

I-**SAVE**

Safe and Affordable

Prescription Drugs

**Australia and New Zealand:
Recommended Expansion of the
Illinois Personal Importation Program**



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EXECUTIVE SUMMARY

The State of Illinois launched the I-SaveRx program in October of 2004 to provide the citizens of Illinois with access to safe and affordable prescription drug refills. This program has generated significant interest in personal importation not only in Illinois, but across the United States as well. Four additional states have joined the program (Wisconsin, Missouri, Kansas, and Vermont), and several others have taken initial steps to do so. Almost 61,000 interested citizens have requested an enrollment form through the toll-free phone line or downloaded a form from the I-SaveRx website; 14,600 have completed the enrollment process; and over 10,000 orders have been placed through the program, each with an average savings of 25 to 50 percent.

The demonstrated safety and success of the I-SaveRx program has prompted ever increasing numbers of Illinoisans and citizens of other participating states to import drugs from Canada and elsewhere around the world. On a national level, public opinion has revealed overwhelming and widespread support for federal legislation that would expand the importation of prescription drugs to wholesalers and pharmacies, with the goal of lowering pharmaceutical prices for all Americans. Unfortunately, the White House and the majority of the legislative leadership in Washington, D.C., have not pursued such legislation, and importation therefore remains available only to individuals for their own personal use.

Recently, however, concerns have been voiced regarding the long-term ability of Canada's pharmaceutical market to supply the U.S. market generally and the I-SaveRx program in particular. The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies have taken actions, such as restricting supply to Canadian wholesalers and pharmacies who have been identified as U.S. suppliers, that have impeded access to safe and affordable medications for millions of uninsured Americans. Furthermore, several members of the Canadian government have recently started to discuss administrative steps and proposed legislation to cut off the Canadian supply of prescription drugs to the United States. In response to these new pressures, and following the precedent set by the Illinois I-SaveRx program, several private companies have expanded the roster of countries that supply medications to their customers and now offer drugs from Europe in addition to Canada. Some—not including I-SaveRx—have even begun to source pharmaceuticals from South America, Asia, and the Middle East.

Responding to the concerns regarding the Canadian market, Illinois officials actively began to explore the ways in which the I-SaveRx program could be expanded, in addition to the United Kingdom and Ireland, in order to ensure the continued availability of approved program drugs. Based on the criteria previously established for I-SaveRx supplier nations—English speaking countries with

Australia & New Zealand:

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stable political systems and highly developed, well-implemented health-care systems comparable to that of the United States—Australia and New Zealand were selected as the most likely sources of an additional supply of prescription drugs for the program.

Following the same procedures implemented to study Canada, Ireland, and the United Kingdom in 2003 and 2004, a team of experts from three State of Illinois departments traveled to Australia and New Zealand to meet with government officials, wholesalers, and pharmacists to determine if the I-SaveRx program could be safely expanded to those countries. Pharmaceutical manufacturing, warehousing, storage, and dispensing practices were examined and compared with those in the United States. The regulation and management of pharmacies and pharmacists were also reviewed closely, and on-site inspections of several pharmacies were completed in both countries.

The research team concluded that pharmaceuticals purchased from approved facilities in Australia and New Zealand are safe, effective, and more affordable than pharmaceuticals purchased in the United States. Safety standards in these countries met or exceeded those required by the State of Illinois. The Australian authorities and pharmacy regulators did not have any concerns with Australian pharmacies filling prescriptions under the I-SaveRx program. However, due to a lack of a definitive determination concerning the ability of a New Zealand doctor to legally re-write prescriptions for U.S. patients after viewing a complete file, we recommend that only medications available over-the-counter (OTC) in New Zealand be made available through the I-SaveRx program.

I-SaveRx participants are projected (net of shipping) to achieve an average savings of 51 percent in Australia compared to the U.S. prices, up from 31 percent in Canada for those program drugs available in both countries (see Table 1, Appendix III).

It is therefore the recommendation of this report that Illinois proceed with the expansion of the I-SaveRx program to include approved pharmacies in Australia for all prescription medications approved in the program as well as New Zealand pharmacies for over-the-counter medications.

THE ILLINOIS PERSONAL IMPORTATION PROGRAM: CURRENT SUCCESSES, POTENTIAL LIMITATIONS, AND RECOMMENDATIONS FOR THE FUTURE

The I-SaveRx Program and the High Cost of Pharmaceuticals

The State of Illinois launched the I-SaveRx website in October 2004, offering the residents of Illinois and Wisconsin (and, more recently, Missouri, Kansas, and Vermont) consistent, significant savings on over 200 brand-name prescription medications through pre-screened pharmacies in Canada and the United Kingdom. Since that time, the website has generated over 87,000 hits from unique visitors, received over 61,000 requests for enrollment forms; 14,600 have completed the enrollment process, and more than 10,000 orders have been filled.¹ The I-SaveRx program broke new ground for state-sponsored personal importation plans, and other states with progressive health-care values were quick to take notice. The program has proved safe and effective, and has become a key element in the national debate regarding the personal importation of prescription drugs.

Americans continue to support personal importation in overwhelming numbers, and a majority would like the government to take a greater role in making prescription drugs more affordable through price regulation. While most adults (78 percent) believe that prescription drugs have positively impacted the health of Americans, according to a February 2005 poll by the Kaiser Family Foundation:

- 65 percent believe the government should do more to regulate drug prices
- 81 percent believe that current drug costs are not justifiable
- 73 percent favor personal importation from Canada
- 70 percent believe that pharmaceutical companies value profits more than people²

A new poll, conducted in April 2005, reports that 77 percent of the American public supports personal importation from Canada and permitting the government to negotiate lower prices for Medicare beneficiaries with pharmaceutical manufacturers (an action currently precluded by the Medicare Modernization Act of 2003)³. Also, 70 percent of those surveyed stated that they did not believe the pharmaceutical industry's argument that personal importation from Canada would reduce investment in

¹ As of July 12, 2005.

² Kaiser Family Foundation, "Views on Prescription Drugs and the Pharmaceutical Industry," Kaiser Health Poll Report, January/February 2005 Featured Topic, http://www.kff.org/healthpollreport/feb_2005/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=51608.

³ Kaiser Family Foundation, "The Public on Prescription Drugs for Seniors," Kaiser Health Poll Report, April 2005.

research and development, and 57 percent did not believe that governmental negotiation of pharmaceutical prices would reduce investment in research and development.⁴

In his recent book *A Call to Action*, Dr. Hank McKinnell (CEO, Pfizer Inc.) criticizes anyone who makes a connection between drug prices and research and development. He writes, “It’s a fallacy to suggest that our industry, or any industry, prices a product to recapture the R & D budget spent in development.” He says that drugs are basically priced the same way as a car or an appliance. “It is the anticipated income stream, rather than repayment of sunk costs, that is primary determinant of price.” He goes on to state that drugs from Canadian pharmacies are safe.⁵

Despite evidence that the public solidly supports less expensive medications, and despite the fact that lawmakers in 27 states had introduced legislation requesting access to these medications from abroad by the end of 2004,⁶ a recently released report from the AARP reveals that the wholesale prices of the brand-name drugs most commonly used by seniors rose by 7.1 percent in 2004.⁷ This increase is 2.5 times the rate of general inflation for the same period, and represents the largest increase when compared to general inflation over the last five years that AARP has studied the issue.⁸ By contrast, generic prices rose only 0.5 percent in 2004.⁹ The trade group Pharmaceutical Research and Manufacturers of America (PhRMA) contends that these figures are misleading, as wholesale prices do not reflect discounts negotiated by large purchasers.¹⁰ However, this argument is flawed in several ways.

First, the Medicare prescription drug benefit does not take effect until January of 2006. According to data from the Kaiser Family Foundation, Illinoisans over age 65 filled a per capita average of 27.7 prescriptions during 2003,¹¹ at an average cost per prescription of \$48.11.¹² The National Center for Policy Analysis reports that in 1998, 31 percent of

⁴ *Ibid.*

⁵ *A Call to Action* by Dr. Hank McKinnell, pages 46, 47 and 69, published by McGraw-Hill.

⁶ National Conference of State Legislators, “2004 Prescription Drug State Legislation,” June 6, 2005.

⁷ AARP, “Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans—2004 Year-End Update,” April 2005.

⁸ *Ibid.*

⁹ AARP, “Trends in Manufacturer List Prices of Generic Prescription Drugs Used by Older Americans—2004 Year-End Update,” April 2005.

¹⁰ Victoria Colliver, “Harder to Swallow: Prices for Seniors’ Brand-Name Drugs Rising Fast, Study Finds,” *San Francisco Chronicle*, April 13, 2005.

¹¹ Kaiser Family Foundation, “Illinois: Retail Prescriptions Filled Per Capita by Age, 2003,” State Health Facts, 2004.

¹² Kaiser Family Foundation, “Illinois: Average Price of Retail Prescriptions Filled, 2003,” State Health Facts, 2004.

Medicare beneficiaries had no prescription drug coverage, and 59 percent had only some private prescription drug coverage.¹³ If we apply these figures to the 2003 Illinois Medicare population of 1,661,454 individuals, this means that 515,050 had no access to these lower, negotiated prices, and 980,257 had only partial access to these lower, negotiated prices. The National Center for Policy Analysis further reports that without the Medicare prescription drug benefit, almost 44 percent of seniors' total drug costs are paid for out-of-pocket.¹⁴

Nationally, 26.3 percent of almost 18,000 seniors surveyed about their prescription drug utilization reported that the high cost of prescription medication had forced them to skip doses, take smaller-than-recommended doses, or not purchase medications at all.¹⁵ Of all survey respondents, 5 percent bought prescription medication from Canada or Mexico, and 10.5 percent of those with no prescription drug coverage bought prescriptions from Canada or Mexico.

Second, we must be very clear about an issue that has not been widely reported in the media: the fact that the Medicare prescription drug benefit represents a cost shift, not necessarily a cost reduction. When the benefit takes effect in January 2006, both seniors and working Americans (who partially fund the Medicare program through payroll taxes and federal general revenues) will pay for this 7.1 percent increase in the cost of prescription drugs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 prevents the Centers for Medicare & Medicaid Services (CMS) from using its size to negotiate lower pharmaceutical prices with manufacturers. As a result, seniors will pay \$57.4 billion out of pocket for their medications in 2006, and most of the remaining costs will shift to taxpayers, who will contribute heavily to the remaining \$44.5 billion to be paid through Medicare.¹⁶ Further, the Medicare prescription drug benefit is NOT comprehensive coverage. While this is a step in the right direction, there are gaps between the claim of comprehensive coverage and the actual benefit. For example, there is no coverage for drug spend between \$2,250 and \$5,100. As a result of this partial funding, states have taken one of two positions - either cut the states funding completely and rely on the federal benefit, or take steps to fill the gaps in coverage such as Illinois's "No Senior Left Behind" legislation.¹⁷

¹³ Andrew Rettenmaier and Zijun Wang, "Medicare Prescription Drug Benefit: What Difference Would It Make?", National Center for Policy Analysis, November 17, 2003.

¹⁴ *Ibid.*

¹⁵ Dana Gelb Safran, et al., "Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey," *Health Affairs*, April 19, 2005.

¹⁶ Dr. Gerard Anderson, et al., "Doughnut Holes and Price Controls," *Health Affairs*, July 21, 2004.

¹⁷ Illinois Public Act 094-0086. <http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=094-0086>

Finally, and perhaps most importantly, we must consider the large number of Americans under age 65 who also depend on many of these same pharmaceuticals listed in the AARP study. In 2004, the cost of prescription drugs rose by 10 percent.¹⁸ In 2003, 45 million Americans lacked health insurance, and 37 percent of uninsured individuals did not fill a prescription because of cost.¹⁹ At the state level, 16.1 percent of Illinoisans under age 65—1.78 million individuals—lacked health insurance coverage in 2002-2003.²⁰ Additionally, a recent study by The Center for Studying Health System Change reported that U.S. residents with chronic medical conditions are facing ever greater difficulties in obtaining and paying for needed medications: in 2003, 18.3 percent of U.S. adults with chronic conditions had trouble obtaining needed prescriptions because of cost compared to 16.5 percent in 2001.²¹ This report chronicles how even insured adults have trouble paying for needed prescriptions: in 2001, 12.7 percent of privately insured adults could not afford to pay for at least one prescription, a number which rose to 15.2 percent in 2003.²² Nearly 60 percent of low-income, uninsured, working-age adults could not afford all of their prescriptions in 2003.²³

LONG-TERM CAPACITY

Based on the continued attempts to restrict Canadian drug supply by the manufacturers and the recent actions announced by the Canadian Health Minister, several questions have arisen regarding continued availability of drug supply from Canada. It is logical that national interest in personal importation—the importation of small amounts of prescribed medicines for personal use—is increasing. In 2004, total sales of pharmaceuticals in the United States reached \$250 billion, and 3.5 billion prescriptions are issued annually (an increase of 67 percent in the last 10 years).²⁴ Lawmakers are racing to keep up with the amplified costs associated with this increase in pharmaceutical consumption. As a result, not only have Kansas, Missouri, Wisconsin, and Vermont joined Illinois's I-SaveRx program, but growing numbers of city, county, and state governments are looking into—and facilitating—personal importation efforts for their own citizens. The cities of Boston, Burlington (Vermont), Montgomery

¹⁸ Kaiser Family Foundation, "Prescription Drug Costs Increased by 10% in 2004, Express Scripts Report Finds," Kaiser Daily Health Policy Report, June 9, 2005.

¹⁹ Kaiser Family Foundation, "The Uninsured: A Primer," November 2004.

²⁰ *Ibid.*

²¹ Center for Studying Health System Change, "An Update on Americans' Access to Prescription Drugs," Issue Brief No. 95, May 2005.

²² *Ibid.*

²³ *Ibid.*

²⁴ Kaiser Daily Health Policy Report, "Associated Press Examines Effects of Increased Prescription Drug Use in the United States," April 18, 2005.

(Alabama), San Francisco, and Springfield (Massachusetts) already aid residents with personal importation of prescription drugs, as do the states of Minnesota (where the Department of Human Services recently released a report recommending the expansion of their prescription drug network beyond Canada to Europe²⁵), New Hampshire, Rhode Island, and Washington. The newest additions include Montgomery County, Maryland, which solicited proposals from Canadian pharmacies regarding the supply of pharmaceuticals for county employees;²⁶ and Nevada,^{27,28} Texas,²⁹ and Montana,³⁰ where lawmakers are proposing that state officials inspect Canadian pharmacies and link them to state personal importation websites.

Members of the U.S. Congress also continue to push for national importation legislation, a move that would allow for both personal importation and parallel importation (the wholesale purchase and sale of pharmaceuticals between countries with different pricing structures). On February 9, 2005, Senators Byron Dorgan and Olympia Snowe (supported by Senators Ted Kennedy and John McCain) reintroduced bipartisan legislation in the Senate (S. 334) that would permit pharmaceutical importation from a select group of foreign countries. Complementary legislation (H.R. 700) was introduced in the House at that time by Representatives JoAnn Emerson and Sherrod Brown.³¹ Furthermore, David Kessler, the former head of the Food and Drug Administration (FDA), supports the Dorgan-Snowe bill and believes that Congress should pass legislation that would replace the present, unregulated reimportation system with a safer system of regulated personal importation.³²

If personal importation increases drastically, it is possible that the I-SaveRx supply chain could be disrupted. This would be especially true for Canadian pharmaceutical suppliers, as most other government-coordinated personal importation programs rely on Canada alone for imported pharmaceuticals. It would therefore be prudent for personal importation program administrators to identify additional market sources to preclude

²⁵ Minnesota Department of Human Services, "Importation of Prescription Drugs from Europe: A Report to Commissioner Kevin Goodno," March 16, 2005.

²⁶ Anna Bailey, "Canadian Prescriptions on the Fast Track," *Washington Examiner*, May 10, 2005.

²⁷ Ed Vogel, "Democrats Preparing Drug Importation Bill," *Las Vegas Review Journal*, February 15, 2005.

²⁸ Kirsten Searer, "Panel Oks Buying of Canadian Drugs on Internet," *Las Vegas Sun*, March 17, 2005.

²⁹ Jeffrey Gilbert, "Bill Would Allow Imports of Cheaper Prescriptions," *Houston Chronicle*, February 17, 2005.

³⁰ Associated Press, "Montana House Endorses Canadian Drug Reimportation," *Billings Gazette*, March 10, 2005.

³¹ U.S. Library of Congress, "H.R. 700: Pharmaceutical Market Access and Drug Safety Act of 2005," <http://www.thomas.loc.gov>.

³² Christopher Rowland, "Ex-FDA Chief Urges Passage of Import Bill," *Boston Globe*, April 20, 2005.

potential supply interruptions. I-SaveRx program administrators anticipated this development when they decided to include UK and Irish-sourced pharmaceuticals in their program.

An additional supply concern was identified when it became known that a number of pharmaceutical manufacturers either had reduced supplies or announced plans to reduce supplies to Canadian wholesalers and pharmacies in an attempt to prevent them from selling their legally purchased products to U.S. residents.³³ Several Canadian wholesalers also have received communications from manufacturers threatening to cut off supplies completely if drugs are redirected to the U.S. market.³⁴ The legality of these actions and the shortages they may create are currently being debated in court.³⁵

Finally, Canadian Health Minister Ujjal Dosanjh has come out strongly against the practice of personal importation in recent months, after a long period of relative neutrality on the part of the Canadian government.³⁶ A March 17, 2005, meeting between Michael Leavitt, U.S. Secretary of Health and Human Services, and Dosanjh confirmed the official Canadian anti-personal importation position.³⁷ Interestingly, Canadian officials in Manitoba—which is home to roughly 60 percent of the cross-border pharmaceutical trade—fully support the personal importation movement. Jim Rondeau, Manitoba's Minister of Industry and Economic Development, claims that there has never been a shortage of pharmaceuticals in Canada because of U.S. demand, and Gary Doer, Premier of Manitoba, notes that the provinces in Canada have the constitutional right to regulate their own pharmacies.³⁸

PROPOSED EXPANSION

When we analyze the factors that may affect the I-SaveRx supply chain from a wider perspective, it becomes clear that we must consider new, potential pharmaceutical sources from beyond the borders of Canada, Ireland, and the United Kingdom. But there are practical considerations to expanding the network. Any new countries added to the I-SaveRx pharmaceutical supply chain would need to conduct business in English, so

³³ Bloomberg.com, "Merck Cuts Off Canadian Pharmacies Selling to U.S.," January 19, 2005.

³⁴ Kaiser Network, "United Senior Action of Indiana Files Class Action Antitrust Lawsuit Against Nine Prescription Drug Companies," Kaiser Daily Health Policy Report, June 14, 2004, <http://www.kaisernetwork.org>.

³⁵ Kaiser Network, "Minnesota Attorney General Appeals Required Confidentiality of GlaxoSmithKline Internal Records on Alleged Collusion," Kaiser Daily Health Policy Report, December 14, 2004, <http://www.kaisernetwork.org>.

³⁶ Patricia Barry, "Canada Dry?," AARP Bulletin Online, February 2005.

³⁷ Marguerite Higgins, "HHS Chief Tackles Drug-Imports Issue," The Washington Times, March 18, 2005.

³⁸ Patricia Barry, "Canada Dry?," AARP Bulletin Online, February 2005.

that patient communication and product labeling are not concerns. Additionally, these countries must have stable political systems and amicable ties to the United States to allow for a solid, long-term business relationship. Their health-care systems must be highly developed, well implemented, and comparable to that of the United States on all levels. Finally, their pharmacy practice regulations must be well developed (comparable to those of the United States) and easily documented. Two countries that meet these conditions are Australia and New Zealand.

FINDINGS OF THE AUSTRALIA-NEW ZEALAND TEAM

Program administrators with the Office of the Special Advocate for Prescription Drugs (OSAPD) and representatives from the Illinois Departments of Public Health and Financial and Professional Regulation made an exploratory trip to Australia and New Zealand in February 2005. They studied pharmaceutical manufacturing, warehousing, storage, and dispensing practices; reviewed the regulation and management of pharmacies and pharmacists; and spoke with national health officials. All facilities inspected by Illinois officials met or exceeded Illinois standards, and regulatory procedures were determined to be comparable to those of the United States.

AUSTRALIA

Illinois officials met with representatives of the Australian Pharmaceutical Benefits Scheme (PBS), including the first assistant secretary of the department. This government office is responsible for negotiating prices after drugs have been approved for sale by the Australian Therapeutic Goods Administration. PBS representatives did not object to Illinois's proposed plan to include Australian pharmacies in the expanded personal importation I-SaveRx network, and indicated that any valid prescription written by an Australian physician would meet pharmaceutical export requirements. PBS officials also explained that enabling Australian citizens to obtain needed pharmaceuticals at a low price is not their only objective; they also are interested in ensuring that pharmaceutical manufacturers receive a fair profit for their products. For this reason, they cautioned, not all prices are lower in Australia than they are in the United States. (See Appendix 2 below.) However, the prices of many drugs are more competitively priced in Australia than in the United States.

The Illinois officials also inspected a total of seven Australian pharmacies. All pharmacy facilities and operations met or exceeded Illinois regulatory standards. (Please see Appendix 1 below for a more thorough description of Australian regulatory processes.)

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In addition to pharmacy inspections and government meetings, Illinois officials met with the Pharmacy Guild of Western Australia, a trade group, and the Pharmacy Council of Western Australia, a regulatory and licensing authority. These groups indicated that Australian pharmacies could fill and export prescription drugs for use by U.S. citizens as long as a valid prescription signed by an Australian physician was presented.

NEW ZEALAND

Illinois officials visited two pharmacies in New Zealand, including the largest Internet pharmacy in the country (which also maintains a large retail store). Of these two pharmacies, one was inspected and subsequently deemed to meet Illinois standards. Additionally, Illinois representatives met with a New Zealand manufacturer and warehouse.

The legal concerns about offering drugs requiring a prescription in New Zealand through the I-SaveRx program stem from a lack of clarity about whether a New Zealand doctor rewriting a prescription without physically seeing a patient is complying with the New Zealand Medicines Act. According to the officials with Medsafe, Public Health Directorate of the New Zealand Ministry of Health, the Act which was written prior to the development of Internet and the international personal importation market, requires a patient to be "under the care of" that doctor to receive a prescription. Because network doctors participating in the I-SaveRx program receive the complete file of an I-SaveRx participant before rewriting their prescription, the legality of rewriting a prescription in New Zealand depends on the interpretation of the phrase "under the care of." To date, no legal ruling has been made to define that phrase, thus leaving New Zealand doctors and pharmacists without clear guidance on what the legal guidelines are for participation in programs like I-SaveRx. Thus, until a case has been heard in court or an interested party in New Zealand requests a legal opinion from the government, this issue will impede the ability of the I-SaveRx program to reliably provide drugs requiring a prescription in New Zealand to program participants. However, drugs that are available over-the-counter (OTC) in New Zealand do not cause the same legal concerns, and could thus be safely supplied from inspected and approved New Zealand pharmacies. Furthermore, because more than 30 drugs currently offered through I-SaveRx are available OTC in New Zealand at a substantially lower cost, the I-SaveRx program could be enhanced by making these OTC drugs available from New Zealand.

GENERALIZED FINDINGS

Specifics regarding pharmacy practice, pharmacy regulations, and pharmaceutical pricing in Australia and New Zealand can be found in Appendices 1 and 2 below, but several key points should be addressed here. First, the FDA's pharmaceutical regulatory counterparts in Australia (the Therapeutic Goods Administration, or TGA) and New Zealand (Medsafe) maintain comparable levels of vigilance in their approval and monitoring of pharmaceutical products. Furthermore, agreements exist between these countries that facilitate the exchange of information and encourage additional layers of system safety. For example, all pharmaceutical manufacturing facilities located in Australia and the United States are open to inspection by officials from both countries to ensure adherence to established good manufacturing practices,³⁹ and bimonthly video-conferences are held between the FDA, the TGA, and Medsafe⁴⁰ to address issues of pharmacovigilance.⁴¹

Second, unlike in the United States, pharmacists in Australia receive separate, additional payments to consult with patients on chronic disease states. They not only measure blood pressure and provide cholesterol screenings, services typically associated with a physician's office in the United States, but they also are paid to actively conduct medication reviews in patients' homes and nursing facilities as needed.⁴² A similar proactive policy in the United States would almost certainly decrease the number of adverse pharmaceutical reactions or prescribing errors.

Third, regulatory bodies in Australia and New Zealand regularly utilize pharmaceutical research findings and safety reviews from the FDA and the EMEA (the European Agency for the Evaluation of Medical Products, the pharmaceutical regulatory authority for the European Union). This ensures that reliable, global research experience is brought to bear on pharmaceutical safety issues.

Finally, the savings to be achieved through the purchase of pharmaceuticals from Australia and New Zealand are substantial. On average, I-SaveRx participants who purchase from those countries are projected to attain savings of greater than 40 percent over U.S. pharmaceutical prices. For a review of the savings methodology utilized in this report, please see Appendix 3.

³⁹ Australian Therapeutic Goods Administration, "Regarding the Exchange of Information on Current Good Manufacturing Practice Inspections of Human Pharmaceutical Facilities," <http://www.tga.gov.au/docs/pdf/fdamou.pdf>.

⁴⁰ FDA, "Office of Drug Safety Annual Report FY 2002," April 9, 2004, <http://www.fda.gov/cder/Offices/ODS/AnnRep2002/default.htm>

⁴¹ Pharmacovigilance is defined as the continued surveillance of quality, safety and side effects after short and long-term use of medicines.

⁴² Pam Mason, "Pharmacy in Australia," *The Pharmaceutical Journal*, Vol. 271, No. 7280, December 2003.

CONCLUSIONS

Since October 2004, the Illinois I-SaveRx program has safely and effectively filled thousands of prescriptions at drastically reduced prices for the citizens of five states. Yet concerns regarding the continued and uninterrupted supply of Canadian pharmaceuticals have prompted state officials to approach the I-SaveRx supply chain from a more global perspective. For this reason, I-SaveRx program officials undertook a fact-finding mission in February 2005 to research the possibility and feasibility of sourcing approved program medications from Australia and New Zealand.

The research team found that pharmaceuticals purchased from approved facilities in Australia and New Zealand are safe, effective, and affordable. National drug approval processes in Australia and New Zealand are comparable to the drug approval process in the United States. Safety standards in New Zealand and Australia met or exceeded those required by the State of Illinois for pharmaceutical warehousing, storage, and prescribing, as well as for pharmacy and pharmacist regulation and prescription dispensing. Export regulations in both countries allow for the export of most pharmaceuticals, and pharmacies in both countries already run successful Internet operations.

AUSTRALIA

A review of all I-SaveRx program medications revealed that 40 of the 205 medications are not currently available from Australia. Of these 40 medications, only nine were in the top 100 program drugs, accounting for 8.75 percent of utilization. It is important to note here that Australia offers other brand name, therapeutically equivalent substitutes for all unavailable program medications. Australia therefore would be an excellent addition to the I-SaveRx network. If Australia were added to the network, and if Canadian supply were compromised, I-SaveRx customers would enjoy continued access to most medications currently offered by the Illinois program.

I-SaveRx participants are projected (net of shipping) to achieve an average savings of 51 percent in Australia compared to the U.S. prices, up from 31 percent in Canada for those program drugs available in both countries (see Table 1, Appendix III).

NEW ZEALAND

As previously mentioned, New Zealand's laws and regulations are not entirely clear regarding the export of prescription-only medications. However, a significant number of medicines and medical products that require a prescription in the United States are available over the counter

in New Zealand. These products, which are priced significantly lower than in the United States, include Zyrtec, Allegra, Flonase, Beconase, Claritin, Clarinex, Zantac, and Rhinocort.

Additionally, Australia and New Zealand are working toward the installation of a single agency governing all pharmaceutical matters in both countries. This agency is projected to be functional by the summer of 2006. For this reason, and because of the savings to be achieved through the current purchase of over-the-counter medications, New Zealand should also be considered for addition to the I-SaveRx program.

APPENDIX 1: PRODUCT APPROVAL AND INDUSTRY REGULATION IN AUSTRALIA AND NEW ZEALAND

AUSTRALIA

Product Approval and Regulation

Australia's Therapeutic Goods Administration (TGA), a subgroup of the Australian Department of Health and Aging, is responsible for evaluating and approving new medicines, granting licenses to pharmaceutical manufacturers, and monitoring the effects of the drugs after licenses have been granted.⁴³ Some drugs—usually those containing new active substances—undergo a more rigorous licensing process. Other drugs—those receiving approval from a pre-determined list of acceptable countries (which include Canada, the United States, the United Kingdom, Sweden, and the Netherlands)—may be granted approval more quickly.⁴⁴ Approved drugs usually traverse the approval process in six months to one year.

Once an application for a new medicine has been received, it is evaluated by the Australian Drug Evaluation Committee (ADEC). ADEC contains within it the smaller subgroups of the Pharmaceutical Subcommittee and the Adverse Drug Reactions Advisory Committee. ADEC's members—medical practitioners, pharmacologists, pharmaceutical chemists, and toxicologists—make recommendations regarding the new medicine applications to the Minister of Health and Aging, but the final decision regarding a new product's approval or denial rests with Secretary of the TGA. After ADEC has reviewed and provided feedback on the application, they share their findings with the National Drugs and Poisons Schedule Committee (NDPSC), which then determines the drug's classification.⁴⁵

If a product is approved, its sponsor—defined as the entity applying for approval (this might be a pharmaceutical importer or a pharmaceutical manufacturer)—can start marketing efforts. If approval is denied, the sponsor may request a review with the Standing Arbitration Committee for Therapeutic Goods or the Pharmaceutical Subcommittee of ADEC. These reviews constitute an informal appeal and are not regulated by the National Health Act (hereinafter, the Act). A formal appeal under the Act also may be made to the Minister of Health and Aging. If the appeal is denied, and if the sponsor believes the Minister has made an incorrect decision, the sponsor may apply for a review with the Administrative Appeals Tribunal.⁴⁶

⁴³ Australian Department of Health and Aging, Therapeutic Goods Administration, "About TGA," <http://www.tga.gov.au>.

⁴⁴ Australian Therapeutic Goods Association, "Australian Regulatory Guidelines for Prescription Medicines," <http://www.tga.gov.au/pmeds/argpm.htm>, June 2004.

⁴⁵ *Ibid.*

⁴⁶ *Ibid.*

Australia maintains strict pharmacovigilance over approved products. Sponsors are required to notify the TGA of any adverse reactions or safety alerts relating to its products (of which it is aware), and also must notify the TGA if another country (with a comparable regulatory system) has recalled its product.⁴⁷

Australian regulatory authorities also require that manufacturers of products adhere to standards of Good Manufacturing Practice (GMP). All Australian manufacturers must follow these standards, and the manufacturing practices of overseas manufacturers are considered when the TGA makes its approval determinations. The TGA has the authority to deny a product's registration if that product's manufacturer cannot show that it has followed the GMP.⁴⁸

Australia's GMP is based on the international practice standard, Guide to Good Manufacturing Practices for Medicinal Products, which is published by the Pharmaceutical Inspection Cooperation Scheme. The Australian GMP, with over 100 pages of standards, focuses on issues of production and quality control. It ensures that all manufacturing processes associated with the production of a pharmaceutical are clearly defined; that significant steps of the process are authenticated; that all personnel have the appropriate and necessary qualifications and training; that manufacturing premises are adequate; that all equipment is appropriate; that proper materials, containers, and labels are used; that all procedures and instructions are followed; that products are stored and transported in an acceptable and legal manner; that instructions and procedures are communicated in a consistent and clear fashion; that operators are properly trained; that correct records (including distribution records) are maintained; that distribution methods do not harm the quality of the products; that a recall system is in place, should the need arise; and that product complaints are seriously addressed.⁴⁹

Regulation of Pharmacies and Pharmacists

Australia restricts pharmacy ownership to registered pharmacists only, and pharmacists can own at most three pharmacies in most Australian states. This system precludes the operation of large chain pharmacies, as are common in the United States. Some construe this regulation as anti-competitive, and several interest groups have recently brought pressure to increase the total number of pharmacies that one individual may own.

⁴⁷ *Ibid.*

⁴⁸ *Ibid.*

⁴⁹ Australian Therapeutic Goods Administration, "Australian Code of Good Manufacturing Practice for Medicinal Products," <http://tga.gov.au/docs/pdf/gmpcodau.pdf>, August 2002.

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Australian pharmacists are required to complete four years of university-level education followed by one year of practical training before they are granted a license to practice pharmacy. When a pharmacy student passes pre-registration training, he or she is qualified to practice pharmacy only in the state where the training has been completed. Further examinations are required for pharmacists who wish to practice in additional states. A reciprocal training agreement exists between Australia, New Zealand, the United Kingdom, and Ireland.

Australian pharmacists must adhere to the Code of Professional Conduct of the Pharmaceutical Society of Australia. Pharmacists must have the health and wellbeing of the individuals in their community as their primary concern; follow the legislation regarding the practice of pharmacy; treat patient information confidentially; maintain a current, working knowledge of pharmacy practice; not practice under conditions that negatively affect their professional judgment and integrity; work cooperatively with other health practitioners; offer complete and truthful information to patients; respect their patients; and guarantee patients' continuity of care even when faced with pharmacy closures or a personal disagreement regarding moral beliefs.⁵⁰

Export Regulation

Australia permits the export of pharmaceutical products into the global personal importation market as long as the exported products have not been subsidized through the Pharmaceutical Benefits Scheme (PBS). It is illegal to ship or export medication that has been reimbursed by the PBS, as this would cause a financial loss to the government and taxpayers. Violators of this law can be sentenced to a jail term of two years and/or be fined. All pharmaceutical goods intended for commercial supply must be listed with the Therapeutic Goods Administration (TGA). Pharmaceutical exporters also must declare all products that are exported, include comprehensive identification and contact information of the prescribers and suppliers, and provide information regarding the entity receiving the shipment of medication.

NEW ZEALAND

Product Approval and Regulation

The New Zealand Medicines Act of 1981 establishes the procedures whereby a new medicine may be manufactured, sold, and supplied. As a first step, pharmaceutical manufacturers must apply for a marketing approval from Medsafe, a department within the Ministry of Health comparable to the FDA in the United States. New, higher-risk medicines (defined as new medicines with a new active substance) are evaluated by

⁵⁰ Pharmaceutical Society of Australia, "Code of Professional Conduct," <http://www.psa.org.au/ecms.cfm?id=45>, March 1998.

the Medicines Assessment Advisory Committee (MAAC), whose members are appointed by the Minister of Health. The Committee is assigned to: “assess and advise on the efficacy, safety and quality of new medicines; recommend the classification of new medicines; consider and advise the Minister on the suitability of medicines for distribution in New Zealand; [and] consider and advise the Minister on any matters regarding new medicines or the distribution of medicines.”⁵¹ New, intermediate-risk medicines (new medicines that do not contain new active substances) and new, low-risk medicines (new medicines not defined as high or intermediate risk, and which are permitted to be supplied without a prescription) are evaluated by Medsafe.

The second step is the application evaluation. During this stage, Medsafe may consider reports regarding products in question from the Australian TGA and the EMEA (of the EU) when making their decisions. MAAC meets four times each year to consider new, high-risk medicines. Applications are reviewed, recommendations made to the Minister of Health, and applicants notified within two weeks of the meeting. If the applicant company is notified that their application has been recommended for denial, it may submit new data in support of its application before a final decision is taken. Appeals pass through the Medicines Appeal Committee. The evaluation period for new, high-risk medicines typically lasts one year or more. Priority assessment—which shortens the evaluation period to four to six months—may be granted for new, high-risk medicines if there is an indication that they represent a “significant clinical advantage” over already-available medications (Medsafe may not volunteer cost savings as a significant clinical advantage, but Pharmac [see below] may do so).⁵¹ New, intermediate- and low-risk medicines are evaluated by Medsafe and sent to MAAC for review and approval. The evaluation period for these medicines typically takes one to five months.⁵³

If a product is approved, it may be granted either full consent or provisional consent. Manufacturers of products granted full consent are permitted to market and sell those products without limitations. Sometimes, MAAC may decide that while a product is valuable in certain limited clinical situations, there is not enough data regarding safety to make the product available to the entire population without strict restrictions. For example, Codalax—used to prevent and relieve constipation—is authorized for use only by terminally ill patients because of an associated carcinogenicity risk. In such cases,

⁵¹ Medsafe, “New Zealand Regulatory Guidelines for Medicines, Volume 1: Guidance Notes for Applicants for Consent to Distribute New and Changed Medicines and Related Products,” Fifth Edition, October 2001, <http://www.medsafe.govt.nz/reg.htm>.

⁵² *Ibid.*

⁵³ *Ibid.*

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these products are granted provisional consent and confined to a limited list of providers and specific patients.⁵⁴

The third step for products that have received approval involves listing the product in the New Zealand Gazette. At this point, the manufacturer may advertise and sell its product legally.

New Zealand is committed to pharmacovigilance and has detailed regulations in place regarding the study of new medicines and human health outcomes after the medicines have been approved. Regulation requires that all adverse reactions and interactions to medicines be reported to the Centre for Adverse Reactions Monitoring (New Zealand has the highest reporting rate for all participating countries in the WHO [World Health Organization] International Drug Monitoring Program). Additionally, the first two drugs (at a minimum) in a new class of medicines introduced in New Zealand are eligible for more intensive monitoring.⁵⁵

Medsafe requires that all medicines be accompanied by documentation of Good Manufacturing Practice, which applies to all manufacturers of finished and intermediary products, all sterilizers of finished products, all packers of finished products, and all sites where products are labeled. All of these entities also must hold a current license to undertake these tasks. Certification regarding these processes, provided by a regulatory board recognized by Medsafe (the FDA in the United States, for example), must be shown for all non-New Zealand manufacturers and packers.⁵⁶

Medsafe requires labels for primary containers (bottles or vials), secondary containers (an outer packaging such as a box), strip packs (if used), and all physicians' samples. Relabeling is permitted, but must be done at a facility currently licensed to package the medicine or at a facility with a current packing license to relabel (although the latter facility must obtain permission from the Director-General of Health).

Regulation of Pharmacies and Pharmacists

On September 18, 2004, New Zealand instituted a new regulatory body for pharmacy: the Pharmacy Council. Prior to that date, pharmacists in New Zealand had been self-regulating. The Pharmacy Council was instituted by the Health Practitioners' Competency Assurance Act, which recognized the need for an external regulatory body.⁵⁷ The Pharmacy Council

⁵⁴ *Ibid.*

⁵⁵ *Ibid.*

⁵⁶ *Ibid.*

⁵⁷ Clare Bellingham, "Learning from New Zealand Pharmacy," *The Pharmaceutical Journal*, Vol. 273, October 16, 2004.

establishes required qualifications for the profession; accredits and monitors educational institutions and degrees, courses of studies, and programs; considers applications for annual certificates; recognizes, accredits, and sets programs to ensure the ongoing competence of health practitioners; and considers the cases of health practitioners who may be unable to perform the functions required for the practice of the profession.

To be eligible for registration as a pharmacist in New Zealand, an applicant must hold a four-year Bachelor of Pharmacy degree (B.Pharm), complete a minimum of 40 weeks of practical training, and complete the Pre-registration Program of the Pharmaceutical Society of New Zealand. In addition to gaining registration with the Society, prospective pharmacists also must hold an Annual Practicing Certificate (APC) and will be required to demonstrate they are maintaining competence in their areas of individual practice. Pharmacists must continue to practice actively in order to maintain their Certificate. Starting in 2006, pharmacists will have to complete a recertification program that determines whether or not they are competent to be recertified. Non-practicing pharmacists will be required to obtain an APC before being registered to practice.⁵⁸ Reciprocal recognition of qualifications exists between New Zealand, the states of Australia, the United Kingdom, and Ireland.

The Pharmacy Council also maintains Standards for Competence and a Code of Ethics. Pharmacists are required to practice pharmacy in a professional manner (work accurately, undertake professional development, comply with legal requirements, and communicate effectively); contribute to the quality use of medicines (obtain patient histories, interpret information about medicines, and maintain records); provide primary health care (determine optimal courses of treatment, provide advice, and apply first aid); apply management and organizational skills (facilitate a safe working environment and take responsibility in the workplace); research and provide information (use reference sources and interpret information); dispense medicines (validate, assess, and interpret prescriptions, review medicines in conjunction with patient histories, fill prescriptions, counsel patients, maintain records, and minimize errors); and prepare pharmaceutical products.⁵⁹ A registered pharmacist must always be present to supervise the activities in a pharmacy during open hours. If a pharmacist cannot be there due to emergency, the pharmacy must be closed.

⁵⁸ Pharmacy Council of New Zealand, "Registration," http://www.pharmacycouncil.org.nz/pharmacists/registration/registration_index.asp.

⁵⁹ Pharmacy Council of New Zealand, "Competence Standards," <http://www.pharmacycouncil.org.nz/pharmacists/standard/documents/Standards1-7Sept04.pdf>.

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Ownership of pharmacies in New Zealand is regulated to a much greater extent than in the United States, and this regulation precludes the existence of large, chain pharmacies such as Walgreens or CVS. Prior to implementation of the Health Practitioners' Competency Assurance Act, individuals in New Zealand were only permitted to own one pharmacy. However, the Act modifies the standards for Good Manufacturing Practice and allows pharmacists to own the majority of shares (51 percent) in up to five pharmacies, and 49 percent in an unlimited number of pharmacies.⁶⁰

Prescription management is also highly regulated. Pharmacists are required to verify that prescriptions are complete, legal, and authentic; to complete any incomplete prescriptions by speaking with the prescriber; to check for inappropriate or incorrect prescribing; to explain the proper use of prescriptions; to address potential noncompliance issues; and to confirm that the medicine has been properly prescribed for the patient.⁶¹ Faxed prescriptions are accepted if the pharmacist is confident the fax originated with the prescriber and is authentic.

Export Regulation

The New Zealand Medicines Act 1981 defines regulations regarding the manufacture, sale, and supply of medicines.⁶² Section 33 of the Act states that "any person may procure a medicine if the person from whom he procures that medicine is authorized by or under this Act to sell or supply the medicine to him," and that "any person may export, in the course or for the purpose of sale, any medicine that, at the time when it is exported, might lawfully be sold by a pharmacist to a person in New Zealand, whether pursuant to a prescription or otherwise."⁶³ Section 51 states that pharmaceutical retail sales may be carried out from any shop "that is open to the public and is situated at least 10 kilometers by the most practicable route from a pharmacy."⁶⁴

Despite the encouraging text of these regulations, however, this report's authors have not been presented with definitive evidence on the ability of the New Zealand doctors to legally rewrite U.S. prescriptions and subsequently export prescription-only medications to the United States. For this reason, and until clarification on this point is received from the

⁶⁰ *Ibid.*

⁶¹ *Ibid.*

⁶² Australian Ministry of Health, "Frequently Asked Questions: Medicine Regulation," http://www.moh.govt.nz/moh.nsf/wpg_Index/About-Medicine+Regulation.

⁶³ Medicines Act 1981, Part II, Section 33, "Exemptions in Respect of Procuring and Exporting Medicines," http://www.legislation.govt.nz/browse_vw.asp?content-set=pa_l_statutes.

⁶⁴ Medicines Act 1981, Part III, Section 51, "Grant of Licenses," http://www.legislation.govt.nz/browse_vw.asp?content-set=pa_l_statutes.

New Zealand regulatory authorities, the I-SaveRx program will not include prescription-only medications from New Zealand. Nevertheless, a number of medications that are sold only with a physician prescription in the United States (such as the allergy medication Zyrtec) are available OTC in New Zealand. As there is no prescription required in New Zealand for these medications, and as the pricing differentials between these two countries for this set group of medications are still quite large, the addition of certain OTC medications from New Zealand to the I-SaveRx program list is desirable.

APPENDIX 2: PHARMACEUTICAL PRICING IN AUSTRALIA AND NEW ZEALAND

AUSTRALIA

Australia's National Health Act of 1953 implemented the Pharmaceutical Benefits Scheme (PBS), which provides government subsidies for most pharmaceuticals to all Australian citizens. Approximately 80 percent of all approved Australian prescription pharmaceuticals are subsidized through the PBS.

As of the date of this report, most Australians pay up to AU\$28.60 (US\$22.06) for most subsidized prescriptions.⁶⁵ Some Australians (such as seniors and veterans), who are eligible for a Concession Card, pay AU\$4.60 (US\$3.55). Once an individual has spent AU\$874.90 (US\$692.76), they qualify for a safety net Concession Card; at that point, they pay AU\$4.60 (US\$3.55) per prescription for the rest of the year. Persons determined to be Concession patients at the start of the year pay a total of AU\$239.20 (US\$189.36), after which all prescriptions are provided free of charge. The same safety net thresholds apply to individuals and families. Premiums—the extra amount paid by a patient in order to receive a drug more costly than the specific drug subsidized by the PBS—do not count toward fulfillment of the safety net. The Australian government spends more than AU\$5.6 billion (US\$4.43 billion) each year to subsidize the PBS, which provides almost 200 million prescriptions.⁶⁶ The government has been sheltering citizens from the rising cost of drugs; as a percentage of overall costs, patients' contributions have actually dropped in recent years. According to PBS data, patients paid 16.98 percent of the total cost of prescription medication from April 1999 to March 2000; but from March 31, 2003 to March 31, 2004, patients paid 15.79 percent of the total cost of the drugs.⁶⁷

Before a new medicinal product is added to the Schedule (but after it has been approved by the TGA), it must be reviewed by the Pharmaceutical Benefits Advisory Committee (PBAC). This committee is comprised of health professionals and consumer representatives. Eighteen new medicinal products were added to the Schedule in 2003. When a product is approved for sale and distribution, the manufacturer must negotiate its price with the government if the product is to be listed on the Schedule

⁶⁵ Australian Government, Department of Health and Aging, "Schedule of Pharmaceutical Benefits for Approved Pharmacists and Registered Practitioners," April 2005.

⁶⁶ Australian Government, Department on Health and Aging, "About the PBS," <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-faq.htm-copy2>.

⁶⁷ Australian Government, Pharmaceutical Benefits Scheme, Research and Statistics, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Pharmaceutical+Benefits+Scheme+%28PBS%29-3>.

of Pharmaceutical Benefits. PBAC considers each product's therapeutic effectiveness, safety, and cost-effectiveness when compared to alternative treatments. A separate economics subcommittee reviews each drug's potential economic impacts on government and private spending. Products not listed on the Schedule are priced at the discretion of their manufacturer;⁶⁸ however, manufacturers of these drugs often lower their prices to more closely match PBS-listed drugs in order to maintain competitiveness and sales.

The Pharmaceutical Benefits Pricing Authority (PBPA) is responsible for recommending prices for new products, to be negotiated by the Department of Health and Aging. PBPA is an independent agency comprised of industry and consumer representatives as well as health department agents.⁶⁹ When reviewing products and considering pricing recommendations, the PBPA evaluates clinical benefits; cost-effectiveness aspects; the price of alternatives; comparisons within therapeutic groups; cost information from the supplier; economies of scale and likely volumes of prescribing and purchasing; any investment, production, and/or research and development being undertaken by Australian companies; the price of the product in similar countries; and any other relevant factors or opinions.⁷⁰

It is important to note that because of the manner in which Australian pricing is undertaken, not all drugs are less expensive in Australia than they are in the United States. For example, a month's supply of the rheumatoid arthritis drug Enbrel is dispensed through the Australian PBS for AU\$1,888.26 (which is equal to US\$ 1,494.23). But in the United States, Drugstore.com lists its price as US\$1,199.99.⁷¹ (Patients need two boxes every four weeks; this is equivalent to the usual dose of two injections a week.) The leukemia drug Gleevec is also less expensive in the United States (where a month's supply sells for US\$2,439.99)⁷² than it is in Australia (where it sells for the equivalent of US\$2,849.55).

Australia actively encourages its doctors, nurses, pharmacists, and patients to prescribe, dispense, and use medications cost-effectively. Additionally, generic use has been encouraged by the government since

⁶⁸ Australian Government, Department on Health and Aging, "About the PBS," <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-faq.htm-copy2>.

⁶⁹ Australian Government, Department of Health and Aging, "Pharmaceutical Benefits—Committees," <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-committ.htm#pbpa>.

⁷⁰ Alan Stevens, Pharmaceutical Benefits Scheme, "Pharmaceutical Pricing and Reimbursement Policies in Australia," <http://pharmacos.eudra.org/g10/docs/tse/Australia.pdf>.

⁷¹ Drugstore.com, June 27, 2005.

⁷² *Ibid.*

1994. Patients may choose to have a generic substituted for their brand prescription if the drug is listed as being equivalent to the prescribed brand in the Schedule. In 1990, generics comprised 4.5 percent of Australian prescription drug market share; in 1999, they comprised 15.5 percent.⁷³ As a point of reference, generics accounted for 51 percent of all pharmaceutical sales in the United States in 2002.⁷⁴ Higher brand drug prices in the United States make the U.S. generic market much more viable and competitive. However, in Australia and other countries where almost all residents are protected from the high prices of brand drugs by national health insurance systems, generics are not as much in demand.

PBPA utilizes several pricing mechanisms when making its pricing recommendations for branded drugs:⁷⁵

Benchmark (Reference) Pricing

PBPA looks at all available drugs in a therapeutic subgroup and chooses a benchmark price based on the lowest priced drug. Other drugs are priced against this benchmark. Supra-benchmark costs may be granted a premium if a drug shows a demonstrable clinical and cost-effective advantage (although this happens only rarely). Price adjustments may be made as new products are listed on the Schedule. Most listed products are priced using benchmark pricing.

Cost-Plus Pricing

Cost-plus pricing involves adding a margin to the cost of a product's manufacture. In this situation, manufacturing costs do not include administration, marketing, promotional, or distribution costs. The margin ranges from 15 percent to 40 percent, and depends on supplier's price for the product, estimation of usage rates, and unit prices.

Weighted Average Monthly Treatment Cost (WAMTC)

This mechanism, a variation of benchmark (reference) pricing, attempts to take a specific list of therapeutic groups of drugs (including SSRIs, proton pump inhibitors, and calcium channel blockers) that have been proven to provide similar health outcomes and price them so that monthly treatment costs are not statistically different. WAMTC reviews actual usage rates, utilization data, and treatment dosages. A weighted average of monthly treatment costs is computed for each drug in a therapeutic subgroup. PBPA then adjusts costs based on the average.

⁷³ Stevens, Pharmaceutical Benefits Scheme, "Pharmaceutical Pricing and Reimbursement Policies in Australia," <http://pharmacos.eudra.org/g10/docs/tse/Australia.pdf>.

⁷⁴ Generic Pharmaceutical Association, "Generic Pharmaceutical Facts at a Glance," <http://www.gphaonline.com>.

⁷⁵ Stevens, "Pharmaceutical Pricing and Reimbursement Policies in Australia."

Payment for pharmaceuticals from the government to the pharmacist consists of the following components: the approved pharmacy price, which is equivalent to the manufacturer's price plus a 10 percent wholesaler margin; an additional 10 percent markup for the pharmacist; a professional pharmacists' fee; an additional pharmacists' fee for the dispensation of dangerous drugs; and additional pharmacist compensation for interaction with and supply of information to patients. There are no direct financial transactions between a pharmaceutical manufacturer and the government. The government and the patient both make payments to the pharmacist, the pharmacist pays the wholesaler, and the wholesaler pays the manufacturer.⁷⁶ Recently, the Australian Health Minister revealed the government's intention to reduce margins enforced by pharmacists in an attempt to reduce PBS expenditure, which may in turn reduce costs to Australian consumers, although the Pharmacy Guild promises a fight.⁷⁷

Concern has been raised recently regarding the Australia-United States Free Trade Agreement (AUSFTA), which became effective January 1, 2005. Some read the Agreement as limiting Australia's ability to export pharmaceuticals to the United States in a manner consistent with a U.S. personal importation program. However, the official website for the Office of the United States Trade Representative states, "The FTA imposes no new barriers to imports...Nothing in this FTA or any other trade agreement prevents Congress from changing U.S. law in the future."⁷⁸

NEW ZEALAND

Once marketing approval has been granted for a new medicine, manufacturers of brand-name drugs, generics, and OTCs are free to set whatever price they wish. However, if manufacturers wish to have their products listed on the New Zealand Pharmaceutical Schedule, which contains a listing of the roughly 2,600 drugs subsidized by the government for the publicly funded health care system (which covers all New Zealand citizens), they must agree to negotiate pricing terms with the board of the Pharmaceutical Management Agency of New Zealand (PHARMAC). PHARMAC is independent from Medsafe, the pharmaceutical regulatory authority discussed above. As of the date of this report, the publicly funded health system provides pharmaceuticals free of charge to all citizens under the age of six; all other citizens pay the lesser

⁷⁶ *Pharmaceutical Journal*, Vol. 273, "Pharmacists Have Key Role in Fighting Global Health Risks, Says FIP President," September 11, 2004.

⁷⁷ Mark Metherell and Louise Dodson, "Pharmacies Gird for a Fees Fight," *Sydney Morning Herald*, March 22, 2005.

⁷⁸ Office of the United States Trade Representative, "U.S.-Australia Free Trade Agreement—Questions and Answers about Pharmaceuticals," <http://www.ustr.gov/>, July 8, 2004.

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of either a co-payment of NZ\$15.00 (US\$11.25) for a three-month supply of each pharmaceutical or the cost of the drug. Additional government subsidies are available to low-income citizens or those who depend on many different drugs for their conditions (and who use more than 20 prescriptions per year).⁷⁹

PHARMAC maintains a list of government-subsidized pharmaceuticals and manages applications from manufacturers that wish to have their products listed in the Pharmaceutical Schedule. When considering a new product for listing with the Schedule, PHARMAC considers the health needs of New Zealanders, particularly those of the Maori and Pacific people; existing medications that may meet the same needs as the proposed product; clinical risks and benefits; the cost-effectiveness of the proposed medicine when compared to other pharmaceutical and non-pharmaceutical treatment; budgetary impact to the government and to health-service users; the government's health funding priorities; and any additional relevant information (to be determined by PHARMAC).⁸⁰

PHARMAC reviews all applicants based on the preceding criteria, and then negotiates with approved manufacturers regarding Schedule pricing. Tentative pricing agreements are submitted to the Board for approval or denial. The Board is advised by the independent Pharmacology and Therapeutics Advisory Committee (PTAC), whose members are clinicians appointed by the Director-General of Health.⁸¹ Prior to a final decision, the Board considers input from pharmaceutical manufacturers, medical and pharmacy groups, and patient advocacy groups.⁸²

Some drugs are fully subsidized; other drugs receive partial subsidization.⁸³ PHARMAC uses three pricing strategies when considering additions to the Schedule.⁸⁴

Reference Pricing

Reference pricing involves the assignation of each drug to a therapeutic sub-group (a group of drugs that produce the same effect, and which are

⁷⁹ New Zealand Ministry of Health, "Guide to Eligibility for Publicly Funded Health and Disability Services in NZ," <http://www.moh.govt.nz>.

⁸⁰ Pharmaceutical Management Agency of New Zealand, "Who Are PHARMAC?," <http://www.pharmac.govt.nz>.

⁸¹ Pharmaceutical Management Agency of New Zealand, "Pharmacology and Therapeutics Advisory Committee," <http://www.pharmac.govt.nz>.

⁸² Richard Braee, PHARMAC, "New Zealand Pharmaceutical Pricing and Reimbursement Policies," <http://pharmacos.eudra.org/F3/g10/docs/tse/NewZealand.pdf>.

⁸³ Pharmaceutical Management Agency of New Zealand, "Who Are PHARMAC?," <http://www.pharmac.govt.nz>.

⁸⁴ Pharmaceutical Management Agency of New Zealand, "Funding Applications," <http://www.pharmac.govt.nz>.

intended to treat the same medical condition). PHARMAC subsidizes each member of the sub-group to the level of the lowest priced drug in that group.

Tendering

Roughly one-third of the 2,600 drugs on the Schedule are acquired through tender (a process through which suppliers bid for a contract to provide a product). Manufacturers bid competitively to become sole-source suppliers of a set list of pharmaceuticals for a limited period of time (usually three years). For example, the cholesterol drugs Zocor and Lipitor are both approved drugs in New Zealand, but Zocor (called Lipex locally) is reimbursed by PHARMAC and costs pharmacies roughly NZ\$12.00 per month. Lipitor is only reimbursed by PHARMAC if a patient suffers from an allergy or intolerance to Zocor. If a patient without a Zocor allergy chooses to purchase Lipitor, that purchase is not reimbursed by PHARMAC, and the cost is about NZ\$48.00 per month.

Caps and Rebates

PHARMAC sometimes negotiates reimbursement caps with manufacturers. Manufacturers are required to rebate the cost of the drug to PHARMAC (through rebates) in excess of the agreed-upon cap.

APPENDIX 3: SAVINGS METHODOLOGY AND FINANCIAL ANALYSIS

As the basis for this savings methodology and financial analysis, the report's authors researched the availability and pricing of I-SaveRx program drugs in the United States, Canada, and Australia. United Kingdom and Irish prices were not included in this analysis as these two areas are not currently facing stock shortages and stock shortages are not expected in these areas in the near future. Additionally, as previously noted, drugs classified as prescription-only in New Zealand will not be recommended for inclusion in the I-SaveRx program at this time (although this decision may be revisited in the future, especially as the planned combined Australia/New Zealand pharmaceutical governing agency comes into being). The authors undertook this research to project what levels of drug availability might exist if either the Canadian or Australian market were compromised by supply deficits.

From the top 100 I-SaveRx line items, the authors compiled a list of drugs—a market basket—that were available from Canada, Australia, and the United States as of May 11, 2005. Seventy-eight line items were available from all three countries. The total expense for purchasing a market basket—the combined cost of a three month supply of every drug—was then calculated for each country. U.S. pharmaceutical prices were computed using an average of three major online U.S. pharmacies as of March 25, 2005. Canadian prices were taken from the I-SaveRx website on May 11, 2005. Australian prices were computed from the latest version of the Australian Pharmaceutical Benefits Schedule, published in April 2005. The non-government subsidized prices of drugs available over-the-counter in Australia were drawn from an Australian online pharmacy, <http://www.emedical.com>, on June 16, 2005.

Current I-SaveRx program data indicates that the average shipped package contains between 1.3 and 1.5 prescriptions. The authors therefore assumed an average of 1.4 prescriptions per shipped package. Seventy-eight prescriptions, shipped in lots of 1.4 prescriptions per package, generate 55.7 individual shipping fees of \$15.00 per shipped package. No shipping fees are included in the cost of U.S. prescriptions. The results are as follows:

TABLE 1: PROJECTED SAVINGS

	Cost of a market basket of 78 prescriptions (3-month supply), no shipping fees	Net savings (%) compared to the United States (not including shipping fees)	Net savings (\$) compared to the United States (not including shipping fees)	Cost of a market basket of 78 prescriptions (3-month supply) including shipping fees	Net savings (%) compared to the United States (including shipping fees)	Net savings (\$) compared to the United States (including shipping fees)
United States	\$28,261.08	0%	\$0.00	\$28,261.08*	0%	\$0.00
Canada	\$18,596.2	34.2%	\$9,664.88	\$19,431.70	31.2%	\$8,829.38
Australia	\$13,084.44	53.7%	\$15,176.64	\$13,919.94	50.7%	\$14,341.14

*Shipping fees from/to the United States are not applicable here.

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APPENDIX 4: VISITED ORGANIZATIONS

Australia

Australian Pharmaceutical Benefits Scheme

Pharmacy Council of Western Australia

Pharmacy Guild of Western Australia

Seven retail facilities and one wholesale facility

New Zealand

Medsafe, Public Health Directorate, New Zealand Ministry of Health (via phone)

Two mail-order and retail pharmacies

One manufacturer/wholesaler

APPENDIX 5: ACKNOWLEDGMENTS

We wish to thank the pharmacies and manufacturing and retailing facilities referenced in this report for their cooperation; the Australian Pharmaceutical Benefits Scheme; the Pharmacy Council and Pharmacy Guild of Western Australia; Medsafe, Public Health Directorate, New Zealand Ministry of Health; Fernando Grillo, Secretary of the Illinois Department of Financial and Professional Regulation; Jonathan C. Dopkeen, Ph.D., Assistant Director of the Illinois Department of Public Health; Caleb Weaver, for his report review and suggestions; and Carrie Radabaugh, for the preparation of this manuscript.

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