INTERNATIONAL PRESCRIPTION SERVICES: AN AERIAL VIEW OF THE INDUSTRY WITH A MANITOBA PERSPECTIVE

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INTRODUCTION

WITH A WIDE DISPARITY BETWEEN the pricing of prescription drugs in Canada and the United States, Americans are turning to International Prescription Services in search of lower priced drugs. These services are accessed primarily through the Internet and telephone, and operate in the following manner: The American purchaser directs their American physician to fax/mail their prescription for the drug sought to the International Prescription Service ("IPS"). This IPS then relays the prescription to a Canadian physician who reviews and re-writes the prescription. This re-written prescription is necessary because Canadian law prohibits Canadian pharmacists from filling foreign prescriptions.[1] Once the Canadian doctor sends the re-written prescription to the International Prescription Services, licensed pharmacists then fill the prescription and the drugs are mailed to the consumer.

As more drugs are being purchased through these services and crossing the border into the United States, numerous questions of regulatory authority and legality are being addressed. The regulatory predicament occurs when International Prescription Services cross international borders, opening their services to out-of-state residents. A Department of Justice official stated at an American Health Lawyers Association conference, "The Internet is not an enforcement-free zone. We try to make sure that what is illegal in the bricks-and-mortar world is equally illegal in the Internet world."[2] However, it is extremely difficult to regulate and enforce within the electronic environment.[3] Furthermore, the ability of the

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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* 144 (March 2004).

[2]Health Care Policy Report (BNA) 1821 (Nov. 13, 2000), quoting Ethan M. Posner, Deputy Assistant Associate Attorney General, U.S. Dep't of Justice.

[3]George S. Takach, "Regulating Information, Technology and e-commerce," *Computer Law* 2nd ed. (Toronto: Irwin Law, 2003) c. 4.

Internet to efficiently arbitrage the differences in currency values, drug prices, and medical/patent law systems has spurned the rapid growth of the International Prescription Service industry.[4] This rapid growth is making it extremely difficult for regulators to keep up.

This paper will explain why certain prescription drugs are cheaper in Canada and how these price differentials are fuelling the growth of the IPS industry. The underlying legal provisions that make the importation of prescription drugs into the United States illegal will be addressed, as well as the parties who have an interest in enforcing the provisions. Emerging events will be examined, which may have a significant impact on the future operations of the IPS industry. Finally, since majority of the Canadian IPS industry is located within the province of Manitoba, leading figures from Manitoban business and regulatory sides have been interviewed to provide further insight.

GROWTH OF THE INDUSTRY

INTERNATIONAL PRESCRIPTION SERVICES have become, and continue to be a huge business, especially in Manitoba. Their success is directly related to providing Americans with access to Canadian prescription drugs, which can be significantly less expensive than their American counterparts. In 1999, there were four Canadian International Prescription Services. In 2003, there were an estimated 120-150 Canadian IPS.[5] Of those, six accounted for about eighty percent (80%) of cross-border sales.

The province of Manitoba has about sixty IPS, accounting for approximately half of all Canadian IPS. U.S. customers purchased an estimated $700 million from Canadian IPS in 2002, up from about $14 million in 1999. Manitoba-based IPS accounted for an estimated $280 million of those U.S. sales in 2003. By comparison, the Manitoba provincial health program spent about $200 million for outpatient drugs. CanMeds.com, one of the pioneers of International Prescription Services, generated revenues of $70 million dollars in 2003.[6] It is estimated that cross-border International Prescription Service revenues generated in 2003 were close

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[4] Krista Foss, "A Borderline Case: Selling Cheap Canadian Drugs to U.S. Customers Is A Grey Area - But It's Putting Internet Pharmacies in the Black," *Report on Business Magazine* (May 2002).

[5] See online: The Washington Post <http://www.washingtonpost.com/wpsrv/health/daily/graphics/rx_102303.html>, based upon information gathered by the Manitoba Pharmaceutical Association, the Canadian Pharmaceutical Association, and IPS.

[6] *Ibid.*

to $1 billion.[7] While sales of International Prescription Services are a tiny fraction of the US $203.6 billion in North American drug sales generated in 2002, the rapid growth of Canada's IPS industry is causing worries on both sides of the border.[8]

WHY ARE CERTAIN DRUGS CHEAPER IN CANADA THAN THE U.S.?

DESPITE THEIR GEOGRAPHIC PROXIMITY, there are substantial differences between Canada and the United States in the pricing of prescription drugs. Specifically, American consumers often pay substantially more for the same medication than Canadians, since the prices of patented prescription drugs are often substantially lower in Canada.

Originally, one of the primary reasons for Canada's lower drug prices was the Canadian government-imposed price regulatory scheme, which controlled the price pharmaceutical manufacturers could charge. Another reason was that the government reduced drug costs in Canada by introducing a patent protection scheme.[9] A final reason was that the government also passed an Act requiring compulsory licensing of drug patents.[10] Compulsory licensing allowed generic drug manufacturers to enter the market before the patent expired for a brand-name drug.[11] If the manufacturer did not accept the price set by the government, the government would force the drug-maker to license the product to a manufacturer to produce a generic.[12]

There were numerous critics of the scheme, especially from foreign jurisdictions where generic equivalents could not be marketed until the expiration of the full patent.[13] Ultimately, legislation was enacted to eliminate compulsory licensing and a new structure was created. The Patented

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[7] David Grazer, "Don't export our drug policy to the US," *National Post* (May 2003).

[8]See online: IMS World Review <http://www.ims-global.com/insight/news_story/0302/news_story_030228.htm>.

[9] Patricia I. Carter, "Federal Regulation of Pharmaceuticals in the United States and Canada" (1999) 21 Loy. L.A. Int'l & Comp. L.J. 215 at 241.

[10] Patricia M. Danzon, "Making Sense of Drug Prices: How to Make Drugs More Affordable without Stifling Beneficial Innovation and Competition" (Spring 2000) 23:1 Regulation 56 at 59, online: The Cato Institute <http://www.cato.org/pubs/regulation/regv23n1/danzon.pdf>.

[11] Carter, *supra* note 9 at 241.

[12] Danzon, *supra* note 10 at 58.

[13] For example, see U.S. drug law 21 U.S.C. 355(j)(4)(d)(1994), United States Code Annotated, Federal Food, Drug, and Cosmetic Act.

Medicine Prices Review Board (PMPRB) was created in 1987 to enforce price controls on patented medicines, and today is one of the predominant reasons for lower-priced drugs in Canada. This Board is a federal, quasi-judicial body that regulates introductory prices of newly patented drugs and price increases of extant patented drugs.[14] The PMPRB "does not purchase drugs; rather, it determines the maximum prices that manufacturers can charge for patented drugs, thereby preventing market participants from negotiating a price. Furthermore, the PMPRB controls only the price at which the manufacturer sells, not the wholesale price, retail price, pharmacist's dispensary fee, or any other distribution cost."[15]

The PMPRB uses the following guidelines to set maximum prices:[16]

1. Prices for most new patented drugs are limited such that the cost of therapy for the new drug does not exceed the highest cost of therapy for existing drugs used to treat the same disease in Canada.
2. Prices of breakthrough patented drugs and those that bring a substantial improvement are limited to the median of prices charged for the same drug in France, Britain, Germany, Italy, Sweden, Switzerland, and the United States.
3. The price of a patented drug cannot exceed the highest price of the same medicine sold in the above seven countries.
4. Price increases for existing patented medicines are limited to changes in the Consumer Price Index.

These guidelines were so effective that between 1994 and 1998, the Board prevented ninety-four percent (94%) of new drugs from entering the Canadian market at a higher price than existing drugs.[17] It is important to realize that while patented drugs are often cheaper in Canada, studies have shown that generic drugs are often cheaper in the U.S. than in Canada.[18] Generic drugs are cheaper in the U.S. as a function of a larger free market system. These drugs account for approximately forty-seven percent (47%) of the U.S. prescription drug market by volume, while in

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[14] John R. Graham, "Seeing Through The Snow. Is Canada's government, or its weak economy, responsible for low drug prices?" Health and Medicine (Vancouver: The Fraser Institute, Spring 2001).

[15] *Ibid.*

[16] *Ibid.*

[17] *Ibid.*

[18] Stephen R. Latham, "An Overview and Analysis of Legal and Policy Responses by the States" (2003) 24 J. Legal Med. 141 at 171; See also online: U.S. Food and Drug Administration <http://www.fda.gov/oc/whitepapers/drugprices.html>.

Canada, forty percent (40%) of all prescriptions written are generics.[19] However, the Americans are turning to the International Prescriptions Services to purchase lower-priced *patented* drugs from the Canadian market.

In addition to the PMPRB, public and private third party purchasers in Canada, particularly the provincial drug benefit plans, have adopted cost management approaches to induce price competition among therapeutically similar drugs.[20] As large purchasers, these payers use cost management tools to enhance their ability to negotiate with drug manufacturers and pharmacies about the terms under which their plans will cover and reimburse drug products.[21]

Many American critics speculate that a reason for the price discrepancy between the United States and foreign nations is that the pharmaceutical industry must recoup their research and development (R & D) costs. Accordingly, drug suppliers are forced to incorporate these costs into the final product, creating inflated prices. Conversely, there exists a body of critics that contend only eleven percent (11%) of revenues are spent on R & D in the United States, and that R & D developments have contributed very little to the marketplace.[22]

Other analysts assert that high profit margins in the pharmaceutical industry are the driving force behind high drug prices. Industry practitioners insist that high profits are a result of high-risk management operations, where only three out of ten drugs generate revenue.[23] In contrast, one critic wrote, "If government interferes with today's high price and profits, (the industry says) the lights go out in the labs, and there is no R & D." In other words, "give us all of your money or we'll let you die."[24] The debate on R & D costs influencing high drug prices in America is polarized

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[19] Graham, *supra* note 14.

[20] See online: AARP <http://research.aarp.org/health/ib62_can_rx.pdf> (last visited June 2004).

[21] For a description of tools to reduce drug prices in Canada's provincial pharmacy benefit programs, see Ake Blomqvist & Jing Xu, "Pharmacare in Canada: Issues and Options," Working Paper, Health Canada, September 2001; U.S. International Trade Commission, 2000.

[22] Martha Ann Holt, "International Prescription Drug Cost Containment Strategies and Suggestions For Reform in the United States" (2003) 26:2 B.C. Int'l. & Comp. L. Rev. 325.

[23] Pharmaceutical Research and Manufacturers of America, "Do Pharmaceutical Companies Make too Much in Profits?" at 19, online: Pharmaceutical Research and Manufacturers of America <http://www.phrma.org/publications/publications/brochure/questions/questions.pdf> (last visited June 2004).

[24] Alan Sager, "Seven Myths Impeding Prescription Drug Reform in the United States" Association of Health Care Journalists, Emory Conference Center (23 March 2001), online: U.S. Health Reform

between the drug manufactures and government/private consumers.

With such high prescription drug prices, many States are taking steps beyond Medicaid coverage to provide relief to its uninsured citizens from high prescription drug costs. Some States, in hope to reduce drug costs for its citizens, have initiated the following proposals:

1. Creating health insurance plans to extend drug coverage to citizens.
2. Subsidizing drug purchases of various citizens, especially of the elderly poor.
3. Attempting to cap or reduce drug prices to certain citizens - in some cases, to very many citizens - through state legislation or federal Medicaid waiver.
4. Joining or creating inter- and intra-state joint purchasing pools to negotiate discounts from pharmaceutical manufacturers.
5. Some states, private firms, and the federal government are considering discount card programs.[25]

Perhaps the most contentious action that has been attracting widespread attention is the State-assisted purchase of cheaper drugs from Canada through State-approved International Prescription Services. New Hampshire plans to allow its residents to visit a State website, and with a prescription from a licensed New Hampshire doctor, an IPS transaction can be facilitated. It also plans to buy prescription drugs in bulk from Canada for its prison inmates and some Medicaid recipients.[26] More than a dozen States are thinking about buying drugs from Canada, including Ohio, West Virginia, Illinois and Minnesota. The city of Springfield, Massachusetts has been allowing employees and retirees to purchase drugs from Canada since July 2003. So far, the FDA has not cracked down on Springfield, although it has sent warning letters to the city's Canadian supplier. Springfield Mayor, Michael J. Albano, said the city has already saved $1 million on its drug costs since July and has the potential to save $9 million a year.[27]

<http://dcc2.bumc.bu.edu/hs/sager/Seven%20Myths%20final.pdf> (last visited June 2004).

[25] Stephen R. Latham, "Pharmaceutical Costs: An Overview and Analysis of Legal and Policy Responses by the States" (2003) J. Legal Med. at 56.

[26] Maeve Reston, "New Hampshire to put Canadian drugs mere click away for its residents" *Pittsburgh Post-Gazette* (12 December 2003), online: <http://www.post-gazette.com/pg/03346/250517.stm>.

[27] *Ibid.*

SAFETY CONCERNS

THE FEDERAL FOOD, DRUGS, and Cosmetic Act (FDCA) provides the authority to regulate the manufacture, distribution, importation, labeling and marketing of all drugs, both prescription and nonprescription.[28] The Food and Drug Administration (FDA), in cooperation with the U.S. Customs Service, has the authority to prevent any product from entering the United States that violates the FDCA, including prescription drugs.[29] The FDA has attempted to characterize drugs coming into the United States from Canada as potentially unsafe.

This argument has been at the forefront of those interested parties opposing the importation of drugs from Canada and other foreign nations into the United States. However, a recent report mandated by the Governor of Illinois found that the pharmacy practice in the Canadian provinces of Manitoba and Ontario is "equal to or superior to pharmacy practice in the State of Illinois."[30] Furthermore, the report found that both countries' methods of ensuring the safety and efficacy of prescription drugs are comparable. Finally, the provincial regulatory systems in Manitoba and Ontario provide equivalent protection for the health and safety of the public as in the State of Illinois.[31]

There are, however, legitimate safety issues that need to be addressed. One of these issues is the practice of International Prescription Services that dispense medication based upon a consumer-answered questionnaire. The American Medical Association (AMA) stated that the scope of questioning may be above the understanding of the layperson, and that there is no means to ensure that the questionnaire has been answered correctly.[32] Furthermore, consumers may not fully understand the importance of each question.[33] Finally, some online questionnaires have pre-selected answers, which can dangerously facilitate the consumer in providing incorrect information.[34]

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[28] *Supra* note 1 at 329.

[29] 21 U.S.C. § 381(a).

[30] Ram Kamath *et al., Report On Feasibility Of Employees And Retirees Safely And Effectively Purchasing Prescription Drugs From Canadian Pharmacies,* Office of Special Advocate For Prescription Drugs, Illinois Department of Central Management Services (27 October 2003) at 2.

[31] *Supra* note 5 at 2.

[32] American Medical Association, Report of the Board of Trustees, 35-A-99, at 1.

[33] Armstrong *et al.,* "Direct Sale of Sildenafil (Viagra) to Consumers Over the Internet" (1999) 18 New Eng. J. Med. 1389, 1391 at 1390.

[34] Bernard S. Bloom & Ronald C. Iannacone, "Internet Availability of Prescription Pharmaceuticals to the Public" (1999) 131 Ann. Internal Med. 830 at 833.

Additionally, distinguishing legitimate International Prescription Services from illegitimate pharmacies raises difficulties given the ease of creating an Internet site that looks like it represents a valid company.[35] There needs to be a method to identify and verify those sites that provide safe procedures to administer approved drugs. The most comprehensive means to do this has been developed by the National Association of Boards of Pharmacy (NABP). The NABP is a professional association representing the State Boards of Pharmacy in all fifty States, eight Canadian provinces, and various other regions. The NABP developed the Verified International Prescription Service Practice Sites (VIPPS) program in 1999.[36] The VIPPS program contains licensing, safety, quality, and other criteria that International Prescription Services must comply with to receive VIPPS certification. The VIPPS certification program has received positive acknowledgment from the FDA, the AMA, and other federal and state enforcement agencies as a framework for future legislative efforts to regulate International Prescription Services.[37]

CANADIAN ORGANIZATIONS

PHARMACY IN CANADA IS A self-governing profession. Professional regulation is the responsibility of the provinces. Those who engage in the provision of pharmaceutical services to the public, such as the dispensing and sale of drugs and the operation of pharmacies, are licensed or registered by Canada's twelve Provincial and Territorial Regulatory Authorities (PRAs).[38] Each province has a self-regulating pharmacy licensing body that grants pharmacist licenses and assesses the competency of pharmacists. Overseeing this operation is an umbrella organization, the National Association of Pharmacy Regulatory Authorities (NAPRA), which has both federal and provincial bodies. NAPRA was founded in 1995 by Canada's pharmacy regulatory bodies to enable members to take a national approach in addressing common issues.

NAPRA is incorporated under the *Canada Corporations Act* as a voluntary, not-for-profit association.[39] The code of ethics for pharmacists, cited

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[35] Rost Kerry Toth, "Policing the "Wild West" World of Internet Pharmacies" (2000) 76 Chicago-Kent L. Rev. 1333.

[36] National Association Boards of Pharmacy (NABP), Who We Are, online: National Association Boards of Pharmacy <http://www.nabp.net>.

[37] *Supra* note 1 at 363. See also "Panel Recommends Verification Standards for Licensing International Prescription Service Companies" (2000) 9 BNA Health L. Report 1354, reporting that Michigan governmental task force on Internet pharmacies recommended basing state regulation on VIPPS model.

[38] See online: National Association of Pharmacy Regulatory Authorities <http://www.napra.org/protect/provincial.html> (last referenced March 2003).

[39] See online: National Association of Pharmacy Regulatory Authorities <http://www.napra.org/docs/0/86/89.asp>.

on the NAPRA website, stipulates that the health and safety of the patient are paramount. Accordingly, prescribing drugs to patients who have not seen or consulted with a pharmacist or doctor has been deemed unsafe, a common practice with IPS. Yet, the Manitoba chapter of NAPRA, the Manitoba Pharmaceutical Association (MPA), has implemented a policy for all companies located in Manitoba who do pharmacy business on the Internet and provide services to persons in the province of Manitoba. The policy, which seemingly attempts to regulate what NAPRA has proclaimed an unsafe practice, can be summarized as follows:[40]

> The home page and any advertising on the Internet site must:
> 1. Indicate that the Manitoba Pharmaceutical Association presently licenses the pharmacy in the province of Manitoba and list the license number assigned.
> 2. Indicate the physical location and telephone number of the Pharmacy.
> 3. Not advertise in such a manner that would contradict the Code of Ethics or lessen the public image of the profession of pharmacy.
> 4. The pharmacy manager must advise the Registrar of the Manitoba Pharmaceutical Association the pharmacy is conducting business over the Internet address of the site and the nature of the business.
> 5. Until such time the electronic transfer of prescriptions is approved, all prescriptions filled must be verbal orders, written orders or sent through a facsimile machine in accordance with the joint statement on the Facsimile Transmission of Prescriptions.
> 6. Pharmacists must comply with the Standards of Practice regarding counseling the Patient about their medication treatment as well as all other practice requirements applicable to a patient accessing the pharmacy services.
> 7. Safeguards must be implemented in the receiving and sending of data and the provision of medication to ensure patient personal health information is kept confidential.
> 8. The pharmacy must not contravene rules or regulations in effect in the jurisdiction where the patient resides.

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[40] See online: National Association of Pharmacy Regulatory Authorities <http://www.napra.org/pdfs/provinces/mb/internet_july01.pdf>.

9. The prescriptions and the other records kept must be in compliance with the pertinent rules and regulations in effect in Manitoba.
10. The prescriptions that are delivered are done so in compliance with the Standards of Practice.

In addition to the Pharmacist Code of Conduct, physicians in Manitoba are faced with similar regulatory dilemmas. The College of Physicians and Surgeons is also a self-regulatory and licensing board, whose Practice Guidelines of Manitoba state that physicians should not engage in practices that they would perceive as unsafe.[41] The consensus amongst physicians in Manitoba and throughout all of Canada is that physicians should not prescribe for a patient that they have not seen personally. A Winnipeg doctor was reprimanded and fined $10,000 for co-signing more than 2,271 prescriptions for three International Prescription Services.[42] However, that fine is small in comparison to the revenue generated from signing the prescriptions. Most International Prescription Services pay Canadian doctors a set fee for each U.S. prescription they review and co-sign.[43] While the College of Physicians and Surgeons has banned doctors from co-signing prescriptions for U.S. patients, in some provinces, including Manitoba, other provincial medical regulators allow the practice.[44] International Prescription Services in Manitoba circumvent the problem of finding a physician to sign the prescription by eliciting the services of doctors from outside the province.

Section 63.1 of the *Manitoba Pharmaceutical Act*[45] stipulates that pharmacists are allowed to disclose health information to those bodies created by legislation in Manitoba; however, they cannot talk to physicians outside Manitoban borders. While the practice of Manitoba doctors signing Internet prescriptions has been virtually eliminated, out-of-province doctors cannot be reported and are therefore able to sign prescriptions. If the *Act* were modified to allow Manitoba pharmacists to report out-of-province doctors, the practice could be restricted dramatically.

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41 See online: The College of Physicians and Surgeons of Manitoba <http://www.cpsm.mb.ca/>.

42 The College of Physicians and Surgeons of Manitoba, Discipline Case of Stewart James Silagry, 30 March 2004. See online: The College of Physicians and Surgeons of Manitoba <http://www.cpsm.mb.ca/core_functions/complaints/discipline/censures/2005/05/35415_0505031314-788>.

43 Joel Baglole, "Special Report: Personal Health: Getting the Gray Out" (2 November 2003), online: Destination Rx <http://www.destinationrx.com/company/press/press.asp?PressId=92>.

44 *Supra* note 42.

45 *Manitoba Pharmaceutical Act*, C.C.S.M. c. P60.

OTHER PLAYERS

CANADA'S FEDERAL ENFORCEMENT mechanisms for illegal online sales include the *Controlled Substances Act*[46] and the *Food and Drugs Act*.[47] However, because pharmacies are provincially regulated, the federal government has played a small role in actively enforcing or investigating any deemed illegal online activity. Thus far, Health Canada has commented that the practice of International Prescription Services is unsafe and has promised further investigation.

The Canadian International Pharmacy Association (CIPA), created in November 2002, has sought to work with American regulators to facilitate cross-border pharmacy sales and represents twenty-seven IPS. Recently, CIPA said its members would not provide drugs for proposed U.S. State employee and retiree programs because supplying such large-scale prescription-purchasing plans would likely create drug shortages in Canada.

What does all this mean for the International Prescription Service in Manitoba? Simply put, Internet drug sales exist in a very grey market. On one hand, regulatory bodies for Manitoba pharmacists and doctors appear to discourage the practice, but the creation of guidelines by these very same regulatory authorities for Internet sales contradicts this premise. Furthermore, the provincial government, by not preventing out-of-province doctors to sign prescriptions and actively talking with U.S. customers, has seemingly given the green light for cross-border sales. Given the large revenue and tax dollars that the International Prescription Service trade generates, it is politically unfeasible that the provincial government will de-regulate the industry any time soon.

JURISDICTIONAL ISSUES

IN ORDER FOR A U.S. COURT to assert jurisdiction over a foreign-based Internet site, it must satisfy the requirements of both subject matter jurisdiction and personal jurisdiction. The United States Supreme Court has acknowledged that with "increasing nationalization of commerce" and "modern transportation and communication," a nonresident defendant could be subject to jurisdiction when he would not have been in the past, while still complying with due process.[48] To determine subject matter jurisdiction, it is paramount to determine where the infraction has taken place. Does the illegality occur where the prescriptions are filled,

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[46] *Controlled Drugs and Substances Act*, S.C. 1996, c. 19.
[47] *Food and Drugs Act*, R.S.C. 1985, c. F-27.
[48] *McGee v. Intl. Life Insurance Co*, [1957] 355 US 220.

where the Internet site is launched, or where the drugs are received? To determine personal jurisdiction, the key factor is to examine the amount of contact the defendant has with the forum state.[49] The courts have already acknowledged that commerce between a user and a website operator can lead to personal jurisdiction in another State.[50]

While the FDA has registered warning letters to "foreign" International Prescription Services, the prosecution and execution of American laws on Canadian pharmacies is virtually unexplored. However, under the emerging law of Internet jurisdiction, the defendant could be brought to court in a foreign forum solely because an Internet site owner provided the patient with medicine and conducted business over the Internet.[51]

The majority of Manitoba-based International Prescription Services have forum-selection clauses within their contracts of sale. In addition to including these terms in the contract of sale, some IPS websites, like Rx Pharmacy Inc., have posted legal notices stipulating that the applicable laws of the Province of Manitoba and the federal laws of Canada shall govern them.[52] Although it is well-accepted policy that forum-selection clauses are prima facie valid,[53] in the event they are not upheld and an IPS faced an American jury trial, the risk of having general and punitive damages awarded against an IPS could potentially be devastating.

The other equally important reason that International Prescription Services structure the *situs* of the transaction to be within Manitoba or Canada is to avoid being in deliberate violation of U.S. law. The FDCA prohibits the exportation of non-FDA approved drugs into the United States. Accordingly, if the *situs* of the transaction took place in the United States, it would be clear that the IPS were directly exporting to the United States. This would be a deliberate violation of U.S. law. Currently, however, the transaction is structured so that the American consumer is importing the prescription drugs into the U.S. Thus, the American consumer is breaking the law and not the IPS. While the difference between exporting and

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[49] Joanna M. Carlini, "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2002) 22 Whittier L. Rev. 157.

[50] *Ibid.*

[51] John A. Irvine & David A. Chaumette, "Personal Jurisdiction and the Internet" A.B.A. Ctr. for CLE Natl. Inst. 1, 3 (Oct. 22-23, 1998; Nov. 12-13, 1998).

[52] See online: Rx1.biz Pharmacy Inc., <www.rx1.biz/canadian_mail_order_pharmacies_legal_notice.htm> (last referenced March 2003).

[53] *British West Indies Guaranty Trust Co., Ltd., v. Banque Internationale A Luxembourg*. Supreme Court, Appellate Division, First Department, New York. Judgment April 9, 1991. *Peter T. Price, Individually and as a Representative Underwriter on Behalf of Those Certain Underwriters At Lloyd's of London v. Brown Group Inc.* Supreme Court, Appellate Division, Fourth Department, New York. Judgment November 16, 1994.

importing may seem semantic, it is a necessary structural portion of the transaction. Due to the infancy of the industry, little jurisprudence has developed testing the enforceability of the choice of forum clause and *situs* of the transaction provisions.

UNITED STATES MEDICARE REFORM[54]

THE UNITED STATES SENATE approved the H.R. 1, *Medicare Prescription Drug, Improvement, and Modernization Act*. This *Act*, which was signed into law by President Bush on December 8, 2003, is an estimated $400 billion overhaul of the Medicare system. The bill adds a prescription drug benefit to the program, provides billions of dollars in subsidies to insurance companies and HMOs, and takes the first step in allowing private plans to compete with Medicare.[55] The upcoming changes to prescription drug benefits will likely have a major effect on future sales by International Prescription Services to American consumers.

The following is an overview of the major provisions in the upcoming legislation:[56]

1. In 2004 and 2005, seniors are eligible to purchase a discount card estimated to yield drug-cost savings of fifteen percent (15%) or higher. Low-income seniors would get an annual subsidy of $600.
2. In 2006, beneficiaries could sign up for a stand-alone drug plan or join a private health plan. They would be charged a premium of $35 per month, or $420 per year. After meeting a $275 deductible, insurance would pay seventy-five percent (75%) of drug costs up to $2,250.
3. There is a coverage gap. This means there will be no coverage for drug costs between $2,250 and $5,100.
4. When out-of-pocket spending reaches $3,600, insurance covers ninety-five percent (95%) of drug costs or requires a modest co-payment.

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[54] See the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, online: BNA Tax Management <http://www.bnatax.com/tm/hr1-conflegtext.pdf>.

[55] See "Senate passes Medicare bill" *CNN* (26 November 2003) online: CNN.com <http://edition.cnn.com/2003/ALLPOLITICS/11/25/elec04.medicare/>.

[56] See "Bush: New Medicare price tag means 'tough choices'" *CNN* (30 January 2004) online: CNN.com <http://us.cnn.com/2004/ALLPOLITICS/01/30/white.house.medicare/>.

5. The premium, deductible and coverage gap would be waived for people earning up to $12,123 a year. The subsidies would be phased out between $12,123 and roughly $13,500 in yearly income.
6. Starting in 2006, up to $70 billion in tax-free subsidies will be given to employers who maintain drug coverage for retirees.
7. Beginning 2010, the bill provides for a six-year program under which new private plans will compete directly with traditional Medicare in areas around the country. Insurance companies are encouraged to offer private plans to millions of older Americans who now receive health care benefits under government fixed terms.

Health care and drug pricing are a paramount concern to the American public. A recent poll revealed that health care has become the number one domestic concern.[57] It is clear that the American government is taking active steps to confront the issue of drug pricing, however, only time will tell the impact of the upcoming legislation on the sales of International Prescription Services.

RECENT JUDICIAL DECISIONS

THERE HAVE BEEN FEW JUDICIAL decisions in this emerging area. Of the few decisions available for review, two cases in particular need to be reconciled. The first case, which was decided on November 6, 2003, is *United States of America, Plaintiff v. RX Depot, Inc. and RX of Canada, LLC.*[58] The second case is *Discount Prescription Center, Plaintiff v. West Virginia Board of Pharmacy.*[59] The first case found in favour of shutting down the storefront operation of a Canadian International Prescription Service, while the second case ruled in favour of the Discount Prescription Center to prevent the State's pharmaceuti-

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[57] See "AP poll: Health care, terror worry U.S." *USA Today* (19 January 2004) online: USATODAY.com <http://www.usatoday.com/news/nation/2004-01-19-ap-poll-worries_x.htm>.

[58] *United States of America, plaintiff, v. Rx depot, inc. and Rx of Canada, LLC, corporations, and Carl Moore and David Peoples, individuals, defendants,* 290 f. supp. 2d 1238; 2003 U.S. Dist. (Lexis) 20135. Case No. 03-cv-0616-ea (m) decided November 6, 2003.

[59] *Discount Prescription Center v. West Virginia Board of Pharmacy and William T. Douglass Jr., Executive Director and General Counsel of the West Virginia Board of Pharmacy.* Circuit Court of Kanawha County, West Virginia. Civil Action No. 03-C-1327, Nov 3, 2003.

cal board from acting against the business. These two opposing decisions send a message to the public of the uncertainty behind pursuing legal action against these operations.

In the first case, an Oklahoma state court ordered the defendants' stores in Oklahoma to close after finding that the defendants acted as storefronts for Canadian pharmacies and, as such, were operating as unlicensed pharmacies.[60] The defendants were found to be in violation of Chapter 9, section 331 of the FDCA, by causing the importation of prescription drugs from Canadian pharmacies. They were also found to be in violation of section 331 (d) each time they cause to be introduced or delivered for introduction into interstate commerce unapproved new drugs in violation of section 355.[61]

The court reaffirmed the position that the purpose of the FDCA is to protect public health, and the defendants' actions encouraged and facilitated the illegal importation of drugs in furtherance of transactions prohibited by the FDCA. While the court expressed their sympathy for individuals who cannot afford the prices of U.S. prescription drugs, the court stated that Congress is the "best forum for weighing all of the costs and benefits of the national statutory scheme regulating prescription drug importation."[62] The court concluded that the defendants are "able to offer lower prices only because they facilitate illegal activity determined by Congress to harm the public interest."[63]

The court made a comprehensive order ceasing the offering, advertising, or promoting through any media, including but not limited to, the websites "www.rxdepot.com" and "www.rxofcanada.net." The order also prohibited any service that causes or facilitates the importation or assistance in importing articles of drug from any place outside the United States.[64] In addition, the court ordered the defendants to inform all of their customers that their business was in violation of U.S. law and that the safety of the drugs could not be assured. Finally, the order granted representatives of the FDA broad access to all of the defendant's property and any other measures necessary to monitor and ensure continuing compliance with the terms of the order.[65]

The second decision was the case of *Discount Prescription Center, Plaintiff v. West Virginia Board of Pharmacy.* This decision ruled in favour of the Discount Prescription Center (DPC) preventing the State's Pharmacy Board from acting against the business. The court decision identified DPC

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[60] *Supra* note 58.
[61] *Ibid.*
[62] *Supra* note 58 at para. 18.
[63] *Ibid.*
[64] *Supra* note 58.
[65] *Ibid.*

as a business with a "primary function to assist its patients by ordering non-narcotic drugs over the Internet."[66] The court noted that the majority of the customers were elderly, low-income individuals who do not have access to the Internet. The court also noted that the medications were acquired through a Canadian pharmacy in Manitoba, and that "anyone with Internet access can use the [Canadian pharmacy Web site] to purchase prescription drugs, often at significantly lower prices than those available in retail pharmacies in West Virginia."[67]

The court ordered that the West Virginia Board of Pharmacy be prohibited from "interfering with the services" provided by Discount Prescription Center.[68] The court noted the safety concerns raised by the Pharmacy Board, but stated that it "does not discount the concerns raised by the Pharmacy Board as to the safety or advisability of ordering prescription drugs from a foreign pharmacy. However, under the current state of the law, neither this court nor the Pharmacy Board has the right, the ability, or the authority to force the citizens of West Virginia to refrain from ordering prescription medications over the Internet from Canada simply because it may be unwise to do so."[69] In light of these opposing decisions, it will be interesting to note how the judiciary will approach upcoming cases.

FDA POSITION

THE FDA IS RESPONSIBLE FOR enforcing the regulations against importing non-approved drugs into the United States in conjunction with the U.S. Customs Service. Up until now, the FDA has used warning letters to highlight its position. In these letters, the FDA has repeatedly stated that they are unable to provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by the FDA. In addition, they continually highlight the illegality of doing so.

Drugs intended for sale in the Canadian market do not bear the FDA stamp of approval, and thus an American consumer importing prescription drugs from a Canadian IPS will receive a drug without the FDA's approval. Importing such drugs is illegal, a clear violation of the provisions found within the FDCA. However, even if the drugs being imported were bearing the FDA approval, the American consumer would nevertheless be in violation of the FDCA provisions. For instance, section 381 (d)(1) of the FDCA prevents a prescription drug that is approved in the U.S. and

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66 *Supra* note 59.
67 *Ibid.*
68 *Ibid.*
69 *Ibid.*

originally manufactured in the U.S. from being imported into the United States from anyone other than the U.S. drug manufacturer.[70] Accordingly, the importation of non-FDA approved, or even FDA approved, prescription drugs by American consumers is illegal.

IPS has restricted sales to consumers to a maximum 90-day supply, perhaps in order to respect the FDA's "personal importation" policy. However, the FDA has clarified that the policy of bringing in a drug supply that will last less than 90 days for personal use is illegal. This "personal importation" policy is used to guide the agency's enforcement discretion with respect to the imports of drugs by individuals for their personal use. The policy is "not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being 'commercialized' to U.S. citizens. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States."[71] The FDA has conceded that it has not often prosecuted those importing illegal drugs into the United States from Canada, but it reserves the right to do so in the appropriate circumstance.[72] Despite the warnings, FDA Director of Pharmacy Affairs, Thomas McGinnis, has made it clear that they will not target the individual consumer.[73]

The FDA issued a warning letter to Discount Prescriptions Center, the business that was afforded judicial protection from action by the State Pharmacy Board against interfering with its services. The FDA "determined the operation to be in violation of the Federal Food, Drug and Cosmetic Act."[74] FDA Commissioner, Mark B. McClellan, stated that issuing a warning is "essential to protecting the public health, and it demonstrates FDA's commitment to supporting States who take action against those who import potentially risky foreign drugs. We are working hard to give Americans greater access to safe and affordable drugs, but illegal drugs that do not assure safety are no bargain."[75]

The FDA continually maintains that safety is the paramount concern, but few believe this argument. As previously mentioned, a recent report found that both countries' methods of ensuring the safety and efficacy of prescription drugs are comparable.[76] With fewer people accepting the

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[70] *Federal Food, Drug & Cosmetic Act* 21 U.S.C. § 381(d)(1)).

[71] William K. Hubbard, *FDA Associate Commissioner for Policy and Planning.* Letter dated February 12, 2003, online: U.S. Food and Drug Administration <http://www.fda.gov/ora/import/kullman.htm>.

[72] *Ibid.*

[73] *Supra* note 26.

[74] "FDA Issues Warning Letter to West Virginia Business Offering Illegal Foreign Drugs" U.S. Food and Drug Administration (20 February 2004) online: FDA <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01025.html>.

[75] *Ibid.*

[76] Ram Kamath *et al, Report On Feasibility Of Employees And Retirees Safely And Effectively Purchasing Prescription Drugs From Canadian Pharmacies.* Office

lack of safety argument, it remains to be seen what position the FDA will follow. It is clear from a political standpoint that the FDA will not go after individual consumers, but from a legal perspective, the FDA could follow-up its warning letters with legal action against those violating the FDCA regulations. It is likely that the FDA will wait in the background until their governing authority provides them with a direct mandate to follow.

PHARMACEUTICAL MANUFACTURER POSITION

LARGE DRUG MANUFACTURERS HAVE also taken a position against International Prescription Services. Recently Pfizer, the largest pharmaceutical company in the world, wrote a letter to Manitoba wholesaler, Universal Drug Store, stating it would no longer provide them with drugs for resale to International Prescription Services. The move comes as a response from big business manufacturers who claim that patient safety is compromised because the practice does not allow for proper monitoring. Furthermore, they contend that drugs can be exposed to all sorts of hazards when they are shipped, rendering them ineffective or potentially harmful.[77] Pfizer is not the only large drug manufacturer to limit its supplies. British drug giant, GlaxoSmithKline, blacklisted dozens of Canadian International Prescription Services who were doing business in the U.S., refusing to supply product to them.

Critics contend that large pharmaceutical companies are not concerned with consumer safety because in reality, a majority of drugs sold in the U.S. are made overseas and brought in by domestic manufacturers with minimal FDA oversight.[78] Rather, the companies are concerned about their bottom line. There is no question that the large pharmaceutical companies maintain a monopoly over the American drug trade, however, Canadian International Prescription Services are undermining their profit margins and autonomy.[79]

Other drug manufacturers like Merck and Bristol-Myers Squibb have also stated that they will reduce drug shipments to Canadian International Prescription Services if the practice is not curtailed. A massive boycott by either the drug companies or consumers would put significant political

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of Special Advocate For Prescription Drugs, Illinois Department of Central Management Services (Oct 27, 2003) at 2.

[77] David Kuxhaus, "An International Prescription Service primer - Manitoba's at forefront of billion-dollar drug war; here's what you should know" *Winnipeg Free Press* (June 2003).

[78] Donald Barlett & James Steele, "Why we pay so much for drugs" *CNN* (27 January 2004) online: CNN.com <http://edition.cnn.com/2004/ALLPOLITICS/01/27/timep.drugs.tm/>.

[79] Catherine Salliant, "Drug giant's actions spark boycott in U.S. Canadian Internet pharmacies" *Winnipeg Free Press* (17 February 2003).

pressure on both Canadian and U.S. governments to resolve the issue. It could also cause long and short-term drug shortages, where the consumer is the ultimate loser.

Despite ongoing threats by drug manufacturers to restrict supply, the IPS industry continues to flourish. International Prescription Services are maintaining this growth by remaining one step ahead of the drug manufacturers through increased creativity in sourcing supply. Supply issues have been temporarily resolved by purchasing excess supply from the corner pharmacy to resell internationally, and by creating alliances with pharmacies in foreign jurisdictions, such as Britain and the Caribbean, to fill and deliver prescriptions to American customers on behalf of the Canadian IPS. Finally, as the stakes rise in this highly lucrative industry, the larger Canadian International Prescription Services will likely invest in establishing a worldwide strategy to source supply and fill prescriptions, making it even more difficult for the drug manufacturers to restrict supply. This could be achieved by setting up pharmacies outside of Canada in jurisdictions with less stringent pharmaceutical guidelines, and by using these locations to fill the orders received through their existing customer base. With a worldwide database of supply prices and drug wholesalers, the IPS would be able to select the most cost effective source from a laundry list of wholesalers, thereby maximizing profit and ensuring delivery.

MANITOBA CASE STUDY

TO CREATE A MORE TANGIBLE understanding of the material encountered in writing this paper, interviews were conducted with individuals at the forefront of the International Prescription Service industry in Manitoba.

Interview of Canadameds.Com CEO

The CEO of Canadameds.com, Mike Hicks, is at the helm of one of the largest International Prescription Services currently in operation. Canadameds.com employs over 225 people, but due to continued supply pressures and the implementation of offshore fulfillment alternatives, staff has been reduced by approximately forty people.

The first issue discussed was of safety in the cross-border sales of pharmaceuticals. Mr. Hicks pointed out that the safety concerns are, for the most part, a political scare tactic employed by the FDA to discourage the American public from purchasing drugs from International

Prescription Services. He stated that even the FDA does not really believe that the drugs coming into the United States are unsafe. Rather, he stated that the FDA is under intense political pressure to maintain the uniform position that they cannot ensure the safety of non-FDA approved drugs. Mr. Hicks mentioned that the irony is that the United States is the only jurisdiction in the world not to recognize another nation's pharmaceutical practices. Practically speaking, there is no way they could affirm the safety of any foreign drug even if they wanted to under current regulations, as the United States lacks a program of inspecting additional manufacturing and intermediary facilities. There are inherent safety issues with the consumption of any pharmaceutical drugs; however, importing a Health Canada-approved drug into the United States does not create such a safety issue.

Mike Hicks made it clear that the practice of Canadameds.com selling drugs in the manner that it does is not illegal. Canadameds.com is legally filling prescriptions by licensed pharmacists. These prescriptions are written by licensed Canadian physicians and are filled with Health Canada approved drugs. What is illegal is the importation by the American buyer of the drugs into the United States.

While Canadameds.com is the name of the website accessed by consumers over the Internet, the actual facility filling the prescriptions is the Point Douglas Pharmacy. It is organized into separate departments, ranging from order taking to order verification, dispensing, and finally shipping. Each department is physically separated to create checks and balances within the system and to ensure the accuracy of each order. The exterior of each package shipped is labeled as containing prescription drugs, in addition to the name and address of the pharmacy in Winnipeg. The contents of the packages are clearly marked, concealing nothing from any FDA or customs official that might encounter the shipment.

With respect to the future of the Internet Prescription Service industry, Mr. Hicks noted that Pfizer, whose drugs are distributed to drug wholesalers throughout Canada, had placed his company (and a number of other IPS pharmacies) on a list directing wholesalers not to sell, directly or indirectly, to pharmacies on this list. In other words, Canadameds.com and many other large IPS pharmacies had their supply cut off. How is Canadmeds.com able to continually fill orders if one of the major drug manufacturers had forced wholesalers to cut off their supply? Mr. Hicks was clear that his company is experiencing difficulty in sourcing supply. He said that they are being forced to purchase supply from other pharmacists and wholesalers who still are willing and able to provide them with Pfizer drugs, despite the prohibition by Pfizer.

Despite supply difficulties facing Canadameds.com, they are cur-

rently expanding their facilities and hiring new employees. Why would Canadmeds.com invest in expansion if drug supplies become continually difficult to source? Mr. Hicks said that the business would change within the next 1-6 months, though specifically what will happen, he would not say. Once the Canadian supply becomes too difficult to source, Canadameds.com will find an alternate way to do business given their experience, knowledge, and resources. One can only speculate as to what alternatives will be utilized. In fact, Canadameds.com is now having a portion of their prescriptions filled by offshore pharmacies.

If the Canadian Internet Prescription Service industry were to disappear, Mr. Hicks mentioned that possibly consumers looking for cheaper drugs in the future would source product from places like the U.K. and Chile. Perhaps with their brand recognition and existing customer base, Canadameds.com and other large International Prescription Services affected could help facilitate this transition. In other words, existing International Prescription Services could continue to take orders, but simply have them filled in another jurisdiction. This would allow them to stay in the industry, although in a more administrative role.

Mr. Hicks made it clear that Big Pharma's lobbying power is unparalleled. With some of the highest return on investment in any industry, they have a lot at stake. He reasoned that the Internet Prescription Service business in itself is not much of a threat, since at most, it is a few billion dollars out of hundreds of billions in sales. Instead, the true threat is the changing mindset of the American consumer. International Prescription Services are making the American consumer painfully aware that they are paying significantly higher prices for drugs than almost all other nations in the world. Once the consumers gather to demand change, the industry will be forced to realign itself.

The pressure on International Prescription Services and the pharmaceutical industry as a whole is mounting primarily because of the economic dilemma faced by Big Pharma. Years and years of unparalleled profits and returns on investment have come at the expense of the highest paying customer: the American consumer. There is nothing wrong with profit, a natural by-product of a well-run business; however, there is something wrong with reaping massive profits from drug sales, consequently making it difficult or impossible for those who need the drugs the most to access them affordably. Mr. Hicks stated that providing consumers with more affordable drugs would help to level the playing field.

Interview of Manitoba Pharmaceutical Association Members

Ronald Guse is the Registrar of the Manitoba Pharmaceutical Association (MPHA). The MPHA is a self-licensing body that regulates the Manitoba pharmacy practice and grants licenses to pharmacies to practice within Manitoba.

Mr. Guse likened the growth of International Prescription Services within Manitoba to that of the Wild West. The MPHA typically issued one pharmacy license per month. As a self-financing body, the MPHA staff and resources corresponded with expected demands. However, as the Internet Prescription Service industry grew, so did the regulatory demands of the MPHA. The demands for pharmacy licenses went from one license a month to approximately six per month. With such a dramatic increase in demand, the MPHA lacked the resources to satisfy the strain. Accordingly, the MPHA increased its fees to those pharmacies selling drugs outside of the country.

According to Mr. Guse, it is troubling that some International Prescription Services may be prioritizing distribution and ultimately profiting, as opposed to the core care function of a pharmacy. He continued by saying that this makes the MPHA's objective to protect the public even more challenging, since the pharmacies they are regulating are pushing the limits of legal and ethical practice.

Dexter Boyd, a member of the Manitoba Pharmaceutical Association, handles complaints, claims, and on-site inspections involving International Prescription Services. Both Mr. Boyd and Mr. Guse stated that International Prescription Services have added to the strain on drug supplies and pharmacy services in Manitoba. Manufacturers like Pfizer have reduced drug supplies in Manitoba, and the demand has now far exceeded supply. Drug supply issues have created delays for Manitoba pharmacists to source supply and have ultimately caused problems for Manitoba consumers to receive their prescriptions.

Starting in 2004, Mr. Boyd and Mr. Guse have noticed a reduction in the number of "start-up" International Prescription Services. In the fiscal periods of 2002 and 2003, the growth was staggering; however, the profitability of International Prescription Services has decreased with the rise of the Canadian dollar and the increased competition among Manitoban and other Canadian pharmacies. Mr. Boyd indicated that he saw this as a sign that the Internet Prescription Service industry has reached a plateau and market forces will level the once rapidly growing industry.

Both Mr. Boyd and Mr. Guse indicated that the pharmaceutical

manufacturers and political decision-makers will ultimately decide the future role of International Prescription Services. Their ability to control the distribution of drugs greatly affects the ability of pharmacies to do business. If other drug companies follow the direction of GlaxoSmithKline and Pfizer, the Manitoba government might be pressured to take action against International Prescription Services.

CONCLUSION

THE FUTURE OF THE INTERNATIONAL Prescription Services industry remains unclear as they continue to operate in a grey market. Mounting pressures from the drug manufacturers, the FDA, consumers, and government bodies are making it extremely clear that a compromise needs to be reached. A compromise, not a one-sided victory, is what is needed. This issue deals with the availability of much-needed drugs, and simply shutting down the International Prescriptions Services industry in one form or another will not solve the underlying problem. According to the U.S. Census Bureau, an estimated 45 million Americans do not have any health insurance coverage, including coverage for prescription drugs.[80] Until an appropriate alternative is provided to people in need of affordable drugs, those International Prescription Services that supply lower-cost drugs, while remaining creative, will continue to thrive.

[80] Julie Appelby, "Ranks of uninsured grow to highest since '98"' *USA Today* (27 August 2004).