluntary scheme is already somewhat in place; however, without the willing involvement of all parties within the

³¹ "Pharmacy groups disagree on internet sales of Tamiflu" *CBC News* (26 October 2005), online: CBC News <<http://www.cbc.ca/story/science/national/2005/10/26/Tamiflu-internet051026.html>>.

³² One World Inc., *Developing A Drug Supply Network and an Export Restriction Scheme* (November 2005), online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/public-consult/consultation/report-rapport/drugs-drogués/measures-mesures/dsn-ers_e.html>.

industry, the required accuracy may not be satisfied. The mandatory scheme would ensure the highest level of accuracy.³³

Those consulted were concerned with the issue of the bulk exportation of drugs to the U.S. While most believed the Internet pharmacy industry was of little issue as it concerned personal importation by individual Americans, if bulk importation was allowed or became common, the effect could be great. Therefore, most of those consulted favoured banning bulk exports of drugs. One industry participant claimed that all Internet pharmacy associations are in support of a ban on bulk exports.³⁴

Third Party Positions

The Canadian Medical Association (CMA) published a response to the proposed legislation that included their outright support for both the export restriction scheme and the network to monitor the supply of drugs in Canada.³⁵ However, they were against a federal government requirement for a physician-patient relationship. The CMA stated that the federal government should support the work of existing regulatory bodies. Furthermore, telemedicine and emergency situations were raised as examples of non-traditional physician-patient relationships that already exist in Canada and would be made illegal by the legislation. Moreover, the CMA stated that transactions with the U.S. do not justify the federal government infringing on provincial jurisdiction by attempting to regulate the medical profession.³⁶ The Minister of Health for Manitoba, Tim Sale, strongly backed the CMA, suggesting that many provinces resent the potential infringement on provincial jurisdiction.³⁷ The CMA, however, fiercely opposes physicians co-signing prescriptions that have been written by American physicians without seeing the patients themselves.³⁸

Like the CMA, The Canadian Pharmacists Association (CPhA), along with medical and pharmaceutical regulators, have supported action

³³ *Ibid.*

³⁴ *Ibid.*

³⁵ See Canadian Medical Association, "Re: Developing a Drug Supply Network and an Export Restriction Scheme" and "Requiring a Patient-Practitioner Relationship as a Condition of Sale of Prescription Drugs in Canada" (8 November 2005), online: CMA

<http://www.cma.ca/multimedia/CMA/Content_Images/Inside_cma/Submissions/2005/English/CMA_respond_to_Health_Canada_Paper.pdf>.

³⁶ *Ibid.*

³⁷ *Supra* note 4.

³⁸ Dr. Dana W. Hanson, MD, FRCPC, "A question of care," online: Canadian Medical Association <http://www.cma.ca/index.cfm/ci_id/9390/1a_id/1.htm>.

being taken by the federal government, fearing the increase in drug prices and potential shortages.³⁹

The Canadian Treatment Action Council (CTAC), a group of patient advocacy organizations, has published a policy paper advocating for the outright ban of the cross-border drug trade.⁴⁰ The paper outlines six reasons for the ban including: drug shortages, price increases, safety of the drug supply, pressure for drug deregulation, access to healthcare providers, and professional ethical issues.

In addition, both the Fraser Institute and the C.D. Howe Institute have published policy papers on the Internet pharmacy industry. Analysts at the C.D. Howe Institute believe more and more pharmaceutical companies are going to restrict the amount of drugs they will offer for sale in Canada.⁴¹ Additionally, provincial governments will not want to lose control of the industry and the jobs that accompany it; therefore, they will not draft legislation that would hinder the industry in any way. Consequently, it is up to the federal government to make legislative decisions concerning the Internet pharmacy industry. Analysts at the C.D. Howe Institute believe that the federal government has three options: 1) remove the PMPRB price control regulations, thereby placing the Internet pharmacy industry at risk, as prices would move closer or on par with the prices in the U.S.; 2) make minimal changes to enforce laws already in place against Internet pharmacies; or 3) amend legislation to ban exports entirely.⁴² The C.D. Howe position is that the best option for the federal government is to amend the *Food and Drugs Act*⁴³ in a way that would ban exports of any drugs reviewable by the PMPRB. This option would ensure adequate brand-name drug supplies and lower prices for Canadian consumers.

The C.D. Howe Institute questions the inaction of the federal government, considering the lengths that they went to when amending the *Patent Act*⁴⁴ to accommodate drugs exported to countries in states of emergency. Bill C-9 included measures to ensure that countries that receive any drugs will have regulations in place to make certain these drugs will not be re-exported.⁴⁵ On the other hand, the Canadian

³⁹ *Supra* note 4.

⁴⁰ See The Consumer Advocare Network, "Position Statement, Cross-border Internet Pharmacy" (19 July 2005), online: Consumer Advocare Network <www.consumeradvocare.org/index.php/ca/content/download/207/813/file/CBIP%20Position%20Statement.pdf>.

⁴¹ *Supra* note 9.

⁴² *Ibid.*

⁴³ *Food and Drugs Act*, R.S.C. 1985, c. F-27.

⁴⁴ *Supra* note 21.

⁴⁵ *Bill C-9, An Act to Amend the Patent Act and the Food and Drugs Act*, 3rd Sess., 37th Parl., 2004, cl. 52 (as passed by the House of Commons 14 May 2004).

government has no regulations against the re-exportation of drugs to the U.S.

The Fraser Institute policy paper fundamentally agrees with the options established by the C.D. Howe Institute.⁴⁶ However, they believe the federal government should not ban exports, but should instead remove the price control function of the PMPRB. This would allow the industry to continue to exist without affecting supplies; on the other hand, prices would likely increase to be on par with American levels. The authors of the Fraser Institute paper suggest drug prices should be left to the market. They claim there would be significant benefits to Canadian consumers, although nothing more is said as to how Canadian consumers would benefit.

The Fraser Institute takes further issue with the increased percentage of generic drugs being sold to Americans through Canadian Internet pharmacies, even though American generic drugs are generally cheaper than the Canadian generic drugs. They conclude that a reason for the increase in generic drug purchases is that drugs that are no longer under patent protection in Canada are still under some form of patent protection in the U.S. Therefore, Canadian Internet pharmacies may be involved in large-scale theft of U.S. intellectual property rights by selling generic Canadian models of U.S. patent-protected drugs to the United States. While theft in a criminal sense would likely be very difficult to prove, the affect on Canada's trade relations could be significant. Under *NAFTA*, member nations are required to respect the intellectual property rights of other members.⁴⁷ The analysis of the intellectual property issue is beyond the scope of this paper, but more research on this topic is necessary.

The Manitoba Health Minister, Tim Sale, was contacted with regards to the Manitoba government position on the proposed legislation, but had not responded by the completion of this paper. Also, Canadameds.com was contacted for their position and they directed all questions to their lawyer who did not respond. Similarly, the Manitoba International Pharmacists Association (MIPA) was contacted, and they stated that their lawyers were still analyzing the legislation; therefore, they could not comment on it. However, the President of the MIPA suggested that he did not believe that new legislation would be tabled, as he considers the shortage fears to be purely politically motivated and without a factual basis.⁴⁸

⁴⁶ *Supra* note 5.

⁴⁷ *Ibid.* at 15.

⁴⁸ Email from the President of Manitoba International Pharmacists Association to the author (20 November 2006).

Legislative Debate

The issue of cross-border drug sales was debated in Parliament on 1 November 2005. Then Health Minister, Ujjal Dosanjh, began by laying the foundation for the government increasing its involvement in the Internet pharmacy industry.⁴⁹ Mr. Dosanjh made reference to the potential Avian flu pandemic and the increased potential for larger scale American drug imports. Mr. Dosanjh then laid out the three fundamental principals of the government's plan. First, the federal government would set up a drug supply network to overview the drug supply across Canada. The network would ensure that the government would be able to act quickly on any shortages that may occur. Second, the federal government would put in place export restrictions on any drugs for which there is a shortage in Canada. Third, all prescriptions would require actual contact between physician and client. This would eliminate the ability of physicians to write prescriptions for clients they have not seen.

The Health Minister responded to questions from opposition parties. Mr. Fletcher, a Winnipeg MP, suggested that the industry has been in decline in recent years, thereby eliminating the need for the proposed legislation.⁵⁰ Furthermore, Mr. Fletcher questioned the need for physicians to see clients, as many individuals in northern communities do not see physicians face-to-face or see only nurse practitioners. Mr. Dosanjh replied that many U.S. lawmakers are trying to destroy the Canadian drug pricing regime. Concerning physician-client transactions, the Minister stated that the prohibitive cost of enforcing regulations put in place by regulatory boards across Canada has made it difficult to stop physicians from co-signing prescriptions from American physicians.⁵¹

Numerous Conservative MPs discussed a 6 October 2005 vote in Parliament initiated by Mr. Merrifield, a Conservative MP from Yellowhead, in which members of Parliament unanimously voted to ban the bulk exports of brand-name pharmaceuticals.⁵² Many questioned why this was not part of the government's proposed legislation. They saw it as a means to ensure pharmaceuticals would be available for Canadian consumers, rather than simply reacting to a real shortage.

Members for the Bloc Québécois focused much of their time on the question of jurisdiction when discussing the regulations of physicians

⁴⁹ *House of Commons Debates*, 145 (1 November 2005) at 1835 (Hon. Ujjal Dosanjh).

⁵⁰ *Ibid.* at 1840 (Hon. Steven Fletcher).

⁵¹ *Ibid.* at 1845 (Hon. Ujjal Dosanjh).

⁵² *Ibid.* at 2020 (Hon. Rob Merrifield).

and pharmacists. The regulation of these professions falls under the jurisdiction of the provinces according to section 92(7) of the Constitution; therefore, they did not believe that element of the proposed legislation would be within the purview of federal legislation.⁵³

The Member of Parliament for Winnipeg North, Judy Wasylycia-Leis, spoke of the issues raised by Archie Orlikow, a Manitoba pharmacist and an original planner of the Manitoba Pharmacare Program. Mr. Orlikow raised issues concerning pharmaceutical costs and the increasing shortage in pharmacists in rural Manitoba.⁵⁴ He also raised concerns about prescription drug shortages, patient safety, and physician ethics due to co-signing prescriptions without having seen or treated the patients.⁵⁵ Mr. Orlikow accused the government of Manitoba of being blinded by the financial success of the Internet pharmacy industry.⁵⁶

Elements of Bill C-83

The federal government's original proposal was to include three elements to amend the *Food and Drugs Act*.⁵⁷ Included among the amendments was the ability of the federal government to monitor the drug supply nationally, restrict the exportation of drugs out of Canada when there is a shortage or expected shortage, and require a patient-physician relationship for prescriptions. The first two amendments were dealt with in the consultation period, while the requirement for a patient-physician relationship was not.⁵⁸ Therefore, the Bill, when tabled in Parliament, only addressed the first two issues. When Bill C-83 was tabled, the summary stated:⁵⁹

The purpose of this enactment is to protect an adequate supply of safe and affordable drugs for Canadians. The enactment amends the *Food and Drugs Act* to

- a. enable the Minister of Health to prohibit, by order, the export of a drug or class of drugs if the Minister is of the opinion that there is a shortage or likely shortage

⁵³ *Ibid.* at 1915 (Hon. Nicole Demers).

⁵⁴ *Ibid.* at 2240 (Hon. Judy Wasylycia-Leis).

⁵⁵ *Ibid.*

⁵⁶ "Pharmacare pioneer worried over Internet pharmacies" *CBC News* (06 October 2003), online: CBC News <http://www.cbc.ca/stories/2003/10/06/Consumers/wpg_epharm031006>.

⁵⁷ *Supra* note 43.

⁵⁸ *Supra* note 32.

⁵⁹ *Supra* note 17.

- of a drug or class of drugs and an order is necessary to protect human health;
- b. enable the Minister to compel manufacturers, importers, exporters and sellers to provide information that the Minister may require for the purpose of exercising the Minister's power to prohibit exports;
 - c. provide increased enforcement powers; and
 - d. increase the maximum penalties available under that Act.

The proposed section 21.1 of the *Food and Drugs Act*⁶⁰ concerned export restrictions. With these amendments, the Minister of Health has the discretion to prohibit the sale and advertising of drugs in a variety of ways if the Minister believes that there is, or could be, a shortage that would harm public health. The prohibition could apply to wholesale or retail sales, or to the export of any class of drugs. The legislation would only apply to drugs that were meant for Canadian consumption. Furthermore, if the Minister decides the drug supply is insufficient for public health, the Minister would be able to prohibit the export of drugs meant for consumption outside Canada, in order to ensure the supply of drugs necessary for Canadian consumption. However, if the drugs were manufactured for the sole purpose of being exported, this restriction would not apply. The duration of the order is 14 days unless approved by Cabinet, and then it is a maximum of 180 days with potential to renew it for periods of 90 days.

Section 21.4 mandates that manufacturers, sellers, importers or exporters must, on the request of the Minister, provide any information concerning the proposed section 21.1 that is within their knowledge or available to them. Once a section 21.1 export restriction order has been established, under section 21.5, there is a universal prohibition on the sale and advertising of the restricted drugs. However, this does not apply to Canadian citizens or permanent residents as per the *Immigration and Refugee Protection Act*,⁶¹ or any other individual in Canada if the amount does not exceed 90 days worth. Furthermore, it does not apply to members of the Canadian Forces that are outside Canada. If an individual were charged with breaching section 21.5, in sentencing, the court would take into account the profits made through the commission of the offence.

Section 23 would be amended to enhance the powers of inspectors to search beyond where drugs are manufactured, prepared, preserved,

⁶⁰ *Supra* note 43.

⁶¹ *Immigration and Refugee Protection Act*, S.C. 2001, c. 27.

packaged, and stored to where they are sold, imported or exported.⁶² Section 23(4) would require anyone under the regulations with a duty to maintain records to ensure that they are available for the inspectors. If the inspector believes there have been actions that breach the *Act*, the inspector has the power to force compliance, stop the contravener from operating activities until they are in compliance, or any other means the inspector believes are necessary. The actions can be taken by the inspector without charges being laid.

The penalties for contravention of the amended *Food and Drugs Act* would be significantly increased under Bill C-83.⁶³ On summary conviction for a first offence, the previous maximum penalty was a fine of not more than \$500 or six months or less of jail time or both. The amendments would change the penalties to a fine not exceeding \$100,000 or incarceration for six months or less or both. On subsequent convictions, the penalty would change from a fine not exceeding \$1,000 or imprisonment of six months or less or both, to a fine not exceeding \$250,000 or imprisonment of not more than 18 months or both. If convicted of an indictable offence, the punishment would change from a fine not exceeding \$5,000 or imprisonment of no more than three years or both, to a fine amount determined at the discretion of the court or imprisonment not exceeding three years or both. Moreover, section 31.2 states that each day that an offence is committed, or continues to be committed, is a separate offence.

Outcome for Bill C-83

With the Liberal government falling on 29 November 2005, Parliament dissolved and Bill C-83 died. Bill C-83 did not get past first reading. There has been no indication that the new government under Prime Minister Stephen Harper has any intention to table new legislation concerning Internet pharmacies, nor is there any indication that the consultation process on the physician-patient element of the original proposal will go ahead.

Discussion on Bill C-83

Since the federal government is trying to avoid brand-name drug shortages and price increases, I will now examine the efficacy of the proposed legislation from that viewpoint. First, I will examine the drug supply monitoring plan; then I will look at the export restriction scheme, increased inspecting powers and the increased penalties for violations of

⁶² *Supra* note 17.

⁶³ *Ibid.*

the amended *Food and Drugs Act*.⁶⁴ Finally, I will look at the patient-physician relationship.

Many issues were raised about the proposed monitoring plan, including the effectiveness of government spending, but the most significant problem is whether the numbers will be accurate by the time Health Canada receives them. Legislative decisions of a pan-Canadian character, like this one, will take a great deal of integration with the pharmaceutical industry to be accurate to the level necessary to ensure effectiveness. Consultation with the pharmaceutical industry would be of utmost importance to ensure the efficacy of this type of legislation. Moreover, provincial pharmaceutical associations and every pharmacist across the country will have to fully accept and abide by the requirements to ensure the accuracy of the system. The monitoring system is purely reactive; it does nothing to ensure that shortages will not occur but hopes to give the federal government the information necessary to deal with shortages when they do occur. If the Internet pharmacy industry is as much of a threat to drug supply as the justifications for the legislation would suggest, actions should be put in place now to stop the threat entirely. The monitoring system only attempts to put in place reactionary doomsday measures. Since Bill C-83 did not pass, no regulations were put in place; therefore, an analysis on the specifics of the monitoring plan is not possible.

The export restriction scheme would be established to allow the government to react when there is a threat to the drug supply. Nothing is done to ensure that shortages do not occur, but the legislation would give the Minister of Health powerful discretionary powers when the Minister thinks there is, or will be, a drug supply shortage. The legislation made no comment of how the Minister would determine if a shortage had occurred or was occurring, nor did it comment on the use of alternative drugs. For example, there may be an insufficient supply of type X heart medication; however, there may be plenty of type Y, a similar heart medication. Does the Minister ban the export of type X or is it sufficient that there is a surplus of type Y?

In the consultation period, the necessity of drugs was questioned. As some argued, anyone that is on medication believes that their medication is necessary. Consequently, how would the government determine what medications are included and excluded from the export scheme and monitoring plan? A cost-benefit analysis must be undertaken before the federal government can go ahead with the proposed legislation. However, in the same fashion as the firearms registry, many will believe this a good plan regardless of cost; however, others will expect the federal government to spend tax dollars in a way that ensures that benefits

⁶⁴ *Ibid.*

equal the costs. A monitoring system and export restriction scheme should have clearly defined obligations; without clearly defined obligations, the potential for waste and mismanagement is far too high. Establishing what types of medications must be monitored would keep the administrative costs of the legislation to a minimum.

During the legislative debate on the issue, most opposition politicians argued that the government should take a more proactive stance on the problem of potential shortages by banning bulk exports of pharmaceuticals from Canada. None of the governing politicians directly addressed this suggestion, even though parliamentarians voted unanimously in favour of it just a short period before Bill C-83 was tabled. A Health Canada press release suggested that a bulk ban may potentially be in violation of trade obligations, such as the *General Agreement on Tariffs and Trade (GATT)* or the *North American Free Trade Agreement (NAFTA)*.⁶⁵ On the contrary, opposition MPs claimed that a bulk ban would not violate obligations under *GATT* or *NAFTA*. Further inquiry on the obligations of Canada under *GATT* or *NAFTA* is necessary before any future legislation could be brought forward establishing a ban on bulk exports of pharmaceuticals from Canada.

A positive aspect of the proposed legislation is the increased powers of inspection that would be put in place to ensure the safety of the Canadian drug supply at all levels of the pharmaceutical industry, which are necessary and long overdue. Pharmaceuticals must be stored under certain conditions. For example, some medications must be stored and shipped in a refrigerated state or they may be damaged.⁶⁶ On the other hand, a determination must be made on how the increased role of inspectors can be put in place in the most cost efficient fashion possible.

Maximum fines of \$500 for a first offence on summary conviction will not likely act as an effective deterrent to a person making large profits. Therefore, the increase in maximum penalties is a welcome addition. By setting higher maximum penalties for all convictions and giving courts full discretion on indictable offence convictions, courts will be able to hand down punishments that will denounce actions and, hopefully, deter future violations of the *Food and Drugs Act*.⁶⁷ Finally, it is important to discuss the patient-physician relationship. There was to be a consultation process dealing with this topic; however, the change in government may cancel that consultation. Regulatory bodies, associations and provinces have come out against this part of the original proposal, which may justify splitting the consultations into two

⁶⁵ *Supra* note 16.

⁶⁶ Milan Korcok, "The Tug-of-war Intensifies" (2004) 170 *Canadian Medical Association Journal* 946, online: CMA Media Inc. <<http://www.cmaj.ca/cgi/content/full/170/6/946>>.

⁶⁷ *Supra* note 43.

sessions, rather than dealing with the entire proposal at once.⁶⁸ The CMA is fundamentally opposed to Canadian physicians co-signing prescriptions written by their American colleagues, but very few Canadian physicians have been disciplined for this practice. Four censures have been made by the College of Physicians and Surgeons of Manitoba since 2004 for co-signing prescriptions, with the largest fine being \$10,000 plus more than \$4,000 in costs.⁶⁹ However, the doctor that received the largest fine had co-signed more than 2,200 prescriptions; therefore, with the average payment for co-signing being \$10, the doctor still came out financially ahead.⁷⁰

Professional ethics has been one of the major debates relating to the growth of the Internet pharmacy industry. The federal government does not have legislative jurisdiction over professional bodies; nevertheless, because the industry contains international elements, jurisdictional oversight by the federal government, although unlikely, may be allowed. In spite of the potential for jurisdictional oversight, the federal government is loath to pick battles with the provinces, especially on issues of this nature. As a result, the federal government will probably leave professional regulations in the realm of the provinces.

A Manitoba doctor, Darcy Johnson, has argued that the government should ban exportation altogether or abolish the rule forcing all prescriptions to be signed by a Canadian doctor.⁷¹ The Manitoba government has publicly supported the Internet pharmacy industry, but at this point, has not been willing to abolish the rule requiring prescriptions to be signed by Canadian doctors. This is probably due to the opinions of the CMA and the College of Physicians and Surgeons, bodies the government does not want to be fighting against. However, if the Manitoba government altered the regulations to allow prescriptions written by American doctors to be filled by Manitoba pharmacists, it would remove the co-signing ethical issue from Manitoba doctors and streamline the Internet pharmacy industry. This simple regulatory change would help ensure the prosperity of an industry that the Manitoba government zealously supports.

⁶⁸ *Supra* note 4.

⁶⁹ See online: The College of Physicians & Surgeons of Manitoba <http://www.cpsm.mb.ca/core_functions/complaints/discipline/censures>.

⁷⁰ *Supra* note 9.

⁷¹ "Doctor fined for signing web prescriptions" *CBC News* (1 November 2004), online: CBC News <http://www.cbc.ca/manitoba/story/mb_webpharm20041101.html>.

CONCLUSION AND RECOMMENDATIONS

BILL C-83 DIED WHEN PARLIAMENT, UNDER THE leadership of Paul Martin's Liberal government, fell and there has been no suggestion that the new government has any plans to re-table any similar legislation. It is unclear that the proposed legislation would have actually solved any potential problems with the Canadian drug supply; for that reason, I would suggest that any action on the Internet pharmacy industry should include a ban on bulk exports, if allowed under Canada's obligations to *GATT* and *NAFTA*. The ban on bulk exports is more proactive in that it puts in place the primary mechanism to prevent drug shortages in Canada, as opposed to the reactionary measures in Bill C-83. The population of Canada is better served with legislative measures that prevent drug shortages before they commence, rather than legislation that attempts establish measures that respond to shortages after they come into existence. The pharmaceutical companies would feel that they have succeeded in controlling the growth of the Canadian Internet pharmacy industry, while the industry would still thrive on personal importation just as it has to this point in time. There is already some suggestion that the Internet pharmacy industry is comfortable with this approach.⁷² Moreover, Health Canada already monitors the supply of pharmaceuticals in Canada and will continue to do so to determine if shortages are occurring, and the PMPRB can continue to perform its price control functions to ensure the brand-name drug supply will continue to be affordable to Canadian consumers.

Further study on the ability of the federal government to put restrictions on the export of pharmaceuticals under its obligations to *GATT* and *NAFTA* is required. Also, further study on the sale of Canadian generic drugs to American consumers that still have patent protection in the U.S. is necessary. The federal government must ensure that it is not tacitly supporting intellectual property theft through its support of the Internet pharmacy industry.

⁷² *Supra* note 32.