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Minnesota: Leading the Way on Canadian Prescription Medicine Importation

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MINNESOTA: LEADING THE WAY ON CANADIAN PRESCRIPTION MEDICINE IMPORTATION

Kevin Goodno[†] and Karen Janisch^{††}

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I. INTRODUCTION

From families trying to make ends meet to a state government working to balance its budget, rising health care costs pose a significant and daunting public policy challenge. Minnesota Governor Tim Pawlenty's Health Cabinet estimates that health care

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costs in Minnesota increase \$70 each second.¹ Every hour, health care in Minnesota costs a quarter of a million dollars more than it did last year.²

The escalating cost of health care is one of the reasons Minnesota faced a projected \$4.2 billion budget shortfall when Governor Pawlenty took office on January 6, 2003.³ The budget of the Department of Human Services, which is one quarter of the state budget, was projected to increase by 22% over the previous biennium largely due to rising health care costs.⁴ In addition, the state as an employer was experiencing a 17% increase in the cost of providing health care insurance to its own state employees.⁵

Besides the direct impacts on the state, increased health care costs incurred by the private sector impact the state in indirect ways. As employers are forced to spend more on non-taxable health care benefits for their workers, they spend less on salaries, which are taxable. This in turn negatively impacts the revenue the state generates from income and sales taxes, making the budget challenge even worse.

Despite all these pressures, Minnesota has consistently had one of the lowest rates of uninsured individuals in the country.⁶ This has been attributed to the generous state health care programs and to the fact that more of Minnesota's employers, as compared to their counterparts in other states, provide health care coverage for their employees.⁷ This is the good news. The bad news is that if health care costs continue to escalate, state government and private employers will be forced to reduce coverage, which will increase the number of uninsured in the state.

In addition to appointing the Minnesota Citizens Forum on

1. State of Minnesota, *Governor's Health Cabinet: Minnesota Department of Employee Relations*, at <http://maximumstrengthhealthcare.com> (last visited Feb. 5, 2005).

2. *Id.*

3. Minnesota Department of Human Services, Office of Budget Management, at <http://www.dhs.state.mn.us> (last visited Jan. 30, 2005).

4. *Id.*

5. Minnesota Department of Employee Relations, at <http://www.doer.state.mn.us> (last visited Feb. 5, 2005).

6. Minnesota Health Department, *Minnesota's Uninsured: Findings from the 2001 Health Access Survey*, (April 2002), available at <http://www.health.state.mn.us> (hereinafter *Minnesota's Uninsured*); see also Minnesota Department of Health, *Health Economics Program Issue Brief: 2002 Minnesota Distribution of Insurance Coverage*, (April 2004), available at <http://www.health.state.mn.us/divs/hpsc/hep/issbrief/2004-03.pdf>.

7. *Minnesota's Uninsured*, *supra* note 6.

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Health Care Costs to address the daunting task of controlling health care costs,⁸ Governor Pawlenty directed his state agencies to develop their own strategies to address health care costs.⁹ A result of this directive was a variety of initiatives to control the high cost of prescription medicines.

As advances in prescription medicines have improved length and quality of life, a hugely disparate international pricing system has evolved in which pharmaceutical companies charge wildly different prices for the same product in different countries. The cost for individuals, particularly seniors with no prescription medicine coverage, has risen so significantly that it has too often forced choices between buying medicines and meeting other basic needs.

In the United States, about \$160 billion is spent on prescription medicines each year, with Minnesotans spending about \$3 billion.¹⁰ The costs of prescription medicines receive so much attention in large part because, although prescription medicine costs constitute only 10.5% of total health care spending, they account for 23% of the total out-of-pocket costs that people incur when purchasing health care.¹¹ Minnesota has been a leader in controlling prescription medicine costs. It has aggressively used purchasing pools when possible, and encouraged the use of lower cost, generic prescription medicines when appropriate.

Even with these efforts to control costs, prescription medicines were still becoming too costly for many Minnesotans to afford. Busloads of senior citizens headed north for Canada.¹² Others used Internet pharmacies, some of which were unsafe.¹³ The need for lower cost prescription medicine alternatives and a desire to protect the safety of Minnesotans who seek them caused Governor Pawlenty, in September of 2003, to direct the Minnesota Department of Human Services to examine the feasibility of

8. Minnesota Citizens Forum on Health Care Cost, *available at* <http://www.mncitizensforum.org> (last updated Feb. 27, 2004).

9. *Id.*

10. Warren Wolfe, *Modest Start for State Drug Sites*, STAR TRIB., July 21, 2004, *available at* www.startribune.com/viewers/story.php?template=a&story=4886132.

11. Donald L. Barlett & James B. Steele, *Why We Pay So Much for Drugs*, TIME, Feb. 2, 2004, at 44, 47.

12. *See, e.g.*, Rx Express, Mark Dayton, United States Senator, *available at* <http://dayton.senate.gov/issues/health/rx-express.cfm>.

13. Press Release, Tim Pawlenty, Governor of Minnesota, Governor Pawlenty Takes Action on Problem of Escalating Prescription Drug Costs (Sept. 24, 2003) (on file with author).

importing prescription medicines from Canada and other international sources.¹⁴ He directed the Commissioner of Human Services to examine methods to address the needs of Minnesota state employees, the citizens served through the state's public assistance programs, and the state's citizens at large.¹⁵

In response to this directive, a three-phase plan was developed.¹⁶ The plan called for the development of a website to empower Minnesota consumers to purchase mail-order prescription medicines for personal use from approved Canadian pharmacies; the option for Minnesota state employees to voluntarily obtain prescriptions for maintenance medications from Canadian pharmacies; and the establishment of a pilot project that allows Minnesotans to purchase Canadian prescription medicines from their local pharmacies.¹⁷

II. MINNESOTA RXCONNECT

On January 30, 2004, Minnesota RxConnect (RxConnect) was launched, making Minnesota the first state in the nation to establish a website to empower its citizens to purchase prescription medicines from Canada.¹⁸ Consumer savings and safety were the driving purposes for establishing RxConnect. Health and safety are not served by Minnesotans foregoing needed prescription medicines because they are too expensive. For more than a decade, many Minnesotans have been physically crossing the border into Canada to purchase needed prescription medicines, often at the encouragement of elected officials.¹⁹ The growth of Internet and mail-order pharmacies has increased Minnesotans' access to prescription medicines from other countries. Various estimates place the total sales of Canadian prescription medicines

14. *Id.*

15. *Id.*

16. Tim Pawlenty, Governor of Minnesota, Testimony to the Congressional Prescription Drug Access Coalition hearing in Boston, MA (Oct. 28, 2003) (transcript *available at* http://www.governor.state.mn.us/Tpaw_View_DF_Article.asp?artid=654).

17. *Id.*

18. Press Release, Tim Pawlenty, Governor of Minnesota, Governor Pawlenty Unveils First-In-The-Nation Effort to Facilitate Purchase of Prescription Drugs from Canada (Jan. 30, 2004) (on file with author).

19. Press Release, Mark Dayton, United States Senator, Dayton Uses First Senate Speech to Press Congress and President To Make Prescription Drugs More Affordable for Seniors (Feb. 26, 2001), *available at* <http://www.dayton.senate.gov/news/details.cfm?id=229450&&>.

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to the United States in a range between \$600 million and \$1 billion a year.²⁰ RxConnect recognizes this reality and provides Minnesotans with information on prescription medicines, safety, and selected Canadian pharmacies.

Minnesota is not alone in its effort to provide information to citizens who seek information on lower cost prescription medicines. Although Minnesota's RxConnect website may have been the first state site to go online, other state and local governments have quickly followed. Wisconsin, North Dakota, Rhode Island, New Hampshire, as well as county and city governments throughout the United States, have all initiated prescription medicine programs for their residents.²¹ In expressing the position of the U.S. Food and Drug Administration (FDA), FDA Associate Commissioner of External Relations, Peter Pitts, claimed that "illegal, unsafe importation presents the very real danger of turning the Internet into the 21st century's virtual drug cartel."²² William Hubbard, the FDA Associate Commissioner for Policy and Planning, in a letter to Governor Pawlenty, specifically attacked RxConnect as "unsafe, unsound, and ill-considered."²³ The criticisms from the FDA and other detractors of RxConnect have centered on concerns about the legality of the website, the safety of the prescription medicines and whether there are actual cost savings to consumers.

III. RXCONNECT INFORMS AND PROTECTS MINNESOTA CITIZENS AND DOES NOT VIOLATE FEDERAL LAW

States play a critical role in our system of government and have traditionally served as the nation's laboratory for innovative programs that provide for the protection and general welfare of their citizens. Although the federal government has authority, within the limitations of the Constitution, to pass laws to govern the country, in areas where Congress has not acted to require or

20. Christopher Rowland, *Canada Threatens to Halt Shipments of Drugs to US*, BOSTON GLOBE, Nov. 11, 2004, (located at Boston Globe Archives, 2004-11-11).

21. Irakli Khodeli, *Prescription Drug Importation Gains Momentum*, STATE NEWS, August 2004, at 14, 15.

22. Peter J. Pitts, Associate Commissioner for External Relations, FDA, Remarks at the NCSL Health Leaders Seminar (Dec. 10, 2003), *available at* <http://www.ncsl.org/programs/health/pitts.htm>.

23. Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Tim Pawlenty, Governor, Minnesota (Feb. 23, 2004), *available at* <http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html>.

prohibit an action, the states generally remain free to exercise their authority.²⁴

Governor Pawlenty's prescription medicine website reflects an appropriate exercise of authority by the State of Minnesota. RxConnect provides information to Minnesotans so that they can make informed decisions in relation to their purchase of prescription medicines.²⁵ The state's efforts to inspect participating Canadian pharmacies fits within the state's general role of actions to inform the public about recommended safety measures for pharmacies and a comparison to the measures used by pharmacies licensed by the state. The information available on the RxConnect website enhances the potential safety for citizens who choose to purchase lower cost prescription medicines from Canada.²⁶

A. *RxConnect Is Consistent with Federal Law*

Although the FDA was quick to criticize and threaten Governor Pawlenty and other state and local officials who created programs to inform their citizens about the significant cost savings on prescription medicines available in the Canadian market,²⁷

24. See U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people").

25. RxConnect provides information about safe purchasing and use of prescription drugs, cost-saving tips and links to assistance programs, instructions for ordering medicine from participating pharmacies, and information on the participating pharmacies and the selection process. Minnesota RxConnect, *How to Use This Site*, at <http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?contentid=536901930&contenttype=EDITORIAL&hpage=true&agency=Rx> (last visited Jan. 28, 2005).

26. For example, RxConnect provides advice on how to properly use and store prescription drugs and advice about shopping for drugs on the internet. Minnesota RxConnect, *Safety First*, at <http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?id=536885275&agency=Rx> (last visited Jan. 28, 2005).

27. See FDA, *Importing Prescription Drugs, Letters to State and Local Officials*, available at <http://www.fda.gov/oc/opacom/hottopics/importdrugs/> (last visited Jan. 27, 2005). Recipients of the letters include: Minnesota Governor Tim Pawlenty, Wisconsin Governor Jim Doyle, Illinois Governor Rod Blagojevich, Rhode Island Governor Donald Carcieri, New Hampshire Governor Craig Benson, Washington D.C. Mayor Anthony A. Williams, and Caldwell County North Carolina administrator Bobby White. Springfield, Massachusetts and Birmingham, Alabama have undertaken importation programs for their residents. The State of Vermont is also currently suing the Secretary of the federal Department of Health and Human Services in relation to the FDA's refusal to allow Vermont to initiate a pilot importation program. In Minnesota, Governor Pawlenty and Human Services Commissioner Kevin Goodno have taken issue with the accuracy of

Minnesota's prescription medicine program is consistent with federal law. RxConnect provides information to consumers so that the consumer can make their own informed choices regarding their health care. Nothing in federal law prohibits states, individuals, or any other entity from providing information or even from advocating the importation of prescription medicines. Moreover, RxConnect reflects Minnesota's exercise of its traditional power as a state to inform and protect its citizens.²⁸ These rights have not been preempted by federal law.²⁹ As a result, Minnesota's program falls squarely within the protection of the First Amendment and the protection of state authority granted by the Tenth Amendment of the United States Constitution.³⁰

B. Importation Under the FDCA

The Federal Food, Drug, and Cosmetic Act³¹ (FDCA) governs importation of prescription medicines in the United States. As to importation of pharmaceutical products from foreign countries, the FDCA distinguishes between importation of pharmaceutical products that were manufactured in the United States and

assertions made by FDA officials and have provided specific responses to the assertions made in the FDA letters. See Letter from Kevin Goodno, Commissioner, Minnesota Department of Human Services, to William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, (Mar. 9, 2004) (on file with author).

28. States traditionally have the power to enact legislation to protect the health and safety of their citizens. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2245 (1996) (quoting *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719, 105 S. Ct. 2371, 2378, 85 L. Ed.2d 714 (1985), *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756, 105 S. Ct. 2380, 2398 (1985)). These traditional powers are called police powers. "[T]he police power of a state embraces regulations designed to promote the public convenience or the general prosperity, as well as regulations designed to promote the public health, the public morals, or the public safety." *Chicago, B. & Q. Ry. Co. v. Illinois*, 26 S. Ct. 341, 349 (1906).

29. Federal preemption requires that state law must give way when it conflicts with or frustrates federal law. See U.S. CONST. art. VI cl. 2. "State law is preempted when Congress expressly prohibits state regulation, when Congress implicitly leaves no room for state involvement by pervasively occupying a field of regulation, and when state law directly conflicts with federal law." *Chapman v. Lab One*, 390 F.3d 620, 624 (8th Cir. 2004); see 16A AM. JUR. 2D *Constitutional Law* § 241.

30. See U.S. CONST. amend. I ("Congress shall make no law. . . abridging the freedom of speech"); U.S. CONST. amend. X ("[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States").

31. 21 U.S.C. § 301 (2000).

products that were manufactured in other countries.³² The FDCA prohibits any importation into the United States of a prescription medicine that was originally manufactured in the United States.³³ Prescription medicines that are initially manufactured within the United States and later exported may be brought back into the United States only by the product's manufacturer.³⁴ Thus, once prescription medicines manufactured within the United States leave the country, nobody except the manufacturer can import the prescription medicine back into the country and into the stream of commerce.

Prescription medicines manufactured in countries other than the United States can be legally imported into the United States if the medicines comply with the FDCA. It is not a violation of the Act to import FDA-approved prescription medicines that were manufactured outside of the United States if the product is properly labeled in accordance with the FDCA and distributed with a valid prescription.³⁵ The FDA has taken the position that almost all importation of prescription medicines manufactured outside of the United States will violate the FDCA.³⁶ The FDA asserts that in order to be FDA-approved the imported medicines must comply with all of the product-specific, manufacturer-specific, process-specific, and labeling-specific requirements established for the manufacturer's FDA application and approved by the FDA in accordance with federal regulations.³⁷ Under the FDA's analysis, any slight variation or technical deviation in the content or packaging from the U.S. equivalent makes the product an "unapproved" product.³⁸

32. *See, e.g.*, 21 U.S.C. at § 381(d)(1).

33. *Id.*

34. *Id.*

35. *See* 21 U.S.C. §§ 355 (unapproved drugs), 352 (labeling requirements), and 353(b)(1) (prescription drugs).

36. Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA to Robert P. Lombardi, Esq., the Kullman firm (Feb. 12, 2003), *available at* <http://www.fda.gov/ora/import/kullman.htm>.

37. *Id.* (citing 21 C.F.R. § 314.50 (2004)).

38. The significance underlying the differences between the importation provisions is highlighted by the reality of the global manufacturing process for prescription medicines. Currently, prescription medicines available in the United States are manufactured around the globe. Lipitor, a popular cholesterol-lowering medicine manufactured by Pfizer, Inc., is manufactured in Ireland. *See* Lipitor Product Information, *available at* http://www.lipitor.com/cwp/appmanager/lipitor/lipitorDesktop?_nfpb=true&_pageLabel=prescribingInformation (last visited Feb. 5, 2005).

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Importation of prescription medicines in violation of the FDCA, or the “causing thereof,” is prohibited by the Act.³⁹ A violation of the Act, if enforced, can result in an administrative warning, civil legal action for injunctive relief, seizure of product, and in some cases, criminal prosecution.⁴⁰

The provisions of the FDCA prohibiting certain importation of prescription medicines may give way to broader legalization of importation programs. Congress has expressly recognized the need to explore the safe importation of prescription medicines. In 2000, Congress made specific factual findings regarding access to affordable prescription medicines in alternative markets:

- (1) The cost of prescription drugs for Americans continues to rise at an alarming rate.
- (2) Millions of Americans, including Medicare beneficiaries on fixed incomes, face a daily choice between purchasing life-sustaining prescription drugs, or paying for other necessities, such as food and housing.
- (3) Many life-saving prescription drugs are available in countries other than the United States at substantially lower prices, even though such drugs were developed and are approved for use by patients in the United States.
- (4) Many Americans travel to other countries to purchase prescription drugs because the medicines that they need are unaffordable in the United States.
- (5) Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries, but efforts to enable such purchases should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States.⁴¹

These congressional findings recognize the plight of millions of Americans: they are struggling to afford costly prescription medicine, they are already crossing borders to obtain their medicines, and the need for appropriate safety protections in relation to accessing affordable prescription medicines available in other markets.

In 2000, Congress amended the FDCA to require the Secretary

39. See 21 U.S.C. § 331(a), (d), (t) (2000).

40. See 21 U.S.C. §§ 331-34, 336-37 (2000).

41. Medicine Equity and Drug Safety Act of 2000, H.R. 4461, 106th Cong. § 745(b) (2000); Pub. L. No. 106-387, § 745(b), 114 Stat. 1549 (2000).

of Health and Human Services, in consultation with the United States Trade Representative, to promulgate regulations permitting pharmacists and wholesalers to import pharmaceutical products covered by the FDCA.⁴² Under these new provisions, the Secretary of Health and Human Services was required to develop safeguards to ensure that imported products comply with key provisions of the FDCA regarding safety and efficacy, and develop safeguards that generally provide for the protection of the public.⁴³ However, the 2000 amendments contained a provision that significantly weakened the directive to the Secretary to create regulations: “[t]his section shall become effective only if the Secretary demonstrates to the Congress that the implementation of this section will (1) pose no additional risk to the public’s health and safety; and (2) result in a significant reduction in the cost of covered products to the American consumer.”⁴⁴ Based on this provision, the Secretary of Health and Human Services under both the Clinton and Bush administrations has declined to make the certification.

In 2003, Congress significantly amended this new provision. The amendments specifically require the development of regulations that permit the importation of prescription medicines from Canada by pharmacists and wholesalers.⁴⁵ Significantly, the 2003 amendments for the first time provide directives to the Secretary of Health and Human Services in relation to importation of prescription medicines by individuals for personal use:

Declarations. Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should

- (A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and
- (B) exercise discretion to permit individuals to make such importations in circumstances in which
 - (i) the importation is clearly for personal use; and
 - (ii) the prescription drug or device imported

42. 21 U.S.C. § 384(a) (2000).

43. *Id.* § 384(b).

44. *Id.* § 384(l).

45. *Id.* § 384(b).

does not appear to present an unreasonable risk to the individual.⁴⁶

The Secretary can address personal use enforcement by either providing for case-by-case waivers to individuals, or by regulation on specific prescription medicines or a class of medicines.⁴⁷ As to prescription medicines imported from Canada, the amendment provides that

the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that (A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply; (B) is accompanied by a copy of a valid prescription; (C) is imported from Canada, from a seller registered with the Secretary; (D) is a prescription drug approved by the Secretary . . . ; (E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 360.⁴⁸

The Secretary can also impose other conditions deemed necessary to ensure public safety.⁴⁹

The 2003 amendments continue the condition that the provisions become effective only if the Secretary certifies that the provision will “pose no additional risk of harm.”⁵⁰ Congress suggested the Secretary of Health and Human Services should conduct a study on the importation of drugs under the 2003 amendments to the FDCA.⁵¹ If the Secretary submits a certification report on the study to Congress within twelve to eighteen months from the date of enactment stating that the benefits do not outweigh the detrimental effects of the amendments, they will cease to have effect.⁵² In December of 2004, the Secretary issued his Report on Prescription Drug Importation to Congress finding that the benefits of drug importation did not outweigh the risks of potential harm to the American public.⁵³ At this point, unless Congress acts to establish a safe importation program, further

46. *Id.* § 384(j)(1)(1).

47. *Id.* § 384(j)(2).

48. *Id.* § 384(j)(3).

49. *Id.* § 384(j)(3)(F).

50. *Id.* § 384(1).

51. *Id.* § 384(1)(2)(A).

52. *Id.*

53. Report on Prescription Drug Importation, HHS Task Force on Drug Importation, United States Department of Health and Human Services, December 2004.

action by the FDA to establish such program appears unlikely.⁵⁴

C. FDA's Current Personal Use Policy

Notwithstanding the 2003 amendment to the FDCA, relating to the possible development of regulations or waiver procedures for the importation of prescription medicines for personal use, the FDA has had a longstanding practice of not enforcing the FDCA's importation prohibitions against individuals who are importing small amounts of prescription medicines for personal use. The FDA has expressly recognized in its Regulatory Procedures Manual an exemption on enforcement for personal importations.⁵⁵ The general guidance in the Regulatory Procedures Manual⁵⁶ provides, in relevant part:

FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments. . . . Commercial and promotional shipments are not subject to this guidance.⁵⁷

The Regulatory Procedures Manual provides that FDA personnel should not examine personal baggage (a function to be

54. There continues to be interest in Congress for establishing a prescription medicine importation program. On February 16, 2005, Governor Pawlenty testified about Minnesota's efforts in relation to lowering the costs of prescription medicines before the Senate Committee on Health, Education, Labor, and Pensions. Governor Pawlenty's testimony is available at http://www.governor.state.mn.us/tpaw_view_article.asp?artid=1260.

55. See OFFICE OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMIN., REGULATORY PROCEDURES MANUAL: Ch. 9 IMPORT OPERATIONS/ACTIONS (2004 ed.), available at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9/default.htm.

56. See *id.* The personal importation provisions are contained in the Regulatory Procedures Manual (RPM), Chapter 9, in the subchapter on Coverage of Personal Importations. As of January 2005, Chapter 9 of the RPM, which addresses import operations/actions, was being revised.

57. *Id.*

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left to the U.S. Customs Service) and that the guidance in relation to personal importations is intended to apply both to personal mail shipments and personal baggage.⁵⁸

As a greater number of Americans have looked to Canada for relief from high prescription medicine prices and the importation issues have grown in national prominence, the FDA has issued several informational letters asserting a narrow application of the personal-use policy.⁵⁹ The FDA has publicly asserted that the discretion provided by the personal-use policy is intended to apply only to allow for “medical treatments sought by individuals that are not otherwise available in the United States” and not in scenarios where the FDA-approved medicines are available more cheaply in the foreign country.⁶⁰

The guidance identifies circumstances in which the FDA may consider exercising enforcement discretion and refrain from taking legal action against illegally imported drugs. Those circumstances are as follows:

- 1) the intended use [of the drug] is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means;
- 2) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue;
- 3) the product is considered not to represent an unreasonable risk; and
- 4) the individual seeking to import the product **affirms in writing** that it is for the patient’s own use (generally not more than a 3 month supply) and **provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment** with the product, or **provides evidence that the product is for the continuation of a treatment begun in a foreign country.**⁶¹

58. *Id.*

59. *See, e.g.*, OFFICE OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMIN., INFORMATION ON IMPORTATION OF DRUGS PREPARED BY THE DIVISION OF IMPORT OPERATIONS AND POLICY, FDA (Apr. 3, 1998), *available at* <http://www.fda.gov/ora/import/pipinfo.htm>.

60. *Id.*

61. OFFICE OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMIN., IMPORTATION OF PRESCRIPTION MEDICINES/DRUGS, TRAVEL ALERT, *available at* http://www.fda.gov/ora/import/traveler_alert.htm (last visited Feb. 5, 2005)

Although the FDA has recently gone out of its way to emphasize that it believes it has a *right* to take enforcement action against individuals importing prescription medicines available in the United States for their personal use, the FDA has generally not pursued such action against individuals.⁶² Recently, however, the FDA took action to seize a number of personal mail shipments of prescription medicines that had been ordered by seniors in Minnesota, Wisconsin, and other states through a Canadian Internet pharmacy.⁶³ When the FDA's action resulted in angry outcries from senior citizen advocacy groups and federal senators from Minnesota and Wisconsin, the FDA released the shipments to the individuals.⁶⁴

D. FDA Enforcement: The Rx Depot, Inc. Case

Although legal action against individuals has not been pursued by the federal government, the FDA has pursued legal action against a private company in relation to importation of prescription medicines. In *United States v. Rx Depot, Inc.*, the United States brought a legal action against Rx Depot, Inc., affiliated companies, and individual officers of Rx Depot to enjoin alleged violations of the FDCA.⁶⁵ Rx Depot sold U.S. customers prescription medicines ordered from a Canadian pharmacy.⁶⁶ The customers brought their prescriptions, required medical forms, and payment information directly to Rx Depot, which transmitted the information to a participating Canadian pharmacy.⁶⁷ Rx Depot received a direct commission on each sale filled by the Canadian pharmacy.⁶⁸ The court found that Rx Depot essentially worked as a commissioned sales force for the Canadian pharmacy.⁶⁹

In issuing the preliminary injunction,⁷⁰ the court found that

(emphasis in original).

62. See, e.g., Letter from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Robert P. Lombardi, Esq., The Kullman Firm (Feb. 12, 2003), available at <http://www.fda.gov/ora/import/kullman.htm>.

63. Julie Appleby, *Drugs from Canada Seized*, USA TODAY, Sept. 17, 2004, at 5B.

64. See *Drug Importation; Wisconsin Senators Ask FDA Why it Intercepted Drugs from Canada*, HEALTH & MED. WK., Oct. 4, 2004, at 455.

65. 290 F. Supp. 2d 1238 (N.D. Okla. 2003).

66. *Id.* at 1240-41.

67. *Id.*

68. *Id.* at 1241.

69. *Id.*

70. *Id.* at 1250. Rx Depot's motion to stay the preliminary injunction imposed by the court was denied in *United States v. Rx Depot, Inc.*, 297 F. Supp. 2d

the United States was likely to prevail on its claims that Rx Depot's role in the transaction "caused" the importation of prescription medicines originally manufactured in the United States, as well as the importation of new unapproved medicines manufactured in foreign countries in violation of the FDCA.⁷¹

E. Minnesota's RxConnect Program Does Not Violate the FDCA

The FDA has been quick to criticize state and local officials who take action to inform their citizens about the availability and affordability of prescription medicines from Canada.⁷² Nevertheless, to date, the FDA has not attempted to enjoin any of the state or local government entities that have set up programs to inform citizens regarding Canadian prescription medicines.

Even if challenged by the FDA, RxConnect does not violate the FDCA. RxConnect is specifically set up to provide information to Minnesotans and through that information help protect the safety of Minnesotans who choose to pursue a purchase of prescription medicines from Canada. Although an individual can obtain information and download order forms from the website, the state of Minnesota does not participate in any manner in the decision made by the consumer or in the transaction conducted with the Canadian pharmacy. The state also does not receive any type of compensation or benefit from the pharmacy or the consumer.

Instead, the RxConnect website merely provides a comparison of prescription medicine costs in the United States with costs in Canada, information on the possibility of cheaper generic medicines in the United States, and safety tips regarding prescription medicines.⁷³ The information provided on the website makes it clear that the purpose of the program is to inform Minnesotans, and "to provide Minnesotans information on issues related to prescription medicine, safety and cost-saving tips, and programs to help low-income Minnesotans pay for prescription medications."⁷⁴ The RxConnect website also provides Minnesotans

1306 (N.D. Okla. 2003).

71. *Rx Depot*, 290 F. Supp. 2d at 1247.

72. *See, e.g.*, Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Tim Pawlenty, Governor, State of Minnesota (Feb. 23, 2004) (on file with author).

73. *See* Minnesota RxConnect Online, at <http://www.state.mn.us/cgi-bin/portal/mn/jsp/home.do?agency=Rx> (last modified Jan. 11, 2005).

74. *See* Minnesota RxConnect Online, at <http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?id=536885395&agency=Rx> (last modified Jan. 11,

with information about, and the identity of, pharmacies that have been visited by Minnesota officials and information regarding the safety standards used by the four pharmacies featured on the website.⁷⁵

Individual consumers ultimately decide whether it is in their interests to purchase their prescription medicines from Canada. Given RxConnect's public safety and information functions, there is no legal basis to conclude Minnesota has violated or "caused" a violation of the FDCA.⁷⁶ The state is no more involved in the transaction than any other public interest group or media outlet that provides information to the public concerning prescription medicines.

Moreover, a conclusion that RxConnect violated the FDCA would implicate important constitutional mandates. First, the state, acting through its public officials, has the right to free speech—especially where such speech bears directly on matters of public policy and the safety of citizens.⁷⁷ State officials could obviously share any of the information contained on RxConnect orally, which includes providing information about the pharmacies that are willing to take orders from Minnesotans. The fact that a website is used as the medium for communication rather than oral communication does not change the nature of the speech.

The key feature of RxConnect is the state's role in visiting Canadian pharmacies, reviewing their safety protocols in comparison with state pharmacy standards and discussing procedures to provide enhanced safety in relation to the importation of prescription medicines.⁷⁸ It is well documented that before Minnesota undertook these functions, many Minnesotans were already crossing the border, either physically or electronically, to purchase necessary prescription medicines. The need for additional information and protection was clear. By providing RxConnect, Minnesota helps to ensure that its citizens who chose to purchase medicines from Canada, have a resource available for making an informed decision.

2005).

75. *Id.*

76. *See* 21 U.S.C. § 301 (2000).

77. *See* U.S. CONST. amend. I.

78. *See* Minnesota RxConnect Online, at <http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?contentid=536902091&contentType=EDITORIAL&subchannel=null&sc3=null&sc2=null&id=-536885147&agency=Rx> (detailing pharmacy screening criteria) (last modified Jan. 11, 2005).

Finally, even assuming that the applicable provisions of the FDCA reflect Congress' valid exercise of authority under the Commerce Clause,⁷⁹ the scope of the FDCA must be interpreted in light of the Tenth Amendment's reservation of authority to the states.⁸⁰ Although Congress has the authority to regulate foreign trade, RxConnect does not in any manner negate Congress' authority to regulate trade, the regulatory structure established by the FDCA, or the FDA's authority to enforce the FDCA.

Nothing in the FDCA prohibits states from traveling to foreign countries to review the safety procedures used by foreign pharmacies.⁸¹ Similarly, there is no prohibition against states, or anyone else, providing information to the public as to the safety standards used by foreign pharmacies or negotiating with such pharmacies for safer, more effective practices.⁸² Without such a prohibition under the Constitution or the FDCA, such power is reserved to the states and to the citizens.⁸³ That the information and efforts of the states or citizens results in more individuals choosing to import prescription medicines from other countries in a manner that the FDA believes violates the FDCA, and which the FDA may or may not choose to enforce against the individual, does not alter the result.

IV. RXCONNECT ENHANCES THE SAFETY OF PRESCRIPTION MEDICINES ORDERED FROM CANADA

The FDA's safety concerns revolve around the operation of the mail-order pharmacies and the safety of the prescription medicines.⁸⁴ The safety issues related to the pharmacies range from allegations of poor operating practices to outright criminal activity.⁸⁵ The FDA has been at the forefront of the warnings about

79. See U.S. CONST. art. I, § 8.

80. See U.S. CONST. amend. X.

81. See 21 U.S.C. § 301 (2000).

82. See *id.*

83. See U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the People.").

84. Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Tim Pawlenty, Governor, State of Minnesota (Feb. 23, 2004) (on file with author).

85. See *id.*; see also *Canadian Prescription Drug Re-importation: Is There a Safety Issue?: Hearing Before the House Committee on Government Reform, Subcommittee on Human Rights and Wellness*, 108th Cong. (June 12, 2003) (statement of William K. Hubbard, Associate Commissioner for Policy and Planning, FDA), available at

the safety of mail-order pharmacies. William Hubbard has argued that the FDA does not “know of people getting sick or dying yet, but people are at risk.”⁸⁶ In his testimony to Congress, Hubbard outlined his agency’s specific concerns regarding the safety of prescription medicines ordered from Canada, primarily that the product could be expired, contaminated, counterfeit, wrong, or sub-potent.⁸⁷ In addition, the product could be of an incorrect dosage, lack an English language label, lack proper directions, or have experienced degradation due to improper handling.⁸⁸ Although warning of the dangers of Canadian mail-order prescription medicines, Pitts has admitted that “Canadian drugs are safe. If you walk into a pharmacy in Windsor, Ontario, and have a prescription filled by a real pharmacist—the drugs you receive will be both safe and effective.”⁸⁹

RxConnect offers Minnesotans a safe alternative to border crossings and unknown, unregulated international websites. The guidelines established for RxConnect and the process followed to select Canadian pharmacies and to limit the prescription medicines listed on RxConnect were rigorous and established with a focus on making certain that consumers are receiving prescription medicines approved for Canada from a real pharmacist—in other words, prescription medicines that are safe and effective. In launching RxConnect the single most important factor in providing for consumer safety and addressing the concerns of the FDA was choosing the participating Canadian pharmacies.⁹⁰

A. Pharmacies Listed on RxConnect are Inspected and Licensed

In November of 2003, the Minnesota Department of Human Services (DHS) developed a request for responses: a document that

<http://reform.house.gov/UploadedFiles/Hubbard%20Testimony%206-12-03.pdf> [hereinafter *Re-importation Hearing*]; Peter J. Pitts, Associate Commissioner for External Relations, FDA, *Prescription Drugs: Latest News, Latest Views*, Remarks at the National Conference of State Legislatures, Health Leaders Seminar (Dec. 10, 2003), available at <http://www.ncsl.org/programs/health/pitts.htm> [hereinafter Pitts].

86. Warren Wolfe, *Modest Start for State Drug Sales*, STAR TRIBUNE, (Minneapolis, St. Paul), July 21, 2004 at A1, available at 2004 WL 83076194 at *1.

87. *Re-importation Hearing*, supra note 85.

88. *Id.*

89. Pitts, supra note 85.

90. See Letter from Kevin Goodno, Commissioner, Minnesota Department of Human Services, to William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Mar. 9, 2004) (on file with author).

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requested responses to a series of questions from identified Canadian mail-order pharmacies. The minimum requirements were that the responder: was licensed to do business as a pharmacy in the Canadian province in which it was located; had been accredited or was eligible for accreditation by the Internet and Mail-order Pharmacy Accreditation Commission and/or be a member of the Canadian International Pharmacy Association; and that all health care professionals employed by or under contract with the responder, including pharmacists and physicians, have the appropriate professional license.⁹¹

The pharmacies were also asked to present detailed information concerning their business experience, staff, facilities, prescription medicine supply sources, prescription-filling process, and other policies and procedures.⁹² DHS received twenty-seven responses that were ranked based on the evaluation of their responses.⁹³ In addition, the following were considered:

1. One responder was excluded from further consideration because it was not a pharmacy but operated a website affiliated with a pharmacy.
2. Some responders were excluded because they did not operate at one location. Instead, a prescription ordered from their websites might be routed to one of several or even many pharmacies for actual filling.
3. Some responders were excluded because of their relatively remote locations. For example, one pharmacy is located approximately two hours away from Winnipeg. Minnesota Board of Pharmacy Surveyors felt that a minimum of three or four hours should be spent at each facility. Therefore, driving to and from the more remote locations was not an option.⁹⁴

Nine pharmacies were chosen for site visits.⁹⁵ The DHS Pharmacy Program Manager and two Board of Pharmacy surveyors,

91. *Request for Responses: Canadian Pharmacies*, Minnesota Department of Human Services, Health Care Administration (Dec. 2003) (on file with author).

92. *Id.*

93. Undated internal memorandum from Cody Wiberg, Pharmacy Program Manager, Minnesota Department of Human Services, to Kevin Goodno, Commissioner, Minnesota Department of Human Services (on file with author).

94. *Id.*

95. Report on the survey of Canadian pharmacies, from Cody Wiberg, Pharmacy Program Manager, Minnesota Department of Human Services, to Kevin Goodno, Commissioner, Minnesota Department of Human Services (June 21, 2004) (on file with author).

all Minnesota licensed pharmacists, visited eight of the nine pharmacies initially selected for further review.⁹⁶ The ninth pharmacy selected for additional review was unable to be reached for a site visit. The team considered the following when visiting the facilities:

1. Quality of the facilities. The physical condition of the facilities was considered, including the “[l]ighting, [the] presence of a thermometer in medication refrigerators, adequate space for the number of staff on duty, general upkeep of facilities” and additional factors.⁹⁷
2. Operational procedures. The workflow, presence of appropriate safety checks and adequate monitoring of non-professional staff by pharmacists were reviewed.⁹⁸
3. Source of prescription medicine. Prescription medicine packages were randomly checked for presence of labeling that indicated the products had been approved for use in Canada.⁹⁹
4. Answers to questions. Questions were posed to staff about: “shipping and returns policies, procedures for counseling patients on proper use of medications, the role of Canadian physicians in the process, adequacy of prescription [medicine] supply, source of prescription medicines dispensed and other issues.”¹⁰⁰
5. Evidence of Licensure. Evidence that the pharmacy and pharmacists were appropriately licensed by the province in which the pharmacy is located.¹⁰¹

Based on the recommendations of the inspection team, two pharmacies were initially selected to participate in the Minnesota program.¹⁰² Both of these pharmacies appeared to operate in an efficient, safe, and professional manner.¹⁰³ Two additional pharmacies were added to the program in June 2004 after a similar selection process was followed.

96. *Id.*

97. Undated internal memorandum from Cody Wiberg, Pharmacy Program Manager, Minnesota Department of Human Services, to Kevin Goodno, Commissioner, Minnesota Department of Human Services (on file with author).

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

To support the FDA position that the Canadian mail-order pharmacies themselves were unsafe, Hubbard cited Minnesota's report on its site inspections of Canadian pharmacies.¹⁰⁴ Hubbard noted that the report listed "dozens of safety problems" with the pharmacies inspected.¹⁰⁵ However, Hubbard's characterization that the report proved that ordering prescription medicines from Canada is unsafe was inaccurate.¹⁰⁶ In a letter to Hubbard, Minnesota DHS Commissioner Kevin Goodno responded to Hubbard's contentions by noting that Hubbard had made "at least eight clear misstatements of fact regarding [the Minnesota] site visit findings."¹⁰⁷ Each misstatement exaggerated either the breadth or the severity of the deficiencies found by [the inspectors] in [their] site inspections of the Canadian pharmacies."¹⁰⁸ Of the specific findings from these visits, most did not relate to the two pharmacies chosen for inclusion in the program.¹⁰⁹ Further, "[s]ome of the findings that were characterized as dangerous practices in [Hubbard's] letter [are] commonly [cited] during inspections of local, U.S. pharmacies."¹¹⁰ Most of the safety problems identified in the Minnesota report "would normally be handled with a finding and order to correct—not by shutting down the pharmacy."¹¹¹

Of the two initial pharmacies selected, there were items identified by the inspectors for improvement. For the first pharmacy selected, two issues were identified: (1) inadequate lighting and (2) the failure of one of the pharmacists to record the drug's Drug Identification Number (DIN).¹¹² Although the lighting was adequate in most work areas it did not meet Minnesota standards. However, "new lighting was being installed the day the surveyors were visiting."¹¹³ Also, the surveyors recommended to the

104. Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Tim Pawlenty, Governor, State of Minnesota (Feb. 23, 2004) (on file with author).

105. *Id.*

106. *See* Letter from Kevin Goodno, Commissioner, Minnesota Department of Human Services, to William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Mar. 9, 2004) (on file with author).

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

Canadian pharmacists that the DIN, Canada's equivalent to the National Drug Code (NDC) used in the United States, be written on the paper prescription when doing the final check.¹¹⁴ One pharmacist at the pharmacy chose not to follow this procedure because he felt it was unnecessary; however, Minnesota pharmacists are not required by Minnesota law to write a drug's NDC on a prescription when it is being checked.¹¹⁵ Accordingly, such a requirement would hold the Canadian pharmacists to a "higher standard than that for Minnesota pharmacists."¹¹⁶

The second pharmacy selected had three issues of concern identified. Like the first pharmacy, its lighting did not meet Minnesota standards but the pharmacy "upgraded its lighting prior to the launch of RxConnect."¹¹⁷ A follow-up inspection in July 2004 revealed that the lighting at this pharmacy now exceeds Minnesota's standard.¹¹⁸ The pharmacy "also had a practice of forwarding only the electronic health information transcribed into its computer system to the Canadian physician, and the surveyors recommended that both the original information and the transcribed electronic information be forwarded for review by the physician."¹¹⁹ This policy was also subsequently changed. Finally, at the request of the inspectors, the pharmacy changed its computer system to default to "allergies unknown" rather than "no allergies" when a customer did not provide allergy information.¹²⁰

All the issues of concern identified by the inspectors were addressed before RxConnect was launched. The Minnesota inspections did reveal that significant differences do exist among Canadian Internet pharmacies regarding the quality of their respective facilities and the safety standards followed in their operations. However, contrary to the representations of the FDA, the inspections showed that there are both high quality pharmacies and lower quality pharmacies operating in Canada. These findings

114. *Id.*

115. *Id.*

116. *Id.*

117. *Id.*

118. Report on the survey of Canadian pharmacies, from Cody Wiberg, Pharmacy Program Manager, Minnesota Department of Human Services, to Kevin Goodno, Commissioner, Minnesota Department of Human Services (June 21, 2004) (on file with author).

119. Letter from Kevin Goodno, Commissioner, Minnesota Department of Human Services, to William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Mar. 9, 2004) (on file with author).

120. *Id.*

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actually support Governor Pawlenty's contention that RxConnect is necessary to protect the safety of Minnesotans who choose to purchase prescription medicines from Canada.

In addition to FDA concerns, the Minnesota Pharmacists Association raised concerns that RxConnect would affect patient safety because it would result in the patient receiving uncoordinated medical care from more than one health care provider.¹²¹ This not only adds inefficiency to patient care, but could also result in harm to the patient if prescribed therapies are not compatible.

This fragmentation of therapy is a real concern not only in ordering prescription medicines from Canada, but in receiving health care services in the United States—it is not a problem unique to ordering prescription medicines from Canada. To minimize the potential negative consequences of therapy fragmentation, the participating pharmacies also practice the following procedures: (1) The initial order placed by an American patient must include a valid U.S. prescription and a health profile of the patient; (2) The forms submitted by the patient are reviewed once received to make certain they are complete; (3) The prescription and health profile are forwarded to a Canadian doctor for review; (4) If the doctor agrees with the prescription, the doctor writes a Canadian prescription; (5) The forms and the Canadian prescription are then reviewed by a Canadian pharmacist who only fills the prescription if everything is in order.¹²²

In addition to meeting the selection criteria and the required procedures outlined above, RxConnect pharmacies agreed to the following:

1. The pharmacy and all its healthcare professionals must maintain licensure in good standing in the province in which it is located.¹²³
2. The pharmacy must follow all applicable Canadian

121. Press Release, Minnesota Pharmacists Association, Minnesota Pharmacists Concerned about Governor Pawlenty's Drug Importation Website (Jan. 30, 2004) (on file with author).

122. Report on the survey of Canadian pharmacies, from Cody Wiberg, Pharmacy Program Manager, Minnesota Department of Human Services, to Kevin Goodno, Commissioner, Minnesota Department of Human Services (June 21, 2004) (on file with author).

123. Agreement between the Minnesota Department of Human Services and the pharmacies selected for inclusion in RxConnect, at 4 (on file with author).

laws.¹²⁴

3. All orders received must include a prescription from a United States physician if the laws of Minnesota require a prescription.¹²⁵

4. The pharmacy must ship no more than a ninety-day supply of medicine, or an amount not to exceed the prescribed amount for personal use to the patient.¹²⁶

5. To the extent possible, the pharmacy must ship the ordered prescription medicine in unopened manufacturer's containers.¹²⁷

6. The pharmacy must not fill any order if it is indicated that the prescription was being filled for the first time.¹²⁸

7. The pharmacy must provide periodic reports to DHS.¹²⁹

8. The pharmacy must allow unannounced site visits by Minnesota inspectors to assure compliance with the program requirements.¹³⁰

9. The pharmacy must only sell prescription medicines that are approved by the government of Canada for sale in Canada.¹³¹

In establishing RxConnect Governor Pawlenty was not willing to compromise patient safety for the sake of low cost prescription medicines. Accordingly, the selection process did not factor in potential price savings to consumers when selecting the Canadian pharmacies. Through RxConnect, Minnesota consumers who wish to purchase prescription medicines from Canada have the added safety of knowing that the listed pharmacies are licensed under the laws of Canada and have been inspected by Minnesota state officials who found that they employ licensed professionals, follow good operating procedures, and operate from quality facilities. In short, the RxConnect pharmacies are "real" pharmacies with "real" pharmacists filling the prescriptions with safe and effective prescription medicines.

124. *Id.* at 3.

125. *Id.* at 2.

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.* at 4.

130. *Id.* at 3.

131. *Id.* at 2.

B. Prescription Medicines Listed on RxConnect are Limited for Safety

In addition to the safety of the pharmacies listed on RxConnect, the safety of the prescription medicines themselves was carefully considered in establishing RxConnect. The United States General Accounting Office (GAO) investigated Internet pharmacies by attempting to place orders for thirteen different prescription medicines from sixty-eight different Internet pharmacies that were located in the United States, Canada, and other foreign countries.¹³²

The investigation found that all eighteen Canadian pharmacies required prescriptions from the patient's physician, which was not true for twenty-four of the twenty-nine United States pharmacies and all twenty-one of the non-Canadian, foreign pharmacies.¹³³ The report further concluded that of the prescription medicines ordered from Canada, sixteen of the eighteen samples were reported by the manufacturers to be unapproved for sale in the United States.¹³⁴ "However, the samples were all found to be comparable in chemical composition to the products . . . ordered."¹³⁵ In other words, the samples ordered from Canada were not sub-potent, contaminated, counterfeit, the wrong product, or degraded, but they were largely considered unapproved because of labeling and packaging.¹³⁶ For example, as mentioned earlier, a prescription medicine can be characterized as unapproved for sale in the United States even if the chemical composition has been approved for use in the United States, it was manufactured in an FDA approved facility, and it was packaged to FDA standards simply because it has a Canadian label on it that meets Canadian standards, but does not meet FDA standards.

To further protect safety, not all available prescription medicines were included in RxConnect. For example, of the thirteen different prescription medicines that the GAO attempted to purchase during its investigation, RxConnect excludes eight of

132. *Internet Pharmacies Some Pose Safety Risks for Consumers and are Unreliable in Their Business Practices: Testimony before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate* (June 17, 2004), available at <http://www.gao.gov/new.items/d04888t.pdf> (Testimony of Marcia Crosse, Director, Health Care—Public Health and Military Health Care Issues).

133. *Id.* at 9.

134. *Id.* at 16.

135. *Id.*

136. *Id.*

them for various safety reasons.¹³⁷ The medications listed on RxConnect are primarily those meant to treat chronic conditions.¹³⁸ Some prescription medicines listed are sometimes taken for acute conditions, but they are sometimes taken on a chronic basis as well, for example, some antibiotics are taken for extended periods of time for acne.¹³⁹ The selected pharmacies have agreed not to ship prescription medicines to United States customers if it is clear that the prescription medicines are meant to treat acute conditions.¹⁴⁰ The list of prescription medicines included was further limited because the state did not include those prescription medicines that were:

1. Controlled substances such as narcotics, benzodiazepines (Valium and related), barbiturates, anabolic steroids, amphetamines, etc. Reputable Canadian pharmacies such as those selected for affiliation with RxConnect will not ship controlled substances.¹⁴¹
2. Medications with special handling requirements such as those needing refrigeration.¹⁴²
3. Medications for which there is not an FDA-approved equivalent in the United States (such as those prescription medicines that are either available generically in Canada, but are not available generically in the United States, or, those prescription medicines available in Canada that are not available at all in the United States).¹⁴³
4. Medications that contain a level of active ingredient different in the United States version than in the Canadian version. For example, the Canadian version of Allegra 24 Hour contains less fexofenadine, an antihistamine, than the United States version and is not listed on RxConnect.¹⁴⁴

137. Compare *id.* at 3, with Medicine Search, Minnesota RxConnect, available at <http://rxconnect.dhs.state.mn.us/Medicines.aspx> (last visited Feb. 14, 2005) (comparing prescription medicines ordered in GAO investigation and those listed on MinnesotaRxConnect.com).

138. Internal Memorandum from Cody Wiberg, Pharmacy Program Manager Minnesota Department of Human Services, to Kevin Goodno, Commissioner, Minnesota Department of Human Services (on file with author).

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*

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Unlike some states that have pursued similar programs to RxConnect that have linked their websites directly to Canadian pharmacies,¹⁴⁵ RxConnect does not use direct links, so the state can control all the information provided on the website regarding the participating pharmacies, the prescription medicines offered, and pricing. This allows the state to control for content and also to control for compliance with the program requirements.

By restricting the prescription medicines included in RxConnect, controlling the information listed on RxConnect, and limiting RxConnect to prescription medicines that are approved for use in Canada or the United States, RxConnect adds an additional layer of protection for Minnesota consumers who want to purchase safe and effective prescription medicines from Canada.

C. Some Prescription Medicines Cost Less in Canada

The perception of many is that all prescription medicines purchased from Canada are less expensive than the comparable product offered in the United States. This is clearly not true. Likewise, some would have you believe that any savings a consumer would see in Canada is negligible or can easily be offset through use of generics or therapy modification. For example, sometimes consumers can reduce their prescription medicine costs by substituting brand name prescription medicines for generics, over-the-counter, or lower dosage medicines. This may work in some cases, but not in all cases.

As a rule of thumb, brand name prescription medicines are cheaper in Canada than the United States; generic prescription medicines are less expensive in the United States than Canada; and, United States generic prescription medicines, when available, are less expensive than either the brand name prescription medicines or the Canadian generics. This rule of thumb has exceptions. For example, the generic prescription medicine tamoxifen, which is used in the treatment of breast cancer, is less expensive when purchased from the Canadian pharmacies affiliated with RxConnect. A consumer can purchase sixty ten-

145. See, e.g., State of North Dakota website, at <http://www.governor.state.nd.us>; State of New Hampshire website, at <http://www.state.nh.us/governor/prescription-drug.html> (last visited Mar. 5, 2005). See generally Congressman Gil Gutknecht, *Prescription Drug State Information*, at <http://www.gil.house.gov/issues/pdrugs/stateinfo.htm> (last visited Mar. 5, 2005) (listing states that have or are proceeding to implement programs to import drugs).

milligram tablets of tamoxifen from the Canadian pharmacies for about \$33, including shipping, as compared to \$66 as listed on the website of a large U.S. pharmacy chain.¹⁴⁶ In contrast, if purchased as a prescription from a Canadian pharmacy, the brand name drug Claritin would be more expensive than purchasing the medication over-the-counter in the United States.¹⁴⁷ Accordingly, it is important for the consumer to compare both prescription medicine prices between the Canadian pharmacy and the American pharmacy and also among Canadian pharmacies and among American pharmacies because prices vary.

To help consumers, RxConnect not only provides information on Canadian pharmacies, but also includes information on state prescription medicine programs for low-income people, a state-sponsored information line that provides assistance in navigating the various free prescription medicine programs run by the pharmaceutical companies and the new Medicare drug discount cards, how to be a smart prescription medicine shopper, and various strategies on how to reduce prescription medicine costs.¹⁴⁸

Of the prescription medicines initially listed on RxConnect about eighty-five percent are less expensive in Canada than in the United States, with the remaining fifteen percent being more expensive in Canada.¹⁴⁹ The statistics on the prescription medicines being purchased through RxConnect indicate that consumers are aware of these price differences as the prescription medicines most commonly purchased are those with the greatest savings compared to the United States prices.¹⁵⁰ Most of the prescription medicines that are more expensive in Canada will be removed from RxConnect in future updates as they offer limited value to the consumer and are rarely ordered.

Through January of 2005, RxConnect had 174,599 website

146. Information provided by Cody Wiberg, Pharmacy Program Manager, Minnesota Department of Human Services (on file with author). Tamoxifen can be purchased for \$42.98, \$35.38 or \$23.87 from various Canadian pharmacies. *Id.* The same dosage is listed on the Walgreens website for \$65.99. Walgreens.com, Tamoxifen, 10 mg. tablets, at <http://www.walgreens.com/library/finddrug/druginfol.jhtml?id=15379> (last visited Jan. 26, 2005).

147. Wiberg, *supra* note 146.

148. Website of the Minnesota RxConnect Program, Minnesota Department of Human Services, at <http://www.minnesotarxconnect.com> (last visited Jan. 26, 2005).

149. *See id.*

150. *Id.*

visits and over 9000 orders have been filled.¹⁵¹ The assumption when the program was established was that the people most likely to take advantage of the program were those individuals who were already purchasing their prescription medicines from unknown mail-order or other discount pharmacies. Minnesota RxConnect was established to provide those individuals with information on Canadian pharmacies that had been inspected and had agreed to follow certain safe practices.

V. ADVANTAGE-MEDS

Phase II of the Minnesota plan provides access to low-cost, Canadian prescription medicines for Minnesota state employees. Advantage-Meds was launched in May 2004.¹⁵² Advantage-Meds built on the work done in setting up and choosing vendors for RxConnect. One of the RxConnect pharmacies was selected by the Minnesota Department of Employee Relations (DOER) to work with its health plan in establishing a state employee program.

DOER identified a list of forty-seven prescription medicines that would provide substantial savings to both the state and its employees if employees purchase them from the Canadian pharmacy.¹⁵³ The employee benefits if he or she orders a ninety-day supply of a selected prescription medicine because the state waives the employee's \$15 per prescription co-pay.¹⁵⁴ This could result in up to a \$180 per year per prescription savings for the employee.¹⁵⁵ The state projects that its savings will be about \$1.4 million per year.¹⁵⁶

The process for ordering is similar to the process for RxConnect, except that the state health plan makes payment directly to the Canadian pharmacy rather than having the employee make the payment and then seek reimbursement from the plan. At the end of 2004, more than 1800 state employees had signed up for the program and more than 3100 prescriptions have

151. *Id.*

152. Press Release, Tim Pawlenty, Governor of Minnesota, Governor Pawlenty Launches Phase Two of Rx Drug Importation: State Employee Website (May 13, 2003) (on file with author).

153. *Id.*

154. State of Minnesota, Department of Employee Relations, *Canadian Prescription Drug Plan for Minnesota State Employees and Dependents*, available at <http://www.advantage-meds.state.mn.us/Factsheet.pdf> (last visited Jan. 26, 2005).

155. *Id.*

156. *Id.*

been filled.¹⁵⁷

VI. PHASE III PILOT PROJECT

Although DHS has had exploratory discussions with the FDA regarding a pilot program in Minnesota that would allow the inclusion of Minnesota pharmacies in the ordering of prescription medicines from Canada, no definitive agreement has been reached.

VII. CONCLUSION

Governor Pawlenty has recognized the reality that many Minnesotans purchase prescription medicines from unknown mail-order pharmacies that hold themselves out as legitimate operators selling Canadian approved prescription medicines. This recognition led to the launch of RxConnect which is consistent with federal law and the duties of the state to provide for the safety of its citizens. Minnesota provided for the safety of its citizens by inspecting Canadian pharmacies to ensure their legitimacy and compliance with applicable laws and safe operating procedures and then shared that information with its citizens through RxConnect. More specifically, Minnesota took steps to ensure that prescription medicines ordered from the RxConnect pharmacies were approved for distribution in Canada. Further, Minnesota verified that the RxConnect pharmacies were licensed and that the professionals who worked for them were licensed and in good standing. In other words, through RxConnect, Governor Pawlenty put a program in place to provide Minnesota consumers who choose to purchase prescription medicines from Canada access to medicines that are, in the words of the FDA, “safe and effective.”

Minnesota has been a leader in addressing the challenges of keeping prescription medicines affordable for Minnesotans and controlling overall health care costs. Sometimes these challenges seem daunting, even impossible, but in the words of Franklin Delano Roosevelt, as quoted by Governor Pawlenty at a congressional hearing on importation, “It is common sense to take a method and try it; if it fails, admit it frankly and try another. But

157. State of Minnesota, Department of Employee Relations, *Advantage Meds Activity* (Jan. 2004), available at <http://www.advantage-meds.state.mn.us/Activity.pdf> (last visited Jan. 26, 2005).

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above all, try something.”¹⁵⁸ Minnesota was the first state in the nation to establish a program such as RxConnect. Minnesota was also the first state in the nation to implement a program for its employees to purchase lower cost medications from Canada. From the Pawlenty Administration’s perspective, Minnesota RxConnect and Advantage-Meds have proven to be effective in helping Minnesotans, and state government, save on the cost of high-quality, safe prescription medicines. Now it is time to try something else, such as Phase III of Governor Pawlenty’s plan, because a more widespread utilization of Canadian-supplied prescription medicines, through wholesale importation by Minnesota pharmacies, would benefit Minnesota consumers and the state’s health care costs.

158. Tim Pawlenty, Governor of Minnesota, Testimony to the Congressional Prescription Drug Access Coalition hearing in Boston, MA (Oct. 28, 2003) (transcript available at http://www.governor.state.mn.us/tpaw_View_DF_Article.asp?artid=654).